WHAT IS CLAIMED IS:

1. A pre-lyophilization formulation comprising:

(a) a chimeric Factor IX (FIX) polypeptide, comprising FIX and a Fc region that extends the half-life of the FIX, at a concentration between 220 IU/vial to 1,000 IU/vial;

(b) L-histidine at a concentration between 3 mg/mL and 15 mg/mL;

(c) sucrose at a concentration between 10 mg/mL and 50 mg/mL;

(d) mannitol at a concentration between 20 mg/mL and 100 mg/mL; and

(e) polysorbate 20 at a concentration between 0.01 mg/mL and 5 mg/mL,

wherein the formulation has a fill volume between 2 mL and 3 mL.

2. The pre-lyophilization formulation of claim 1, wherein the fill volume is about 2.65 mL.

3. The pre-lyophilization formulation of claim 1,
wherein the L-histidine is present at a concentration of about 7.76 mg/mL;
wherein the sucrose is present at a concentration of about 23.8 mg/mL;
wherein the mannitol is present at a concentration of about 47.6 mg/mL; and
wherein the polysorbate 20 is present at a concentration of about 0.2 mg/mL.

4. The pre-lyophilization formulation of claim 1, wherein the fill volume is about 2.5 mL.

5. The pre-lyophilization formulation of claim 1, wherein the chimeric FIX polypeptide comprises the FIXFc-sc polypeptide of SEQ ID NO: 2 and the Fc sc polypeptide of SEQ ID NO:4.

6. The pre-lyophilization formulation of claim 1, wherein the fill volume allows for reduced reconstitution time when the formulation is lyophilized, wherein the reduced reconstitution time is less than 30 seconds.

7. The pre-lyophilization formulation of claim 1, wherein the lyophilization cycle time is about 4 days or less.

8. A pre-lyophilization formulation comprising:

(a) a chimeric Factor IX (FIX) polypeptide, comprising (i) the FIXFc-sc polypeptide of SEQ ID NO:2, without the C-terminal lysine and (ii) the Fc sc polypeptide of SEQ ID NO:4, without the C-terminal lysine, at a concentration between 220 IU/vial to 1,000 IU/vial;

(b) L-histidine at a concentration of about 7.76 mg/mL;

(c) sucrose at a concentration of about 23.8 mg/mL;

(d) mannitol at a concentration of about 47.6 mg/mL; and

(e) polysorbate 20 at a concentration of about 0.2 mg/mL,

wherein the formulation has a fill volume of about 2.65 mL.

9. The pre-lyophilization formulation of claim 1, wherein the chimeric FIX polypeptide comprises the FIXFc-sc polypeptide of SEQ ID NO: 2, without the C-terminal lysine, and the Fc sc polypeptide of SEQ ID NO:4, without the C-terminal lysine, wherein the FIXFc-sc polypeptide and the Fc sc polypeptide are bound together through two disulfide bonds in the hinge region of Fc.

10. A pre-lyophilization formulation within a vial comprising:

(a) between 1,100 IU to 10,000 IU of a chimeric Factor IX (FIX) polypeptide, comprising FIX and a Fc region, in an amount of between 1,100 IU to 10,000 IU;

(b) L-histidine at a concentration between 3 mg/mL and 15 mg/mL;

(c) sucrose at a concentration between 10 mg/mL and 50 mg/mL;

(d) mannitol at a concentration between 20 mg/mL and 100 mg/mL; and

(e) polysorbate 20 at a concentration between 0.01 mg/mL and 5 mg/mL,

wherein the formulation has a fill volume between 2 mL and 3 mL.

11. The pre-lyophilization formulation of claim 10, wherein the fill volume is about 2.65 mL or about 2.5 mL.

12. The pre-lyophilization formulation of claim 10, wherein the lyophilization cycle time is about 4 days or less.

13. The pre-lyophilization formulation of claim 10, comprising about 1,100 IU, about 1,200 IU, about 1,300 IU, about 1,400 IU, about 1,500 IU, about 2,000 IU, about 2,500 IU, about 3,000 IU, about 4,000 IU, about 5,000 IU, about 5,500 IU, about 6,000 IU, about 6,500 IU, about 7,000 IU, about 7,500 IU, about 8,000 IU, about 8,500 IU, about 9,000 IU, about 9,500 IU or about 10,000 IU of the chimeric FIX polypeptide.

