

**“Dead Lice Don’t Lay Eggs!”
A Product Development Story**

Piedmont Pharmaceuticals, LLC

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- Research & Development pharmaceutical company.
- Located in Greensboro, North Carolina
- Started in August 2001
- Consists of a 9 member staff, all doing many jobs.

Piedmont Pharmaceuticals, LLC

- All work is contracted.
- Staff is well-experienced in biology, entomology, safety, manufacturing, and formulation development
- Piedmont Pharmaceuticals is the 3rd successful start-up Life Science Company for our group
- Primary experience in parasitology and drug delivery

How was the lice project born?

People kept asking, “ Why don’t you work on head lice? A good head lice product is really needed!”

Head Lice Competition

- Existing treatments contain neurotoxic insecticides (Rx and some OTC)
- Lice are resistant to many insecticide-based treatments
- Lack of efficacy results in misuse/overuse of insecticide-based products.

Initial Brainstorming (scientists, house wives, non-scientists, etc.)

The Product Requirements were:

- Safe
- Efficacious
- Low to No odor
- Simple to apply

**Results of Initial Product Test
(In Vitro Body Lice)**

- Preliminary Formulation: Ivermectin, Methoprene, Isopropyl Myristate, Cyclomethicone
- Effects were seen almost immediately
- Killed all lice tested in 10 minutes
- Raised Questions about the Active?
“Ivermectin should have taken up to 8 hours to work – not 10 minutes”
(Methoprene works slowly)

**Results of Initial Product Test
(In Vitro Body Lice)**

- Evaluate the contributory effect of each component of the original formulation
- Discovered that the excipient - Isopropyl Myristate is the Active Ingredient killing Adult & Nymphal Body Lice
- Developed a New formulation – Isopropyl Myristate & Cyclomethicone D₅
- Filed Patents

New Development Question

- Which Formula should Piedmont take forward to treat Head Lice?
Isopropyl Myristate
Or
Isopropyl Myristate & Ivermectin
- Problem: In Vitro models do not exist to evaluate compounds for the treatment of Head Lice – only Body Lice.

**Ecuador Clinical Head Lice Study
“Proof of Concept” (22 Patients)**

- Evaluate the effectiveness of two formulations to treat Head Lice

 1. Isopropyl Myristate
 2. Isopropyl Myristate & Ivermectin

With 100% kill of Adult and Nymphal Head Lice at 1 hour – Piedmont moves forward with Isopropyl Myristate as its active ingredient.

Preclinical Studies Conducted

- Acute – eye, skin, oral and dermal
- Subchronic – Repeat Dermal (pig)
Repeat Oral (Rat)
- Teratology – Rat and Rabbit
- Reproduction – D₅ on file
- Genetox – 3 studies (major areas)
- Chronic - D₅ on file

Clinical Studies Conducted

- Ecuador
- Canada
- UK & Ireland
- US (Phase IIs Complete; Phase IIIs ongoing)
- US - Sensitization (> 200 subjects)
- US - Cumulative Dermal Toxicity (30 subjects)
- US - Pharmacokinetic (12 subjects; 4-12 years old)

Phase II Study - Canada

- Conducted in Winnipeg
- Enrolled 29 cases
 - Could treat up to 3 times (all with Resultz)
- Results
 - 1 subject failed (1 louse after 3rd treatment)
 - T-test statistic – pValue = 0.0001
 - 96% Success

RESULTZ™ Head Lice Treatment

- Insecticide-free, colorless, and odorless
- Patented Formulation
- Unique mechanical mode of action not likely to development resistance
- New Approach – Dissolves wax (insects are covered with wax) results in quick dehydration and disrupts osmoregulation which results in dead lice
- Canadian approval April '06
- Altana Pharmaceuticals launches RESULTZ™ Sept 06


