

Foaming Surgical Antiseptic: An Effortless Solution for Infection Prevention

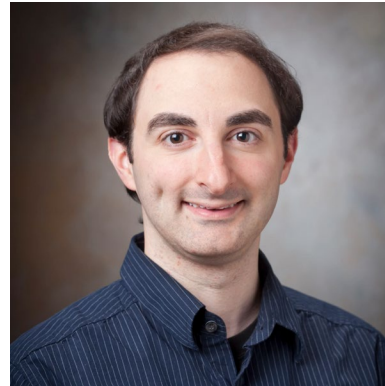
Transforming preoperative antisepsis through a self-expanding foam

THE TEAM



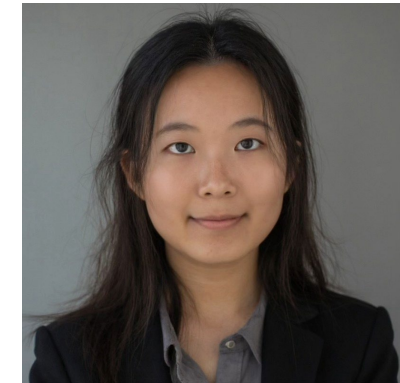
Daniel Wiznia, MD

- Co-founder, Co-PI
- Associate Professor of Orthopaedics & Rehabilitation at Yale University
- Orthopaedic surgeon with experience in surgical site infection prevention



Steven Tommasini, PhD

- Co-founder, Co-PI
- Research Scientist of Orthopaedics & Rehabilitation at Yale University
- Medical device design



Sarah Li

- Co-founder
- Molecular Biophysics & Biochemistry at Yale University
- Biology/chemistry laboratory experience

The Cost of Surgical Site Infections

- SSIs cost U.S. hospitals **\$3.3B** annually
- **50M+** surgeries annually in the U.S.
- Each SSI adds **\$20K-\$40K** per patient
- Nearly **10,000** die each year due to SSIs
- Up to **60%** of SSIs may be preventable with evidence-based guidelines (Kaye 2015)



The Problem With Current Sponge Applicators



Inconsistent coverage

Pooling and runoff

Limited visibility

Sponge spreads bacteria

...leads to

Preventable surgical-site
infections and **prolonged** hospital
stays

OUR SOLUTION: Foam-based Antiseptic Spray

Improved anatomical coverage:

Covers vertical & contoured surfaces
Uniform distribution

Simplified application:

Easy-to-use
No user-to-user variability

Reduced prep time:

