

Microbiome-Based Skin Therapeutics

Overview Naked Biome



- We are a translational microbiome-therapeutics company leveraging breakthrough science from the Human Microbiome Project to find microbiome-based applications for skin disease
- Lead product is the a topical Live Biologic Therapeutic for treatment of acne
- Science-based, entered Phase IB clinical trials



Illustration: Charis Tsevis



Opportunity – Antibiotic Alternatives

Problem-Abx resistance

- Worldwide Problem
 - Cost US \$20 billion annually
 - Dermatologists-long course Abx for acne, rosacea
 - CDC/NIH/CARB-X initiatives to reduce Abx

• Acne

- \$4.5 Billion market
- 55-75% of *P.acnes* is resistant
- Little innovation in several decades
- Majority of Rx are combinations of generic drugs
- High side effect profile to topicals and orals





Naked Biome Solution-To provide Dermatologists better, safer, alternative treatments, develop an entirely new class of microbial-based therapeutics, and minimize antibiotic resistance

Walsh, TR, et al. Systemic review of antibiotics in acne: an increasing topical and oral threat. Lancet Infectious Disease. 2016 16: e22-32

Why now?-Genomic Revolution



Sequencing Advances

- Cheaper
- Faster
- Strain-level resolution
- Enables microbial profiling for disease and health specific signatures
- Diseased bacteria have genotypic and phenotypic differences that have clinical relevance
- Before sequencing we knew 90% of facial skin flora was *P.acnes*, irrespective of health
- Now we know characteristics of bacteria that are associated with health and disease
 NAKED BIOME Fitz-Gibbons et al 2013

Summary Accomplishments in Seed De-risking

- Technical Risk- sourced, genotype, & phenotyped optimal candidate strains
- Intellectual Property-formal notice of allowances for IP covering pharmaceutical composition and methods of treatment
- ✓ Manufacturing *P.acnes* GMP manufacturing process established
- ✓ Regulatory-obtained an approved FDA IND to enter Phase IB trials
- Competition-FTO completed with no immediate threats to our first product
- ✓ **Funding-**Raised \$5 million in seed capital
- □ Clinical Trial-Phase IB Clinical trial initiated to capture both safety and early engraftment/efficacy

