Slow release injectable for post-operative pain

**Overview**
Every year, over 40 million surgeries are performed on dogs and cats. As a result, many pet owners administer painkillers once or more daily to ensure their pet is comfortable while recovering from a surgical procedure. Administering pain medication can be inconvenient and frustrating when the pet does not wish to cooperate. It also enables substance abuse by the pet owner. To address this, a slow release injectable lasting 5-7 days has been developed. This post-operative formulation is designed to be given by the veterinarian immediately after surgery and provide pain relief through the recovery stage for most minor surgeries.

**Advantages**
- Uses off-patent, FDA approved drug and polymers for quicker regulatory approval
- Steady release of drug for up to seven days
- Injectable form ensures that animals receive proper dosage and prevents misuse by pet owners

**Description**
Existing options for extended treatment of pain include diffusion wound catheters and daily administration of pain killers, both of which are inconvenient. Topically-applied ointments such as Recuvyra are limited to use in dogs and can result in unintentional contact of owners or their children with the medication. Buprenorphine is a well-known off-patent FDA-approved semisynthetic opioid used to treat moderate to severe pain. Its current use in animals is for light to moderate pain but requires frequent injection to remain effective over long time periods. A prolonged-release injectable delivery system for buprenorphine has been developed that consists of off-patent PLA/PLGA polymers mixed with drug. Formulations are stable at 4°C and release rates can be adjusted for faster or slower release ranging from 3-7 days. Studies in rats showed a near-linear release of buprenorphine over 7 days when injected intramuscularly using gamma-radiated, sterilized nanoparticles.

**Target Market**
It’s estimated that there are 70-80 million dogs and 74-96 million cats owned in the United States. A survey of pet owners found that 95% consider their pets to be members of the family. This current trend of spending and changing perspective indicate that most owners care about their pet’s wellness and will show interest in products that decrease pain and stress in their animals. Receptiveness of the target market was explored through in-person interviews with veterinarians and pet owners.

Veterinarians were concerned that many clients forget doses or stop dosing as soon as the pet shows signs of feeling better. The majority was intrigued by the use of a slow-release pain medication as it would increase client compliance, which would translate to less pain for the animal. Veterinarians also liked that an injectable would allow them more control over their patient’s comfort level and ensure that they receive the medication necessary for a full recovery. They saw this product as a way to increase return visits, too - that patients would need to return to their clinic to receive the medication instead of the owner going to the local pharmacy to fill a prescription.

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Target Market (cont.)
We also interviewed over 50 pet owners and found that most were interested in injectable pain medication, particularly if their pets are stubborn in taking medications orally. Many were willing to pay more for long-term efficacy in order to avoid the hassle of giving medications themselves. In turn, this also spares the pet from unnecessary stress post-operatively, as they are not being chased down or forced to take their daily medication.

Although any difficult-to-dose animal would be a target for this product, cats stood out as a particularly valid patient segment. Treatment in cats is limited due to their unique physiology. Their small size also translates to lower doses which are more affordable for pet owners. In addition, many cat owners already lean towards injectables when they’re available due to the difficulties many cats exhibit when taking oral medications.

Need for feline-friendly post operative pain management. Current approved slow release pain ointments are not for use with cats, limiting pain management options to pills or regular injections. A single injection for week-long coverage of post-operative pain was attractive to many cat owners interviewed. (picture taken from http://veterinaryteam.dvm360.com/image-quiz-identifying-postoperative-pain-cats)

Status
- Subject of US Patent 9,566,241 and an additional non-provisional application
- Near-linear release demonstrated over 7 day period in rats

Licensing Opportunities
- This technology is available for exclusive or non-exclusive licensing
- Joint development opportunities include funded research or a joint venture

Extended release nanoparticles. (A) Scanning electron micrograph of buprenorphine nanoparticles. (B) Release of buprenorphine in rats over time. Intramuscular injection shows a near-to-linear release profile, releasing at levels close to control daily injections through day 7.