Single-pass application
Faster drying time

IP Status

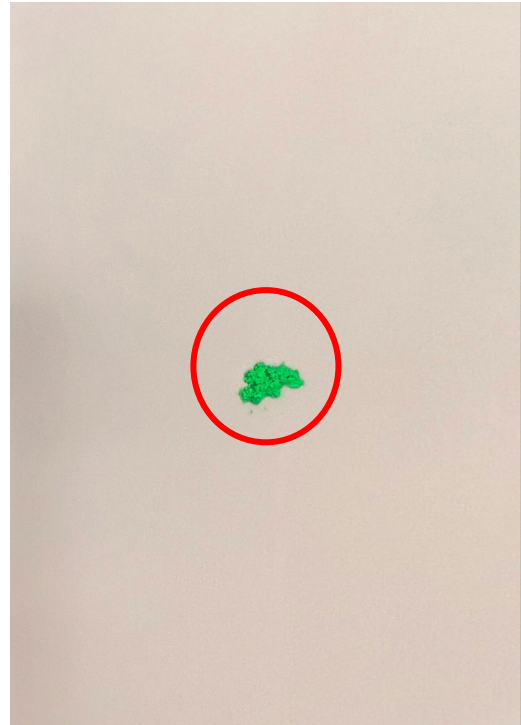
Provisional patent filed April 2025

Novel composition of chemicals in a non-traditional form

Novel delivery mechanism



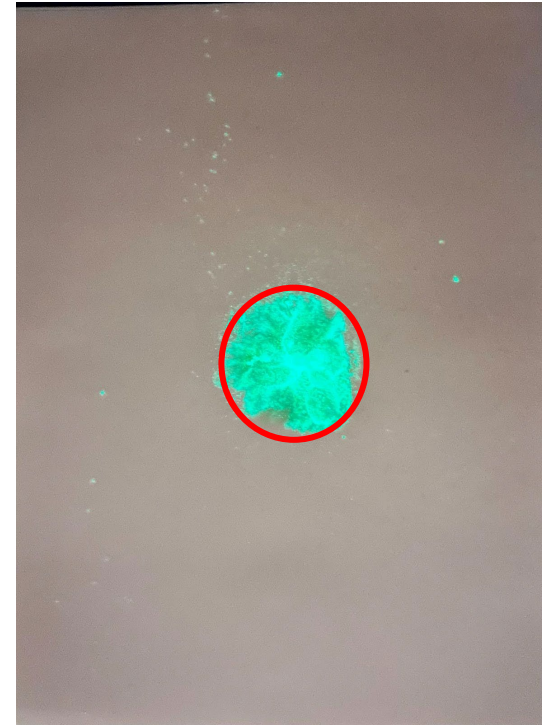
Other Applicators Spread Potentially Harmful Bacteria



Bacteria* applied to surface before antiseptic application



Sponge applicator spreads bacteria over the entire surface



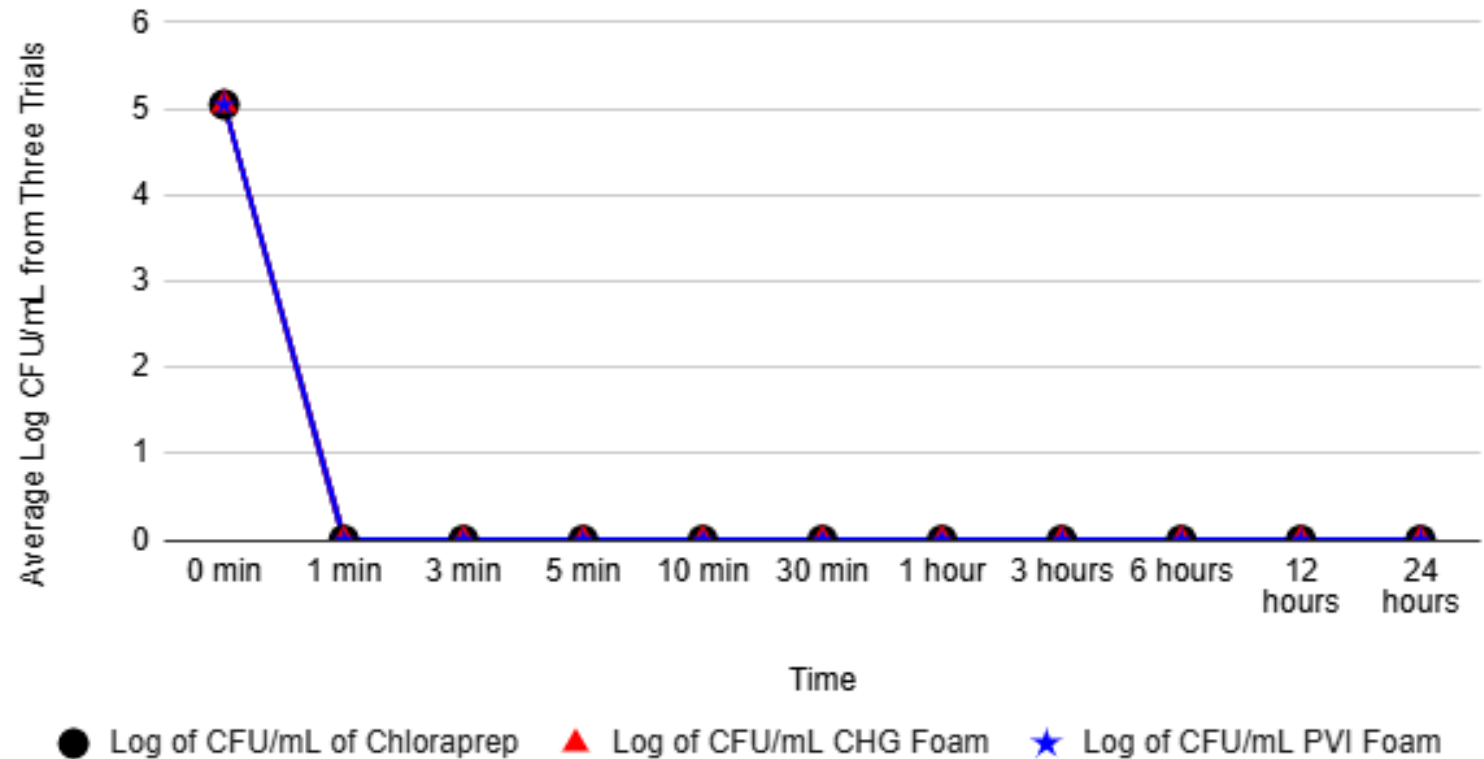
Foaming antiseptic limits dispersion of the bacteria

