Leveraging Particle Size and Structure to Control Release of Pharmaceuticals for Human and Animal Health

Cory Berkland[1,2], PhD and Xiang Wang[2], PhD

[1]Orbis Biosciences, Inc, [2]The University of Kansas

Orbis Biosciences advances human and animal health pharmaceuticals and vaccines by leveraging controlled release platform technologies. Using Precision Particle Fabrication (PPF) technology, Orbis provides desired delivery rates, including sustained release, pulsatile delivery for single-shot vaccines, and differentiated delivery of novel and generic drugs. By partnering with pharmaceutical companies, Orbis integrates PPF technology into client's products. As a proof point, the team formulated a single injection, 10-day pain relief drug for pets that tightly maintained constant blood levels of the drug.

Pharmaceutical and biotech companies do not have a robust, affordable, and scalable solution for controlled release and delivery of drugs. Today's high-cost and low-yield solutions for controlling the size and properties of drug particles have led to:

- Unpredictable release profiles driven by little control over particle size and morphology;
- Batch processes that are extremely costly and difficult to scale; and
- Undesirable toxicity for localized drug delivery.

The U.S. market for controlled release is $17BN for human pharmaceuticals and $2.5BN for animal health. Reformulation of an approved drug in a new delivery system is significantly less costly than developing a new drug altogether. This approach optimizes product life cycle by extending patent protection by 10-15 years and recapturing much of the 60-75% drop in revenue attributable to competition from generics.

In one example, current postoperative pain medicine options for pets provide relief for only hours at a time. Pet owners have a strong willingness to pay, but available options are inconvenient (repeatable oral doses) or impractical (repeatable visits to the vet). The market calls for a long-acting drug that is safe, convenient, and practical. Using PPF, Orbis has formulated a 10-day pain relief drug for pets to address the U.S. pain relief market.

PPF technology produces uniform particles or capsules with a narrow size distribution and precise control over particle morphology (e.g., porosity or coating

thickness). This solution provides an affordable, scalable solution for controlled release of active ingredients to:

- Eliminate the need for multiple administrations and increase patient compliance;
- Reduce side effects by maintaining a safe, effective drug concentration;
- Establish greater treatment effectiveness and predictability;
- Protect active ingredients from interacting with one another or irritating the stomach; and
- Taste-masking foul-tasting and -smelling ingredients.

This development is possible through collaboration of regional organizations including:

Public laboratories

- The University of Kansas Particle Characterization & Formulation Lab works at the interface of medicine and engineering with an emphasis on precisely controlling the physical and chemical properties of particles and biomaterials.
- PharmCATS, a bioanalytical laboratory affiliated with Kansas State University, provides bioanalytical services and *in vivo* studies.

Private companies

- Orbis Biosciences, Inc. works with pharmaceutical clients to integrate controlled release technology into products.
- Beckloff Associates, Inc., advises the team on the clinical path to obtain FDA approval for drugs.