CLAIMS

1. A pharmaceutical composition comprising:
   (a) between about 25 IU/ml and about 700 IU/ml of a Factor IX polypeptide comprising human Factor IX fused to an FcRn binding partner;
   (b) between about 10 mg/ml and about 20 mg/ml of sucrose;
   (c) between about 20 mg/ml and about 40 mg/ml of mannitol;
   (d) between about 3 mg/ml and about 4 mg/ml NaCl;
   (e) between about 3 mg/ml and about 6 mg/ml L-histidine; and
   (f) between about 0.08 mg/ml and about 0.2 mg/ml of polysorbate 20 or polysorbate 80.

2. The pharmaceutical composition of claim 1, comprising about 11.9 mg/ml sucrose.

3. The pharmaceutical composition of claim 1, comprising about 16.7 mg/ml sucrose.

4. The pharmaceutical composition of any one of claims 1 to 3, comprising about 23.8 mg/ml mannitol.

5. The pharmaceutical composition of any one of claims 1 to 3, comprising about 33.3 mg/ml mannitol.

6. The pharmaceutical composition of any one of claims 1 to 5, comprising about 3.25 mg/ml NaCl.

7. The pharmaceutical composition of any one of claims 1 to 6, comprising about 3.88 mg/ml L-histidine.

8. The pharmaceutical composition of any one of claims 1 to 6, comprising about 5.43 mg/ml L-histidine.

9. The pharmaceutical composition of any one of claims 1 to 8, comprising between about 0.08 mg/ml and about 0.15 mg/ml polysorbate 20 or polysorbate 80.

10. The pharmaceutical composition of any one of claims 1 to 9, comprising about 0.10 mg/ml polysorbate 20 or polysorbate 80.

11. The pharmaceutical composition any one of claims 1 to 9, comprising about 0.14 mg/ml polysorbate 20 or polysorbate 80.

12. The pharmaceutical composition of any one of claims 1 to 11, comprising 50 IU/ml of the Factor IX polypeptide.

13. The pharmaceutical composition of any one of claims 1 to 11, comprising 100 IU/ml of the Factor IX polypeptide.

14. The pharmaceutical composition of any one of claims 1 to 11, comprising 200 IU/ml of the Factor IX polypeptide.

15. The pharmaceutical composition of any one of claims 1 to 11, comprising 400 IU/ml of the Factor IX polypeptide.

16. The pharmaceutical composition of any one of claims 1 to 11, comprising 600 IU/ml of the Factor IX polypeptide.

17. The pharmaceutical composition of claim 1, comprising:

(a) about 50 IU/ml of the Factor IX polypeptide;

(b) about 11.9 mg/ml of sucrose;

(c) about 23.8 mg/ml of mannitol;

(d) about 3.25 mg/ml NaCl;

(e) about 3.88 mg/ml L-histidine; and

(f) about 0.10 mg/ml of polysorbate 20 or polysorbate 80.

18. The pharmaceutical composition of claim 1, comprising:
    (a) about 100 IU/ml of the Factor IX polypeptide;
    (b) about 11.9 mg/ml of sucrose;
    (c) about 23.8 mg/ml of mannitol;
    (d) about 3.25 mg/ml NaCl;
    (e) about 3.88 mg/ml L-histidine; and
    (f) about 0.10 mg/ml of polysorbate 20 or polysorbate 80.

19. The pharmaceutical composition of claim 1, comprising:
    (a) about 200 IU/ml of the Factor IX polypeptide;
    (b) about 11.9 mg/ml of sucrose;
    (c) about 23.8 mg/ml of mannitol;
    (d) about 3.25 mg/ml NaCl;
    (e) about 3.88 mg/ml L-histidine; and
    (f) about 0.10 mg/ml of polysorbate 20 or polysorbate 80.

20. The pharmaceutical composition of claim 1, comprising:
    (a) about 400 IU/ml of the Factor IX polypeptide;
    (b) about 11.9 mg/ml of sucrose;
    (c) about 23.8 mg/ml of mannitol;
    (d) about 3.25 mg/ml NaCl;
    (e) about 3.88 mg/ml L-histidine; and
    (f) about 0.10 mg/ml of polysorbate 20 or polysorbate 80.