*Fluorescent powder dusted over a controlled area of synthetic skin before varying applicators were used as an analog of bacteria

Our Foaming Antiseptic Performed as well as Market Leaders

Conducted on ATCC 8739 *e. coli*

Log of CFU/mL for Escherichia coli in Chloraprep, CHG Foam, and PVI Foam



We interviewed over **40** surgeons, nurses, and surgical technicians at YNHH across specialties including **Orthopaedics, Cardiology, and Plastics**



Extremely positive feedback:

- Penetrates skin effectively and sprays irregular surfaces efficiently
- Quick-drying, user-friendly, and easy to apply
- Packaged conveniently for efficient use
- Environmentally friendly: reduces product/material

“I love the simplicity and efficiency this product can bring, I can see it revolutionizing OR prep[aration] procedures!”

-YNHH Surgical Technician

Business Model

B2B Healthcare Sales

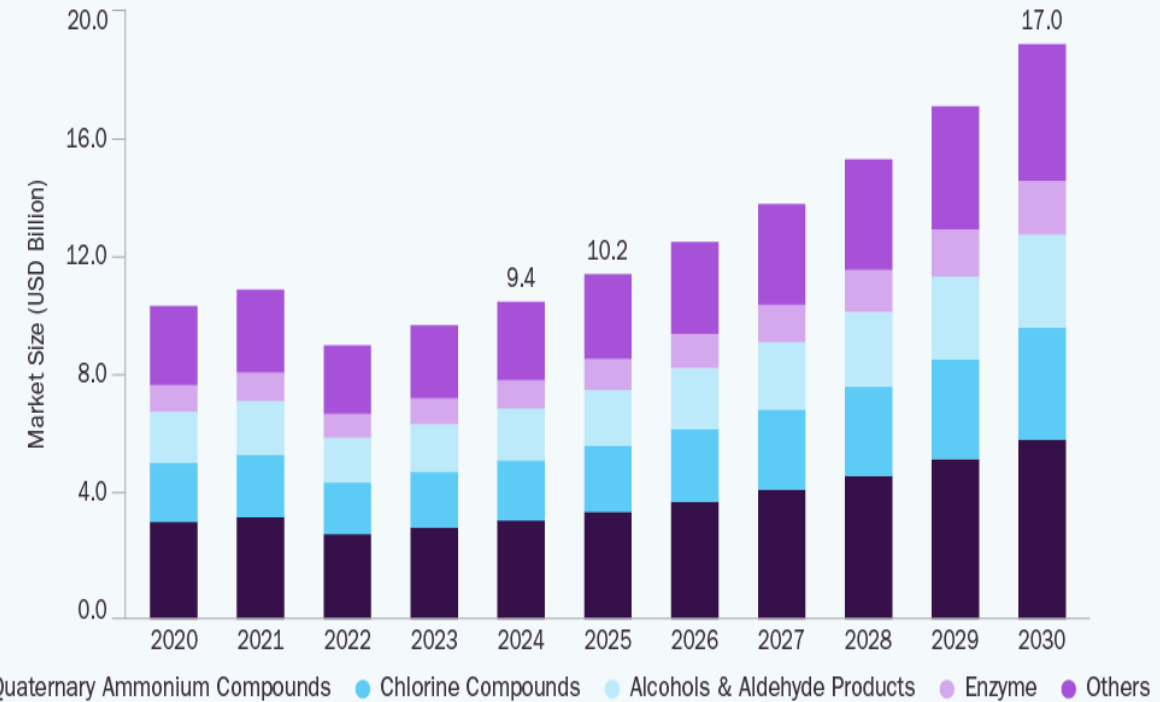
- Direct sales to hospitals & surgical centers
- Unit pricing: \$8-12 per 50mL applicator
- Volume-based contracts with healthcare systems

\$9.4B U.S. preoperative antiseptic market (2023, growing 3.5% YoY)

10% market share = **\$940M annual opportunity**

U.S. Antiseptic And Disinfectant Market

Size, by Type, 2020 - 2030 (USD Billion)



Grand View Research, 2024



Key Differentiators	Foam-Based Antiseptic (Our Solution)	Chloraprep (CHG 2% + IPA 70%)	DuraPrep (Iodine 0.7% + IPA 74%)
Pressure-Independent Application	✓	✗	✗
Superior Anatomical Coverage	✓	✗	✗
Visual Coverage Indicator	✓	✗	✓
Single-Pass Application	✓	✗	✗
Rapid Kill Time (<1 min)	✓	✓	✓
Persistent Activity (48-72h)	✓	✓	✓
GRASE Active Ingredients	✓	✓	✓
Reduced Operator Training	✓	✗	✗

