

HALLUX FOCUS AND MISSION

- Hallux is a clinical-stage nail care therapeutics company focused on developing the first subungual topical antifungal drug therapy for treating chronic onychomycosis (toenail fungus).
- To date, treatments for toenail fungus have been either low cure topical products that must be applied daily for 12 months or pills that are taken daily for three months that can cause systemic side effects.
- The Company's mission is to provide a highly effective topical solution for patients with chronic onychomycosis that delivers a reliable cure without the risk of systemic side effects.

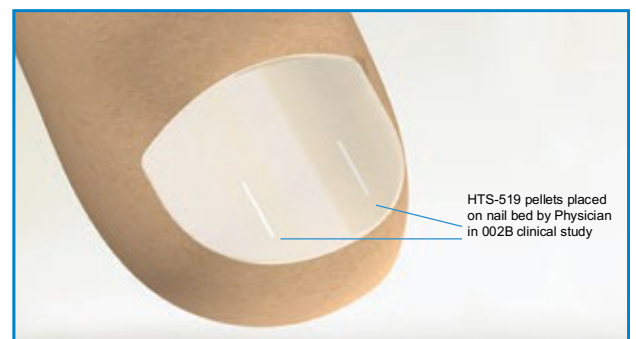
HALLUX ONYCHOMYCOSIS SOLUTION

The Only Local, Direct to the Nail Bed Approach for treating Toenail Fungus

- Our treatment goal is focused on safely treating onychomycosis with a topical subungual dosage form that is highly effective, without the systemic safety issues associated with oral medications.
- Our innovative subungual treatment approach delivers high concentrations of terbinafine, a proven fungicidal (fungus-killing) drug, directly to the nail bed site of the infection.
- Delivering this proven fungicidal drug to the nail bed enables high concentrations of terbinafine to reach the site of infection where it is needed instead of introducing it systemically where it can affect the liver and interact with other drugs patients may be taking.
- The Hallux subungual topical is administered straight to the nail bed creating a depot of fungicidal drug at or above the MICs (minimum inhibitory concentration) that kills fungal invaders enabling the regrowth of disease-free nail and ultimately complete cure of the infection.

Without the Risks Associated with Oral Medication

- At Hallux, our approach to treating onychomycosis is to safely deliver high concentrations of the powerful, fungus-killing drug terbinafine directly to the nail bed.
- In this way, we kill the fungus at the infection site without exposing the body and vital organ systems to systemic medications.
- Our approach to treating onychomycosis directly and locally in the toenail bed eliminates the:
 - Need for systemic medications
 - Risk of liver toxicity associated with oral medications
 - Potential for other systemic side effects
 - Need for liver function tests before filling prescriptions
 - Need for brush on topicals that must be applied daily for twelve months or more



Hallux's subungual technology enables direct administration of terbinafine to the site of the infection resulting in high drug concentrations throughout the mycotic tissue in the nail bed and plate.

CLINICAL DEVELOPMENT STATUS

- A Phase 2A 48-week clinical trial for the Company's first subungual dosage form HTS-519 completed September 2018.
- This encouraging subungual pilot study enrolled 30 moderate-to-severe onychomycosis patients from a high volume podiatric clinic in the greater Phoenix, Arizona area.
- The Company has completed long-term toxicity studies of a new subungual gel that will soon be evaluated in a 52-week efficacy, safety, tolerability, and pharmacokinetic study in patients with mild to moderate onychomycosis.

LEADERSHIP

- The Leadership team at Hallux consists of experienced operators in drug/device development, onychomycosis clinical trial execution, regulatory affairs, commercial planning and execution, and business development.
- The team includes:
 - Mark Taylor – Chief Executive Officer, Co-Founder/Board Member, Stockholder
 - Robert Orr – Board Member, Co-Inventor, Formulation/CMC, Stockholder
 - Jay Birnbaum PhD – Co-Founder, Co-inventor, Board Member, Clinical Advisor, Stockholder
 - Chris Agee – Co-Inventor, Analytical Development, Stockholder
 - Geert Cauwenbergh PhD – Clinical Advisor
 - Jeff Cole – Finance and Administration, Clinical Operations, Stockholder
 - Margie Mohler – Bioanalytical and PK
 - Fred Reno PhD – Toxicology
 - Feng-Yu Lee – Regulatory & Compliance
 - William P. Forbes – Board Member
 - Lewis Freed DPM – Principal Investigator
 - Mahmoud Ghannoum PhD – Mycology Advisor
 - Tracey Vlahovic DPM – Chief Clinical Advisor

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