21. The pharmaceutical composition of claim 1, comprising:
    (a) about 600 IU/ml of the Factor IX polypeptide;
    (b) about 16.7 mg/ml of sucrose;
    (c) about 33.3 mg/ml of mannitol;
    (d) about 3.25 mg/ml NaCl;
    (e) about 5.43 mg/ml L-histidine; and
    (f) about 0.14 mg/ml of polysorbate 20 or polysorbate 80.

22. A pharmaceutical kit comprising

(a) a first container comprising a lyophilized powder, where the powder comprises
   (i) from about 200 IU to about 4000 IU of a Factor IX polypeptide comprising human Factor IX fused to an FcRn binding partner;
   (ii) about 59.5 mg or about 83.3 mg of sucrose;
   (iii) about 119 mg or about 167 mg of mannitol;
   (iv) about 19.4 mg or about 27.2 mg of L-histidine; and
   (v) about 0.50 mg or about 0.7 mg of polysorbate 20 or polysorbate 80; and

(b) a second container comprising 0.325% (w/v) NaCl at a volume sufficient to produce, when combined with the lyophilized powder of the first container, a solution comprising:
   (i) about 50 IU/ml, about 100 IU/ml, about 200 IU/ml, about 400 IU/ml, or about 600 IU/ml of the Factor IX polypeptide;
   (ii) about 11.9 mg/ml or about 16.7 mg/ml of sucrose;
   (iii) about 23.8 mg/ml or about 33.3 mg/ml of mannitol;
   (iv) about 3.25 mg/ml NaCl;
   (v) about 3.88 mg/ml or about 5.43 mg/ml L-histidine; and
   (vi) about 0.10 mg/ml or about 0.14 mg/ml of polysorbate 20 or polysorbate 80.

23. The pharmaceutical kit of claim 22, comprising:

(a) a first container comprising a lyophilized powder, where the powder comprises
   (i) about 250 IU of the Factor IX polypeptide,
   (ii) about 59.5 mg of sucrose;
   (iii) about 119 mg of mannitol;
   (iv) about 19.4 mg of L-histidine; and
   (v) about 0.50 mg of polysorbate 20 or polysorbate 80; and

(b) a second container comprising 0.325% (w/v) NaCl at a volume sufficient to produce, when combined with the lyophilized powder of the first container, a solution comprising:
   (i) about 50 IU/ml of Factor IX polypeptide;
   (ii) about 11.9 mg/ml of sucrose;
   (iii) about 23.8 mg/ml of mannitol;
   (iv) about 3.25 mg/ml NaCl;

(v) about 3.88 mg/ml L-histidine; and

(vi) about 0.10 mg/ml of polysorbate 20 or polysorbate 80.

24. The pharmaceutical kit of claim 22, comprising:

(a) a first container comprising a lyophilized powder, where the powder comprises

(i) about 500 IU of the Factor IX polypeptide,

(ii) about 59.5 mg of sucrose;

(iii) about 119 mg of mannitol;

(iv) about 19.4 mg of L-histidine; and

(v) about 0.50 mg of polysorbate 20 or polysorbate 80; and

(b) a second container comprising 0.325% (w/v) NaCl at a volume sufficient to produce, when combined with the lyophilized powder of the first container, a solution comprising:

(i) about 100 IU/ml of the Factor IX polypeptide;

(ii) about 11.9 mg/ml of sucrose;

(iii) about 23.8 mg/ml of mannitol;

(iv) about 3.25 mg/ml NaCl;

(v) about 3.88 mg/ml L-histidine; and

(vi) about 0.10 mg/ml of polysorbate 20 or polysorbate 80.

25. The pharmaceutical kit of claim 22, comprising:

(a) a first container comprising a lyophilized powder, where the powder comprises

(i) about 1000 IU of the Factor IX polypeptide,

(ii) about 59.5 mg of sucrose;

(iii) about 119 mg of mannitol;

(iv) about 19.4 mg of L-histidine; and

(v) about 0.50 mg of polysorbate 20 or polysorbate 80; and

(b) a second container comprising 0.325% (w/v) NaCl at a volume sufficient to produce, when combined with the lyophilized powder of the first container, a solution comprising:

(i) about 200 IU/ml of a Factor IX polypeptide;

(ii) about 11.9 mg/ml of sucrose;

(iii) about 23.8 mg/ml of mannitol;

(iv) about 3.25 mg/ml NaCl;

(v) about 3.88 mg/ml L-histidine; and

(vi) about 0.10 mg/ml of polysorbate 20 or polysorbate 80.