WHAT WE HAVE ACHIEVED SO FAR

- ✔ Proof-of-concept validation: Foam maintains equivalent antimicrobial efficacy to market leaders
- ✔ Clinical feedback collected - strong receptivity from OR clinicians
- ✔ Bacterial time-kill assay completed (E. coli ATCC 8739) - zero growth at 72 hours
- ✔ Packaging design finalized (50mL PET foaming cylinder)



Three potential pathways; Well studied active ingredients

Chlorhexidine based products with sterile applicator

Pathway 1:

505(b)2

- **505(b)(2):** – Route allows reliance on existing safety and efficacy data for previously approved drug while supporting changes such as new formulation or delivery system.
- **Precedent:** 3M followed this pathway for SoluPrep, which introduced a film-forming sterile solution

Pathway 2:

ANDA

- Abbreviated New Drug Application to approve generics
- Precedent: ChlorPrep approved via NDA in 2000 with identical active ingredients (2% CHG + 70% IPA)
- Generic Route: ANDA demonstrates pharmaceutical equivalence to approved reference listed drug
- Novel Element: Foam formulation is delivery innovation, not new drug entity

Povidone-iodine products w/o sterile applicator

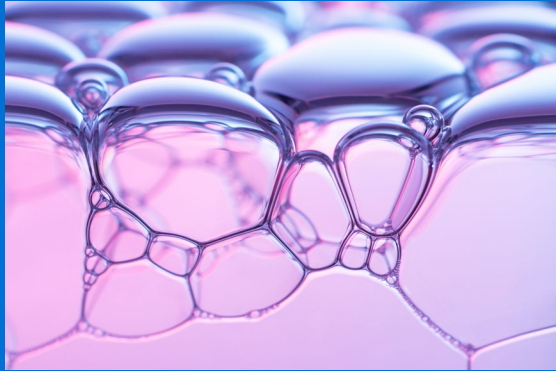
Pathway 3:

OTC monograph

- The FDA OTC monograph for first aid antiseptics (Monograph M003) sets the conditions under which products like **povidone-iodine** + isopropyl alcohol surgical site antiseptics can be marketed
- No premarket approval, no product-specific clinical trials required if conditions are met.
- **Precedent:** BD PurPrep and Carefusion Prevail

What makes
our formulation
qualify for
505(b)2?

Why no clinical
trials?



ChloroPrep™

Common chemical composition

Chlorhexidine gluconate

Isopropyl alcohol

Yale Foaming Surgical Antiseptic

Chlorhexidine gluconate*

Isopropyl alcohol

Unique chemicals <1%

*GRAS/GRASE stabilizers
and vehicles present in
multiple vaccines and
food products*

* Our tests have demonstrated
efficacy with **either** Chlorhexidine or
Povidone Iodine

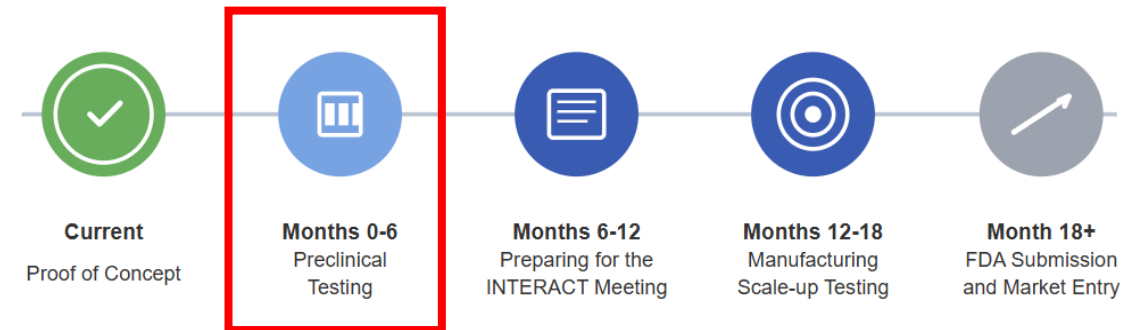
\$100K BLAVATNIK FUNDING

What this funding would be put towards:

- Regulatory consultant - \$40K
- Full bacterial panel, MIC studies, Time-kill assays - \$20K
- Contract manufacturer / DFM (delivery mechanism) - \$40K

