

# Staval LLC

# Executive Summary

Staval LLC. is a Corporation registered in the state of New Jersey, with its primary office in Princeton, New Jersey. The Company was founded in 2007, solely for the purpose of developing, patenting and commercializing a family of target specific use healthcare related disinfectant products. The products are specifically and uniquely designed to eliminate fungi and other organisms which are present in footwear (“shoes, insoles, boots and sneakers” regardless of material; collectively “footwear”) and which constitute a major factor in the transmission of infections of the feet including Athlete’s Foot (“tinea pedis”) and toenail fungus (“onychomycosis” or “tinea unguium”).

According to US Health and Nutrition Examination Survey (NHANES 1) conducted by the US Health Department, 11% of the US population (32 million people) have Athlete’s Foot, with a subset of about 6.2 million having toenail fungal infections caused over time by persistent Athlete’s Foot infection. There is a direct connection between Athlete’s Foot infection and toenail fungus. Left untreated, even on a sub clinical level, Athlete’s Foot infection may develop into toenail fungus.

In recent years, substantial improvements have been made with medications (such as Lamisil and Lotrimin) intended to treat these infections on the foot. Even though these treatments improved our ability to manage these infections, the failure rate is unacceptably high. Moreover, recurrence rates with each of the various prescriptions (“Rx”) and over the counter (“OTC”) treatments are high. Consequently, the anti-fungal product category is one of the highest turnover categories in the market and pharmacy.

The reason for the high failure and recurrence rates (52% to 77%)<sup>1</sup> is incomplete eradication of the fungus and/or re-exposure to the fungus. Shoes from people with Athlete’s Foot and onychomycosis are contaminated with the fungus that causes these diseases. Fungi are capable of surviving in shoes for long periods of time; months or even years.

Patients can treat their disease with one of the existing topical or oral treatments and can wash their socks, but there are no effective methods available for treating the fungus within the footwear. Although the patient may complete a recommended course of topical and/or oral antifungal treatment they have not addressed the persistent fungus in the shoes. Once the shoes are put back on, the patient is once again exposed to the fungus.

Failure to eradicate the fungus in the shoes makes the existing medications for treating Athlete’s Foot limited in their effectiveness. To achieve a complete cure and reduce the likelihood of recurrence necessitates the use of a complimentary antifungal product for the disinfection of the contaminated footwear to complete the treatment.

Recognizing this need and the lack of any existing products, Staval was founded to develop, patent and commercialize such products. A provisional patent was filed in October of 2005 and testing for product development has been performed at the Center for Medical Mycology, University Hospitals of Cleveland. Testing in support of the Company’s intellectual property was completed in April of 2006 and a comprehensive domestic and international patent application was filed in October of 2006. Additional testing will continue to assure product optimization, development and improvement over time.

The Staval products can be sold through multiple channels in the US, internationally, and the military. Staval products can be sold in multiple brand names through multiple channels of distribution. Perhaps the largest market is the consumer channel followed by the professional channel. Staval is open to consider licensing arrangements with major consumer and healthcare companies to best reach these markets on a rapid basis.

Recognizing the need to create market and physician awareness to alter a treatment paradigm, an extensive direct to consumer (“DTC”) sales and marketing campaign may be necessary as well as presentations at National meetings (AAD, APMA Podiatry... etc.). This will result in sell through at the consumer level and also raise awareness at the physician and specialty levels. Given the potential size of the market estimated at \$950 million (\$650 million consumer; \$300 million Rx) significant sales and marketing related investment will clearly result in an increased ROI.

It is important to note that this is not a drug related product and therefore FDA involvement and approval are not required. Disinfectant products are regulated by the Environmental Protection Agency (“EPA”). It is expected to take 12-18 months to develop the submission and receive marketing clearance from the EPA. Sales to the military need not be approved through EPA channels. Depending on timing in opening a relationship with a licensee, Staval will begin marketing to the potentially huge military market worldwide as soon as possible to generate initial and immediate revenues at minimal cost of sales and marketing.

Progress and results to date have been self-funded by the Founders. Presently plans call for formulations and stability tests in the delivery system with an aerosol-like manufacturer to assure the product will be delivered as planned. This will require more lab work however, once this has been accomplished, sales can begin almost immediately to the Department of Defense (“DoD”). Simultaneously, laboratory and clinical work will begin as previously stated for the purpose of product improvement, claims support and line extensions.

- 1- Journal of the American Academy of Dermatology (Elewski, et al. JAAD 32(2, Part I):290-292 (1995), Long-Term Outcome of Patients with Interdigital Tinea Pedis Treated with Terbinafine or Clotrimazole.

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