



Inventors:



Dr. William Ravis
Professor
Dept. of Drug Discovery



Dr. Yub-Jing Lin
Research Fellow (former)
Dept. of Drug Discovery

Contact:

Troy Brady
Auburn University
Innovation Advancement
& Commercialization
334-844-4977
lifesci@auburn.edu
iac.auburn.edu
Reference: Post Operative Pain



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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:

- **FDA-FRIENDLY** - Off-patent, FDA approved ingredients for quicker regulatory approval
- **NEAR-LINEAR RELEASE** - Steady release of drug for up to seven days
- **ABUSE RESISTANT** - Prevents misuse by pet owners and ensures proper delivery

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.



Animal post-operative care. The use of pain-relieving ointments requires pets be isolated from children and interaction with adult family members is limited. An injectable slow release pain medication could allow pets more interaction with their human families during recovery. (picture taken from <http://www.pets4homes.co.uk/pet-advice/5-steps-in-post-operative-care-cats-dogs.html>)

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 were 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.

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Slow release injectable for post-operative pain (Cont'd)

Veterinarians 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.

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.

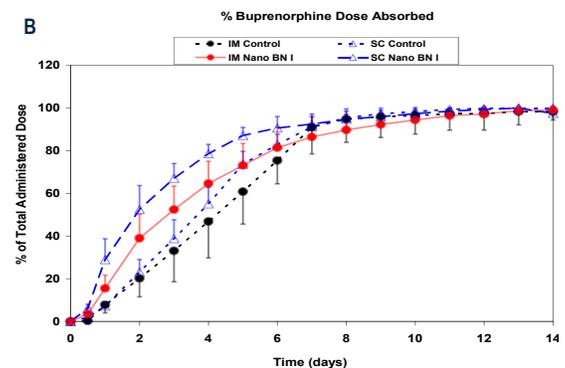
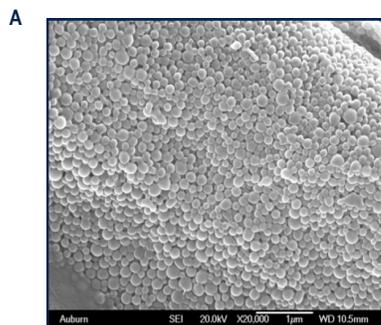
Although any difficult-to-dose animal would be a target for this product, cats stood out as a particularly valid patient segment. Treatment in cats is limited due to their unique physiology. Their small size also translates to lower doses which are more affordable for pet owners. In addition, many cat 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 Patents [9,566,241](#) and [10,154,968](#)
- Near-linear release demonstrated over 7 day period in rats
- This technology is available for exclusive or non-exclusive licensing



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.

Early Stage

Lab testing

Animal POC

Animal Trials