CLAIMS

1. A microsphere formulation, comprising:

polymer microspheres, each polymer microsphere comprising:

(i) ibrutinib; and

(ii) a biodegradable polymer,

wherein each polymer microsphere comprises a drug load of the ibrutinib of greater than 30% by weight of the polymer microsphere, and

wherein the polymer microspheres have a particle size of less than 110 μm (D_{50}).

2. The microsphere formulation of claim 1, wherein the biodegradable polymer comprises a poly(D,L-lactide-co-glycolide).

3. The microsphere formulation of claim 1, wherein the biodegradable polymer comprises a poly(D,L-lactide-co-glycolide) having a lactide:glycolide ratio of 50:50.

4. The microsphere formulation of claim 3, wherein the biodegradable polymer is ester-terminated.

5. The microsphere formulation of claim 1, wherein the biodegradable polymer comprises a poly(D,L-lactide-co-glycolide) having a lactide:glycolide ratio of 55:45.

6. The microsphere formulation of claim 5, wherein the biodegradable polymer is ester-terminated.

7. The microsphere formulation of claim 1, wherein the biodegradable polymer comprises a poly(D,L-lactide-co-glycolide) having a lactide:glycolide ratio of 85:15.

8. The microsphere formulation of claim 7, wherein the biodegradable polymer is acid-terminated.

9. The microsphere formulation of claim 1, wherein the biodegradable polymer has an inherent viscosity between about 0.2 dL/g and about 0.24 dL/g.

10. The microsphere formulation of claim 1, wherein each polymer microsphere comprises a drug load of the ibrutinib of about 50% by weight of the polymer microsphere.

11. The microsphere formulation of claim 1, wherein the polymer microspheres have a particle size of between about 20 μm (D_{50}) and about 60 μm (D_{50}).

12. The microsphere formulation of claim 1, characterized in that about 75% to 100% of the ibrutinib is released over a period of about 12 to about 16 days of injection into a subject, but not more than about 20% of the ibrutinib has been released within 24 hours of injection into the subject.

13. The microsphere formulation of claim 1, characterized in that about 75% to 100% of the ibrutinib is released over a period of between about 25 to about 31 days of injection into a subject, but not more than about 20% of the ibrutinib has been released within 24 hours of injection into the subject.

14. A pharmaceutical composition comprising the microsphere formulation of claim 1.

15. The microsphere formulation of claim 1 for use in the treatment of a B-cell malignancy.

16. A microsphere formulation, comprising:

polymer microspheres, each polymer microsphere comprising:

(i) ibrutinib; and

(ii) a biodegradable polymer comprising an ester-terminated poly(D,L-lactide-co-glycolide) having a lactide:glycolide ratio selected from 50:50, 55:45, and 75:25, or a combination thereof;

wherein each polymer microsphere comprises a drug load of the ibrutinib of between about 30% and about 55% by weight of the polymer microsphere, and

wherein the polymer microspheres have a particle size of between about 25 μm (D_{50}) and 40 μm (D_{50}), and

wherein the microsphere formulation is characterized in that about 75% to 100% of the ibrutinib is released over a period of between about 12 to about 16 days of injection into a human subject, but not more than about 20% of the ibrutinib has been released within 24 hours of injection into the human subject.

17. A microsphere formulation, comprising:

polymer microspheres, each polymer microsphere comprising:

(i) ibrutinib; and

(ii) a biodegradable polymer comprising an acid-terminated poly(D,L-lactide-co-glycolide) having a lactide:glycolide ratio of 85:15;

wherein each polymer microsphere comprises a drug load of the ibrutinib of between about 45% and about 55% by weight of the polymer microsphere, and

wherein the polymer microspheres have a particle size of between about 30 μm (D_{50}) and 40 μm (D_{50}), and

wherein the microsphere formulation is characterized in that about 75% to 100% of the ibrutinib is released over a period of between about 25 to about 31 days of injection into a human subject, but not more than about 20% of the ibrutinib has been released within 24 hours of injection into the human subject.