Pallivex

Executive Summary

Contact Information
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Industry
Combination Product
Pain Control

Development stage
Academic Endeavor in Stealth Mode

Funding Opportunity
$3,000,000 to complete pre-clinical work within one year

Other Support Needed
- CEO experienced with biotechnology startups
- Introduction to implant makers or pharmaceuticals interested in partnering

Current Funding
- Federal Grants
  - MIRA R35
- Foundational Grants
  - Connections Grant
- Institutional Funds
  - UConn
  - Connecticut Children's

Implantable biodegradable pain relief film to eliminate pain after surgery

SURGERY HURT

- **Surgery hurts**
  - 40 million adults and 4 million children have surgery each year.
  - 3 in 4 have uncontrolled pain, putting them at risk of chronic pain (1 in 4 patients after surgery) or opioid addiction (1 in 600) and overdose (1 in 3,500).
- **Our current solutions are inadequate**
  - Local anesthetic injections are **too short-lasting.**
  - Continuous infusions and nerve blocks are **too complicated.**
  - Over the counter pills are **too mild** for most surgical pain.
  - Opioid pain medications treat severe pain, but are **too risky** in terms of addiction.

SOLUTION

- Our films release **strong** non-addictive local anesthetic for **7 days**, are flexible, can be cut to size, and degrade when no longer needed.
- Patented brush technology allows for precise and targeted drug delivery, making our film **safe.**
- FDA-approved local anesthetic Bupivacaine is bound to our films during manufacturing, then released at the surgical site to block pain nerves and eliminate the sensation of pain without risk of addiction.
- Our IP can be used for two products, both **simple** for the customer:
  1. ***Stand-alone film*** placed in the surgical site by the surgeon.
  2. ***Combined with an implant*** such as a breast implant or hernia mesh.

POTENTIAL RETURN

- ***Stand-alone film***: ESM of **$130M** for first indication of inguinal hernia. The global market for pain control after surgery is growing 5% annually.
- ***Combined with an implant***: ESM of **$256M** for partnership with two implant makers to provide film incorporated into their product, allowing for a surgical implant with embedded pain control. The global implant market is growing 7% annually.

COMPETITION

- Recently FDA-approved products (Exparel from Innocoll) provide only 24 hours of pain relief.
- Startups in this space have no clinician on their executive management team (PainReform).
- Large companies are not currently innovating (Pfizer, Johnson & Johnson).
- Our film can bind a new drug or combinations of drugs if a disruptive medication arrives.

EXECUTION PLAN

With appropriate funding, we will complete pre-clinical work on the stand-alone film by 2024. Phase 2 trials will begin in 2026. Phase 3 trials will begin in 2027. We anticipate **FDA approval for the film in 2030**.

FINANCIALS

- Angel Round (2024): $3M for Preclinical work
- Seed Round (2025): $10M for Phase 2 Trial
- Series A (2027): $15M to start Phase 3 Trial
- Series B (2028): $20M to complete Phase 3 Trial and obtain FDA approval
- Exit strategy (2030): Acquisition or IPO after FDA approval

THE TEAM

We have a cross-functional team with the experience to complete pre-clinical work and oversee clinical trials. Our collaboration allows us to perform **clinically-based design**: our products are developed with the clinical need and realities of modern health care built into the design from day one.

- ***Courtney Rowe, MD, Surgeon***
  - Director of Reconstructive Urology at Connecticut Children's, with translational research experience in large animal models and early clinical trials.
- ***Kelly Burke, PHD, Polymer Scientist***
  - Director of the Polymer Program at UConn, with expertise in synthesis and structure-property relationships of multifunctional polymeric materials.
- ***Chris Foster, MA, Cell Biologist***
  - Researcher at UConn Health, with extensive experience in molecular and cell biology