14. The pre-lyophilization formulation of claim 10, wherein the L-histidine is at a concentration between 5.82 mg/mL and 9.7 mg/mL.

15. The pre-lyophilization formulation of claim 10, wherein the L-histidine is at a concentration of about 7.76 mg/mL.

16. The pre-lyophilization formulation of claim 10, wherein the sucrose is at a concentration between 17.85 mg/mL and 29.95 mg/mL.

17. The pre-lyophilization formulation of claim 10, wherein the sucrose is at a concentration of about 23.8 mg/mL.

18. The pre-lyophilization formulation of claim 10, wherein the mannitol is at a concentration between 35.7 mg/mL and 59.5 mg/mL.

19. The pre-lyophilization formulation of claim 10, wherein the mannitol is at a concentration of about 47.6 mg/mL.

20. The pre-lyophilization formulation of claim 10, wherein the polysorbate 20 is at a concentration between 0.05 mg/mL and 1 mg/mL.

21. The pre-lyophilization formulation of claim 10, wherein the polysorbate 20 is at a concentration of about 0.2 mg/mL.

22. The pre-lyophilization formulation of claim 10, wherein the chimeric FIX polypeptide is at a concentration between 600 IU/mL and 2,750 IU/mL.

23. A pre-lyophilization formulation within a vial comprising:

(a) 1,100 to 10,000 IU of a chimeric Factor IX (FIX) polypeptide, comprising FIX and Fc;

wherein the chimeric FIX polypeptide is a heterodimeric protein comprising

(i) a FIXFc-sc polypeptide of SEQ ID NO:2, without the C-terminal lysine, and

(ii) a Fc single chain (Fc-sc) polypeptide of SEQ ID NO:4, without the C-terminal lysine,

wherein the FIXFc-sc polypeptide and the Fc-sc polypeptide are bound together through two disulfide bonds in the hinge region of Fc;

(b) about 7.76 mg/mL of L-histidine;

(c) about 47.6 mg/mL of mannitol;

(d) about 23.8 mg/mL of sucrose; and,

(e) about 0.2 mg/mL of polysorbate-20;

wherein the formulation has a fill volume between 2 mL and 3 mL.

24. The pre-lyophilization formulation of claim 23, wherein the formulation has a fill volume per vial of about 2.65 mL or about 2.5 mL.

25. The pre-lyophilization formulation of claim 24, wherein the formulation has a fill volume per vial of about 2.65 mL.

26. The pre-lyophilization formulation of claim 10, comprising 2,000 IU of the FIX polypeptide.

27. The pre-lyophilization formulation of claim 10, comprising 3,000 IU of the FIX polypeptide.

28. The pre-lyophilization formulation of claim 10, comprising 4,000 IU of the FIX polypeptide.
29. The pre-lyophilization formulation of claim 23, comprising 2,000 IU of the FIX polypeptide.
30. The pre-lyophilization formulation of claim 23, comprising 3,000 IU of the FIX polypeptide.
31. The pre-lyophilization formulation of claim 23, comprising 4,000 IU of the FIX polypeptide.
32. The pre-lyophilization formulation of claim 10, wherein the chimeric FIX polypeptide comprises the FIXFc-sc polypeptide of SEQ ID NO: 2, without the C-terminal lysine, and the Fc sc polypeptide of SEQ ID NO:4, without the C-terminal lysine, wherein the FIXFc-sc polypeptide and the Fc sc polypeptide are bound together through two disulfide bonds in the hinge region of Fc.
33. The pre-lyophilization formulation of claim 23, wherein the chimeric FIX polypeptide comprises the FIXFc-sc polypeptide of SEQ ID NO: 2, without the C-terminal lysine, and the Fc sc polypeptide of SEQ ID NO:4, without the C-terminal lysine, wherein the FIXFc-sc polypeptide and the Fc sc polypeptide are bound together through two disulfide bonds in the hinge region of Fc.