What is claimed is:

1. A pharmaceutical formulation comprising: (i) an antibody that binds specifically to human proprotein convertase subtilisin/kexin type 9 (human PCSK9); (ii) a buffer at pH of 6.0 ± 0.3; (iii) a non-ionic detergent; and (iv) a stabilizer.

2. The pharmaceutical formulation of claim 1, wherein the antibody comprises an HCDR1 of SEQ ID NO:2, an HCDR2 of SEQ ID NO:3, an HCDR3 of SEQ ID NO:4, an LCDR1 of SEQ ID NO: 6, an LCDR2 of SEQ ID NO:7, and an LCDR3 of SEQ ID NO:8.

3. The pharmaceutical formulation of any one of claims 1 and 2, wherein the antibody comprises a HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5.

4. The pharmaceutical formulation of any one of claims 1-3, wherein

(a) over 90% of the antibodies have a molecular weight of 155 kDa ± 1 kDa;

(b) over 50% of the antibodies have an isoelectric point of about 8.5; and

(c) from 75% to 90% of the antibodies are fucosylated.

5. The pharmaceutical formulation of any one of claims 1-4, wherein the antibody concentration is from 50 mg/mL ± 7.5 mg/mL to 175 mg/mL ± 26.25 mg/mL.

6. The pharmaceutical formulation of any one of claims 1-4, wherein the buffer is histidine.

7. The pharmaceutical formulation of claim 6, wherein the histidine concentration is 10 mM ± 1.5 mM.

8. The pharmaceutical formulation of any one of claims 1-7, wherein the non-ionic detergent is polysorbate 20.

9. The pharmaceutical formulation of claim 8, wherein the polysorbate 20 concentration is from 0.01% w/v ± 0.0015% to 0.2% w/v ± 0.03%.

10. The pharmaceutical formulation of any one of claims 1-9, wherein the stabilizer is sucrose.

11. The pharmaceutical formulation of claim 10, wherein the sucrose concentration is from 5% ± 0.75% to 12% ± 1.8% (w/v).

12. The pharmaceutical formulation of any one of claims 1-11, wherein the antibody concentration is 175 mg/mL ± 26.25 mg/mL, the buffer is 10mM ± 1.5mM histidine, pH 6 ± 0.3, the non-ionic detergent is 0.01% w/v ± 0.0015% polysorbate 20, the stabilizer is 5% w/v ± 0.75% sucrose, and further comprising 50mM ± 7.5mM arginine.

13. The pharmaceutical formulation of any one of claims 1-11, wherein the antibody concentration is 150 mg/mL ± 22.5 mg/mL, the buffer is 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, the non-ionic detergent is 0.2% w/v ± 0.03% polysorbate 20, and the stabilizer is 10% w/v ± 1.5% sucrose.

14. The pharmaceutical formulation of any one of claims 1-11, wherein the antibody concentration is 150 mg/mL ± 22.5 mg/mL, the buffer is 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, the non-ionic detergent is 0.01% w/v ± 0.0015% polysorbate 20, and the stabilizer is 10% w/v ± 1.5% sucrose.

15. The pharmaceutical formulation of any one of claims 1-11, wherein the antibody concentration is 100 mg/mL ± 15 mg/mL, the buffer is 20 mM ± 3 mM histidine, pH 6 ± 0.3, the non-ionic detergent is 0.2% w/v ± 0.03% polysorbate 20, and the stabilizer is 12% w/v ± 1.8% sucrose.

16. The pharmaceutical formulation of any one of claims 1-11, wherein the antibody concentration is 50 mg/mL ± 7.5 mg/mL, the buffer is 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, the non-ionic detergent is 0.1% w/v ± 0.015% polysorbate 20, the stabilizer is 6% w/v ± 0.9% sucrose.

17. The pharmaceutical formulation of any one of claims 1-16, wherein at least 91% of the antibody has native conformation after 28 days at 45°C.

18. The pharmaceutical formulation of any one of claims 1-16, wherein at least 35% of the antibody is the main charge variant of the antibody after 28 days at 45°C.

19. The pharmaceutical formulation of any one of claims 1-16, wherein at least 94% of the antibody has native conformation after six months at 25°C.

20. The pharmaceutical formulation of any one of claims 1-16, wherein at least 45% of the antibody is the main charge variant of the antibody after six months at 25°C.

21. The pharmaceutical formulation of any one of claims 1-16, wherein at least 96% of the antibody has native conformation after six months at 5°C.