26. The pharmaceutical kit of claim 22, comprising:

(a) a first container comprising a lyophilized powder, where the powder comprises

(i) about 2000 IU of the Factor IX polypeptide,

(ii) about 59.5 mg of sucrose;

(iii) about 119 mg of mannitol;

(iv) about 19.4 mg of L-histidine; and

(v) about 0.50 mg of polysorbate 20 or polysorbate 80; and

(b) a second container comprising 0.325% (w/v) NaCl at a volume sufficient to produce, when combined with the lyophilized powder of the first container, a solution comprising:

(i) about 400 IU/ml of a Factor IX polypeptide;

(ii) about 11.9 mg/ml of sucrose;

(iii) about 23.8 mg/ml of mannitol;

(iv) about 3.25 mg/ml NaCl;

(v) about 3.88 mg/ml L-histidine; and

(vi) about 0.10 mg/ml of polysorbate 20 or polysorbate 80.

27. The pharmaceutical kit of claim 22, comprising:

(a) a first container comprising a lyophilized powder, where the powder comprises

(i) about 3000 IU of the Factor IX polypeptide,

(ii) about 83.3 mg of sucrose;

(iii) about 167 mg of mannitol;

(iv) about 27.2 mg of L-histidine; and

(v) about 0.7 mg of polysorbate 20 or polysorbate 80; and

(b) a second container comprising 0.325% (w/v) NaCl at a volume sufficient to produce, when combined with the lyophilized powder of the first container, a solution comprising:

(i) about 600 IU/ml of a Factor IX polypeptide;

(ii) about 16.7 mg/ml of sucrose;

(iii) about 33.3 mg/ml of mannitol;

(iv) about 3.25 mg/ml NaCl;

(v) about 5.43 mg/ml L-histidine; and

(vi) about 0.14 mg/ml of polysorbate 20 or polysorbate 80.

28. The kit of any one of claims 22, wherein the first container is a glass vial comprising a rubber stopper.

29. The kit of any one of claims 22, wherein the second container is a syringe body, and wherein the syringe body is associated with a plunger.

30. The pharmaceutical composition of claim 1 or the kit of claim 22, wherein the FcRn Binding Partner is an Fc region.

31. The pharmaceutical composition or kit of any one of claims 1 to 30, wherein the Factor IX polypeptide comprises an amino acid sequence at least 90% or 95% identical to amino acids 1 to 642 of SEQ ID NO: 2.

32. The pharmaceutical composition or kit of any one of claims 1 to 31, wherein the Factor IX polypeptide is a rFIXFc polypeptide which comprises a first subunit comprising an amino acid sequence at least 90% or 95% identical to amino acids 1 to 642 of SEQ ID NO:2, and a second subunit comprising an amino acid sequence at least 90% to 95% identical to amino acids 1 to 227 of SEQ ID NO:4.

33. The pharmaceutical composition or kit of claim 32, wherein the rFIXFc polypeptide comprises a first subunit comprising amino acids 1 to 642 of SEQ ID NO:2, and a second subunit comprising amino acids 1 to 227 of SEQ ID NO:4.

34. The pharmaceutical composition of any one of claims 1 to 21, which is a liquid formulation, a lyophilized powder, or a suspension.

35. A vial comprising the pharmaceutical composition of any one of claims 1 to 21.

36. A cartridge comprising the pharmaceutical composition of any one of claims 1 to 21.

37. A syringe comprising the pharmaceutical composition of any one of claims 1 to 21.

38. The pharmaceutical composition of any one of claims 1 to 21 for use in reducing or preventing a bleeding episode in a subject in need thereof.

39. The pharmaceutical composition of any one of claims 1 to 21 for use in treating hemophilia B in a subject in need thereof.

40. The pharmaceutical composition of any one of claims 1 to 21, wherein the composition is to be administered intravenously.

41. The pharmaceutical composition of any one of claims 1 to 21, wherein the composition is to be administered subcutaneously.