



LifePharms LLC
143 Shaw Street
New London, CT 06320

E. Edward Mena, PhD
Cell 860-46-4474
Lab 860447-8583

Industry: Human Fungal Disease

Management:

E. Edward Mena, PhD
(Biochemistry, Washington
University, St. Louis)
Founder, CSO

Seeking:
Business Advisor
Financial Officer
Scientific Officer-
experienced with
IND studies

Board: Seeking members

Scientific Advisory Board:

Timo Ovaska PhD., the Hans and
Ella McCollum '21
Valteick Professor of
Chemistry at Connecticut
College.

Bruce Blough PhD.,
Research Triangle
Institute. Senior Chemist

Mahmoud Ghanoun PhD Professor
of Dermatology, Director
of Center for Medical
Mycology, Case Western
Reserve University.

Number of Employees: 1

Finance:

SBIR Auditor:
Peter Witts. CPA
(www.wittscca.com)

Funding to Date:
SBIR I \$300,000
SBIR II 1.5 million

Financing Sought:

Finish IND studies 2M
If Necessary-
Phase I 2.5 M
Phase II 7-14M

IP: Cantor-Colburn

Business Description / Company Background:

LifePharms LLC has discovered a novel compound that is active against drug resistant fungal infections both *in vitro* and *in vivo* in animal models of systemic infection. The founder, E. Edward Mena, previously was employed at Pfizer in Groton, CT. He left Pfizer to found LifePharms, a company with 25,000 samples of basidiomycetes and ascomycetes (mushrooms) collected in the wild throughout the USA by the founder. This collection is the source of compounds for LifePharms antifungal program.

Market Opportunity/Unmet need.

For decades the foundation of AF treatment has been the azoles, but their success is undermined by the emergence of azole-resistant species. The other two classes of AFs are amphotericin B (polyenes), and echinocandins. Amphotericin B and its lipid formulation cause liver toxicity, particularly at high doses or prolonged administration. Echinocandins are often ineffective against *Aspergillus* and ineffective against non-albicans *Candida*. Further the echinocandins are only effective intravenously. *Candida* sp cause a large percentage of hospital-acquired bloodstream infections and those diagnosed with invasive candidiasis have mortality rates of approximately 40%. Infections due to non-albicans *Candida* species account for an increasing proportion of cases. Unfortunately, many *Candida auris* and *C. glabrata* species are resistant to at least one class of AF. Resistant forms of *Aspergillus fumigatus* is a growing health concern. In addition, *A. fumigatus* causes invasive aspergillosis, chronic pulmonary aspergillosis (CPA), and allergic bronchopulmonary aspergillosis (ABPA). Also, CPA and ABPA affects six million patients and half of patients with CPA die within five years and 40% of patients with ABPA do not improve with AF treatment.

Commercial/Technical Milestones

The antifungal market was 22B in 2022 and expected to grow to 30B by 2030. LifePharms LLC isolated, structure identified, prepared 25 analogs and has identified a lead compound. Several of the analogs were active *in vivo*. (Case Western Reserve University) We have completed initial ADME, Human cell and mouse toxicological studies (by Cyprotex Inc, Ma).

Competition / Competitive Advantages / Customer Benefits: The introduction of mechanistic distinct antifungals has been slow to occur. The last class that was introduced was the echinocandins. Caspofungin, the first of three echinocandins was introduced in 2001. All of the drugs approved prior to 2021 were improvements of existing classes. Two new drugs were approved in 2022. Fosmanogepix was introduced by Amlyx and licensed by Pfizer. The compound targets a new fungal membrane target. There are some reports of resistance, similar to azoles, although more information is difficult to find. Also, Ibrexafungerp was introduced by Scynexis for vulvovaginal Candidiasis. It may be the first oral echinocandin. Pulmocide is developing an inhaled azole (Opelconazole) and Cidara an iv echinocandin (Rezafungin). The last three drugs will have the same resistance problems as existing drugs.

Financial Forecast (Unaudited): LifePharms' initial goal is to finish and obtain IND approval from the FDA. LifePharms' intention is to license the drug as soon as possible. Depending on the licensee, this may be accomplished at very early stage. We plan on initiating license discussions as the studies progress.

	2024	2025	2026	2027	2028
Expenses	2M to finish IND studies,			2.15 M Phase I	7-14M Phase II
Revenue	0	0	0	0	

License to For Further Development