22. The pharmaceutical formulation of any one of claims 1-16, wherein at least 58% of the antibody is the main charge variant of the antibody after six months at 5°C.

23. The pharmaceutical formulation of any one of claims 1-16, wherein at least 96% of the antibody is the main charge variant of the antibody after three months at -20°C, -30°C, or -80°C.

24. The pharmaceutical formulation of any one of claims 1-16, wherein at least 56% of the antibody is the main charge variant of the antibody after three months at -20°C, -30°C, or -80°C.

25. A pharmaceutical formulation comprising (a) 175 mg/mL ± 26.25 mg/mL of an anti-PCSK9 antibody, (b) 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, (c) 0.01% w/v ± 0.0015% polysorbate 20, (d) 5% w/v ± 0.75% sucrose, and (e) 50 mM ± 7.5 mM arginine, wherein:

(a) the antibody comprises an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5;

(b) over 90% of the antibodies have a molecular weight of 155 kDa ± 1 kDa;

(c) over 50% of the antibodies have an isoelectric point of about 8.5; and

(d) from 75% to 90% of the antibodies are fucosylated.

26. The pharmaceutical formulation of claim 25 consisting of (a) 175 mg/mL ± 26.25 mg/mL of the antibody, (b) 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, (c) 0.01% w/v ± 0.0015% polysorbate 20, (d) 5% w/v ± 0.75% sucrose, and (e) 50 mM ± 7.5 mM arginine, in water.

27. A pharmaceutical formulation comprising (a) 150 mg/mL mL ± 22.5 mg/mL of an anti-PCSK9 antibody, (b) 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, (c) 0.2% w/v ± 0.03% polysorbate 20, and (d) 10% w/v ± 1.5% sucrose, wherein:

(a) the antibody comprises an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5;

(b) over 90% of the antibodies have a molecular weight of 155 kDa ± 1 kDa;

(c) over 50% of the antibodies have an isoelectric point of about 8.5; and

(d) from 75% to 90% of the antibodies are fucosylated.

28. The pharmaceutical formulation of claim 27 consisting of (a) 150 mg/mL mL ± 22.5 mg/mL of the antibody, (b) 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, (c) 0.2% w/v ± 0.03% polysorbate 20, and (d) 10% w/v ± 1.5% sucrose, in water.

29. A pharmaceutical formulation comprising (a) 150 mg/mL mL ± 22.5 mg/mL of an anti-PCSK9 antibody, (b) 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, (c) 0.01% w/v ± 0.0015% polysorbate 20, and (d) 10% w/v ± 1.5% sucrose, wherein:

(a) the antibody comprises an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5;

(b) over 90% of the antibodies have a molecular weight of 155 kDa ± 1 kDa;

(c) over 50% of the antibodies have an isoelectric point of about 8.5; and

(d) from 75% to 90% of the antibodies are fucosylated.

30. The pharmaceutical formulation of claim 29 consisting of (a) 150 mg/mL mL ± 22.5 mg/mL of the antibody, (b) 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, (c) 0.01% w/v ± 0.0015% polysorbate 20, and (d) 10% w/v ± 1.5% sucrose, in water.

31. A pharmaceutical formulation comprising (a) 100 mg/mL mL ± 15 mg/mL of an anti-PCSK9 antibody, (b) 20 mM ± 3 mM histidine, pH 6 ± 0.3, (c) 0.2% w/v ± 0.03% polysorbate 20, and (d) 12% w/v ± 1.8% sucrose, wherein:

(a) the antibody comprises an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5;

(b) over 90% of the antibodies have a molecular weight of 155 kDa ± 1 kDa;

(c) over 50% of the antibodies have an isoelectric point of about 8.5; and

(d) from 75% to 90% of the antibodies are fucosylated.

32. The pharmaceutical formulation of claim 31 consisting of (a) 100 mg/mL mL ± 15 mg/mL of the antibody, (b) 20 mM ± 3 mM histidine, pH 6 ± 0.3, (c) 0.2% w/v ± 0.03% polysorbate 20, and (d) 12% w/v ± 1.8% sucrose, in water.

33. A pharmaceutical formulation comprising (a) 50 mg/mL mL ± 7.5 mg/mL of an antibody comprising an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5, (b) 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, (c) 0.1% w/v ± 0.015% polysorbate 20, and (d) 6% w/v ± 0.9% sucrose, wherein:

(a) the antibody comprises an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5;

(b) over 90% of the antibodies have a molecular weight of 155 kDa ± 1 kDa;

(c) over 50% of the antibodies have an isoelectric point of about 8.5; and

(d) from 75% to 90% of the antibodies are fucosylated.

