Claims:

1. A composition for use in a method of treating tissue calcification in a pre-diabetic subject or a subject with diabetes, with chronic kidney disease, or at risk of cardiovascular disease or a combination thereof, and in need thereof, wherein the composition comprises menaquinone-7 (MK-7) and/or menaquinol-7 (MKH2-7), wherein at least 2 mg of the MK7 and/or MKH2-7 are administered to the subject per day for at least 6 weeks, and whereupon the administration of the MK7 and/or MKH2-7:

(i) increases a plasma level of Fetuin A relative to the plasma level of Fetuin A prior to administration; or

(ii) decreases a plasma level of Highly Sensitive C Reactive Protein (hs-CRP) relative to the plasma level of hs-CRP prior to administration.

2. The composition for use of claim 1, wherein the subject has diabetes, such as type II diabetes, or has been diagnosed as pre-diabetic.

3. The composition for use of claim 1, wherein the subject

has chronic kidney disease; or

has stage 4 or 5 chronic kidney disease/end stage renal disease.

4. The composition for use of claim 1, wherein the subject is undergoing hemodialysis.

5. The composition for use of claim 1, wherein the subject is receiving non-warfarin-based anti-coagulant therapy, such as oral anti-coagulation therapy, and optionally wherein the anti-coagulation therapy comprises an inhibitor of Factor Xa activity or Factor IIa activity.

6. A composition for use in a method of treating tissue calcification in a subject in need thereof, the composition comprising menaquinone-7 (MK-7) and/or menaquinol-7 (MKH2-7), wherein the composition is administered wherein at least 2 mg of the MK7 and/or MKH2-7 are administered to the subject per day for at least 6 weeks, wherein the composition is a pharmaceutical composition, and wherein the administering the MK7 and/or MKH2-7 causes at least one of the following:

(i) increase the subject's serum T50 value relative to the subject's serum T50 value prior to administration of the MK-7 and/or MKH2-7,

(ii) increase a ratio of a carboxylated to a non-carboxylated form of a Vitamin K-dependent protein in the subject's plasma relative to the ratio prior to administration of the MK-7 and/or MKH2-7,

(iii) increase the plasma level of Fetuin A relative to the plasma concentration of Fetuin A prior to administration of the MK-7 and/or MKH2-7, or

(iv) decrease the plasma level of D-Dimer or Highly Sensitive C Reactive Protein relative to the plasma concentration of D-Dimer or Highly Sensitive C Reactive Protein (hs-CRP) prior to administration of the MK-7 and/or MKH2-7, thereby to treat tissue calcification in the subject; and wherein the subject:

(i) has diabetes;

(ii) has been diagnosed as pre-diabetic;

(iii) has chronic kidney disease; or

(iv) is undergoing hemodialysis.

7. The composition for use of claim 6, wherein the composition is for use in a method of treating tissue calcification in a subject with stage 5 chronic kidney disease and undergoing oral, non-warfarin-based anticoagulant therapy, and in need thereof, and wherein upon administration of the MK7 and/or MKH2-7:

(i) increases a plasma level of Fetuin A relative to the plasma level of Fetuin A prior to administration; or

(ii) decreases a plasma level of Highly Sensitive C Reactive Protein (hs-CRP) relative to the plasma level of hs-CRP prior to administration.

8. The composition for use of claim 7, wherein the subject:

(i) is diabetic;

(ii) has been diagnosed as pre-diabetic; or

(iii) is undergoing hemodialysis.

9. The composition for use of claim 7, wherein the anti-coagulation therapy comprises an inhibitor of Factor Xa activity or Factor IIa activity.

10. The composition for use of claim 1, whereupon administration of the MK-7 and/or MKH2-7 to the subject increases the subject's serum T50 value relative to the subject's serum T50 value prior to administration of the MK-7 and/or MKH2-7.

11. The composition for use of claim 1, wherein administration of the MK-7 and/or MKH2-7:

(a) increases a ratio of a carboxylated to a non-carboxylated of a Vitamin K dependent protein; or

(b) decreases an amount of a non-carboxylated Vitamin K dependent protein in plasma of the subject relative to the ratio or amount present prior to administration of the MK-7 and/or MKH2-7.

12. The composition for use of claim 11, wherein the Vitamin K-dependent protein is selected from Matrix Gla Protein, Growth Arrest Specific Gene 6 (Gas-6) protein, PIVKA-II protein, osteocalcin, activated Protein C, or activated Protein S.

13. The composition for use of claim 1, wherein upon administration of the MK-7 and/or MKH2-7 to the subject decreases a plasma level of D-Dimer or Highly Sensitive C Reactive Protein (hs-CRP) relative to the plasma level of D-Dimer or Highly Sensitive C Reactive Protein (hs-CRP) prior to administration of the MK-7 and/or MKH2-7.

14. The composition for use of claim 1, wherein, when the subject has a dermal lesion and/or vascular lesion, the administration of the MK-7 and/or MKH2-7 reduces the size of the dermal and/or vascular lesion.