This Preclinical and Clinical Summaries section contains a summary of the preclinical work performed as well as three detailed summaries for toxicology, pharmacokinetics, and pharmacology. Finally, this section contains the synopses from the three pre-pivotal trials (BMTI-2005-03, 2005-04, and 2006-03-EU) as well as from the pivotal trial (BMTI-2006-01) for Augment™ Bone Graft.