34. The pharmaceutical formulation of claim 33 consisting of (a) 50 mg/mL mL ± 7.5 mg/mL of the antibody, (b) 10 mM ± 1.5 mM histidine, pH 6 ± 0.3, (c) 0.1% w/v ± 0.015% polysorbate 20, and (d) 6% w/v ± 0.9% sucrose, in water.

35. A method for preparing a composition that comprises an anti-PCSK9 antibody and less than 0.3% water, the method comprising the steps of:

a) in a glass vial combining water, an anti-PCSK9 antibody, histidine, sucrose, and polysorbate 20;

b) holding the combination of step (a) at about 5°C for about 60 minutes; then

c) decreasing the temperature at a rate of about 0.5°C per minute; then

d) holding at about -45°C for about 120 minutes; then

e) reducing the atmosphere pressure to about 100 mTorr;

f) increasing the temperature at a rate of about 0.5°C per minute; then

g) holding at about -25°C for about 78 hours; then

h) increasing the temperature at a rate of 0.2°C per minute; then

i) holding at about 35°C for about 6 hours; then

j) decreasing the temperature at a rate of about 0.5°C; then

k) holding at about 25° for about 60 minutes, prior to storage.

36. The method of claim 35, further comprising the steps of:

l) backfillng the glass vial containing the combination of step (k) with nitrogen gas; and

m) stoppering the vial under about 80% of atmospheric pressure.

37. The method of claim 35 or 36 wherein the composition is brought to 2-8°C after step (i), (j) or (k) and prior to the step of stoppering the vial.

38. The method of any one of claims 35-37, wherein 50 mg/mL ± 7.5 mg/mL of anti-PCSK9 antibody, 10 mM ± 1.5 mM histidine (pH 6.0), 0.1% ± 0.015% polysorbate 20, and 6% ± 0.9% sucrose are combined at step (a), and wherein the anti-PCSK9 antibody comprises an HCDR1 of SEQ ID NO:2, an HCDR2 of SEQ ID NO:3, an HCDR3 of SEQ ID NO:4, an LCDR1 of SEQ ID NO: 6, an LCDR2 of SEQ ID NO:7, and an LCDR3 of SEQ ID NO:8.mAb-316P.

39. The method of any one of claims 35-38, wherein the anti-PCSK9 antibody comprises an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5.

40. The method of any one of claims 35-39, wherein (a) the antibody comprises an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5; (b) over 90% of the antibodies have a molecular weight of 155 kDa ± 1 kDa; (c) over 50% of the antibodies have an isoelectric point of about 8.5; and (d) from 75% to 90% of the antibodies are fucosylated.

41. A pharmaceutical composition comprising an anti-PCSK9 antibody and less than 0.3% water, produced according to the method of any one of claims 35-40.

42. A pharmaceutical composition comprising a pharmaceutical composition of claim 41 resuspended in water.

43. The pharmaceutical composition of claim 42 consisting of 50 mg/mL ± 7.5 mg/mL antibody, 10 mM ± 1.5 mM histidine (pH 6.0), 0.1% ± 0.015% polysorbate 20, and 6% ± 0.9% sucrose, in water.

44. The pharmaceutical composition of claim 42 consisting of 100 mg/mL ± 15 mg/mL antibody, 20 mM ± 3 mM histidine (pH 6.0), 0.2% ± 0.03% polysorbate 20, and 12% ± 1.8% sucrose, in water.

45. The pharmaceutical composition of claim 42 consisting of 150 mg/mL ± 22.5 mg/mL antibody, 30 mM ± 4.5 mM histidine (pH 6.0), 0.3% ± 0.045% polysorbate 20, and 18% ± 2.7% sucrose, in water.

46. The pharmaceutical composition of claim 42 consisting of 175 mg/mL ± 26.25 mg/mL antibody, 35 mM ± 5.25 mM histidine (pH 6.0), 0.35% ± 0.0525% polysorbate 20, and 21% ± 3.15% sucrose, in water.

47. The pharmaceutical composition of any one of claims 41-46, wherein (a) the antibody comprises an HCVD of SEQ ID NO:1 and an LCVD of SEQ ID NO:5; (b) over 90% of the antibodies have a molecular weight of 155 kDa ± 1 kDa; (c) over 50% of the antibodies have an isoelectric point of about 8.5; and (d) from 75% to 90% of the antibodies are fucosylated.

48. A pharmaceutical composition of any one of claims 1-34 and 41-47, wherein said composition is contained in a container.

49. The pharmaceutical composition of claim 48, wherein the container is a vial.

50. The pharmaceutical composition of claim 49, wherein the vial is glass.

51. The pharmaceutical composition of claim 48, wherein the container is a syringe.

52. The pharmaceutical composition of claim 51, wherein the syringe is low-tungsten glass.

53. The pharmaceutical composition of claim 51, wherein the syringe is a NUOVA OMPI 1 mL long glass syringe equipped with a 27-G thin wall needle, a FLUROTEC–coated 4023/50 rubber stopper, and a FM 27 rubber tip cap.

54. A kit comprising a pharmaceutical composition of any one of claims 1-34 and 41-47, a container, and instructions.

55. The kit of claim 54, wherein the container is a prefilled syringe.

56. The kit of claim 55, wherein the syringe is a NUOVA OMPI 1 mL long glass syringe equipped with a 27-G thin wall needle, a FLUROTEC–coated 4023/50 rubber stopper, and a FM 27 rubber tip cap.

What is claimed is:

1. A liquid pharmaceutical formulation comprising:

(a) 50 ± 7.5 mg/mL to 250 ± 37.5 mg/mL of an antibody or antigen-binding fragment thereof that specifically binds human proprotein convertase subtilisin kexin-9 (PCSK9), wherein the antibody comprises a heavy chain complementarity determining region (HCDR) 1 of SEQ ID NO:2, an HCDR2 of SEQ ID NO:3, an HCDR3 of SEQ ID NO:4, a light chain complementarity determining region (LCDR) 1 of SEQ ID NO:6, an LCDR2 of SEQ ID NO:7, and an LCDR3 of SEQ ID NO:8;

(b) 10 ± 1.5 mM histidine (pH 6.0 ± 0.3);

(c) 0.01 ± 0.0015% w/v polysorbate 20; and

(d) 10 ± 1.5% sucrose.

2. The liquid pharmaceutical formulation of claim 1, wherein the antibody comprises a heavy chain variable domain (HCVD) comprising SEQ ID NO:1, and a light chain variable domain (LCVD) comprising SEQ ID NO:5.

3. The liquid pharmaceutical formulation of claim 1, wherein: over 90% of the antibodies have a molecular weight of 155 kpa ± 1 kpa; over 50% of the antibodies have an isoelectric point of about 8.5; and from 75% to 90% of the antibodies are fucosylated.

4. The liquid pharmaceutical formulation of claim 1, wherein at least 91% of the antibody has native conformation after 28 days at 45 °C.

5. The liquid pharmaceutical formulation of claim 1, wherein at least 35% of the antibody is the main charge variant of the antibody after 28 days at 45 °C.

6. The liquid pharmaceutical formulation of claim 1, wherein at least 94% of the antibody has native conformation after six months at 25 °C.

7. The liquid pharmaceutical formulation of claim 1, wherein at least 45% of the antibody is the main charge variant of the antibody after six months at 25 °C.

8. The liquid pharmaceutical formulation of claim 1, wherein at least 96% of the antibody has native conformation after six months at 5 °C.

9. The liquid pharmaceutical formulation of claim 1, wherein at least 58% of the antibody is the main charge variant of the antibody after six months at 5 °C.

10. The liquid pharmaceutical formulation of claim 1, wherein at least 96% of the antibody is the main charge variant of the antibody after three months at -20 °C, -30 °C, or -80 °C.

11. The liquid pharmaceutical formulation of claim 1, wherein at least 56% of the antibody is the main charge variant of the antibody after three months at -20 °C, -30 °C, or -80 °C.

12. The liquid formulation of claim 1, wherein the formulation comprises about 175 mg/mL of the antibody.

13. The liquid formulation of claim 1, wherein the formulation comprises about 150 mg/mL of the antibody.

14. The liquid formulation of claim 1, wherein the formulation comprises about 100 mg/mL of the antibody.

15. The liquid formulation of claim 1, wherein the formulation comprises about 75 mg/mL of the antibody.

16. The liquid formulation of claim 1, wherein the formulation comprises about 50 mg/mL of the antibody.