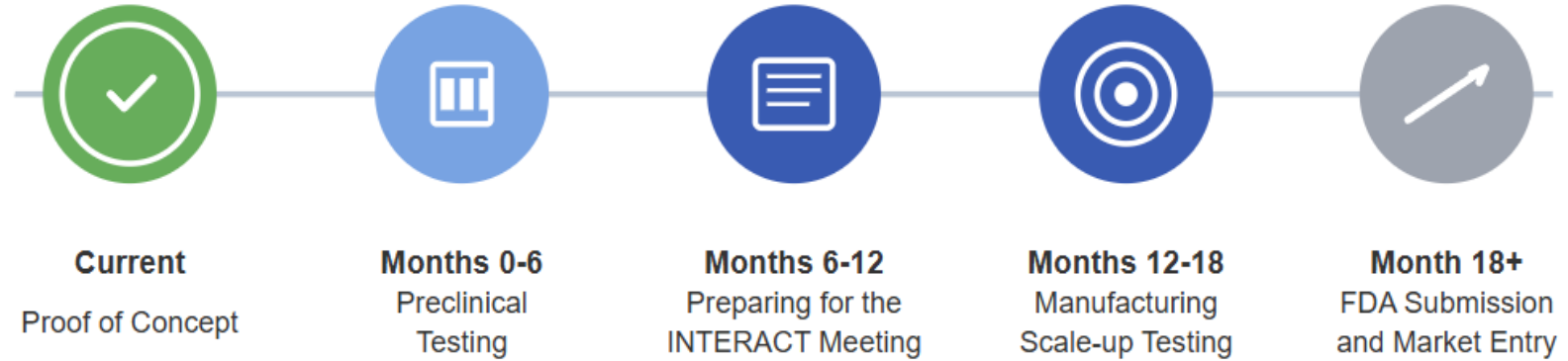
What we will achieve:

- FDA INTERACT meeting & defined regulatory pathway
- Regulatory-grade antimicrobial efficacy data (50+ organisms)
- Validated, shelf-stable optimized formulation
- Investment-ready data package for \$3-5M Seed round



Quick Return on Investments

With **many** potential licensing partners:



Launch within 2 years, and **immediately** start earning royalties

WHY DOES THIS MATTER?



350M+

Surgical procedures
annually worldwide



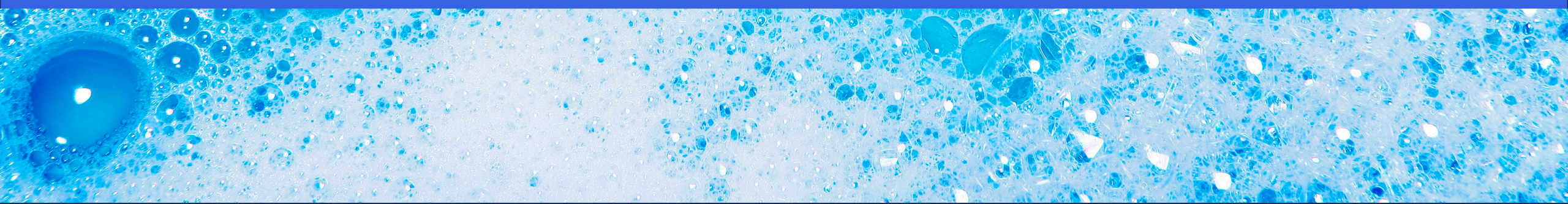
\$3.3B

Annual SSI costs in U.S.
alone



First

Pressure-independent
antiseptic delivery system



Appendix

Product	Manufacturer	Active Ingredients	FDA Pathway	Sterile Applicator	Indications & Use Cases	Key Differentiators
ChloroPrep™	BD	2% CHG + 70% IPA	NDA (505(b)(1))	Yes	Preoperative surgical site antisepsis	Persistent antimicrobial activity up to 7 days; widely used in hospitals
SoluPrep™ S	3M	2% CHG + 70% IPA	NDA (505(b)(2))	Yes	Surgical site antisepsis; improved drape adhesion	Film-forming polymer; tinted option for visibility
DuraPrep™	3M	Iodine povacrylex (0.7%) + 74% IPA	NDA (505(b)(1))	Yes	Preoperative surgical site antisepsis	Creates water-insoluble film; strong drape adhesion; persistence ≥48 hrs
PurPrep™	BD	Povidone-Iodine + Isopropyl Alcohol	OTC Monograph	Yes	Preoperative skin preparation	First fully sterile PVP-I + IPA applicator; OTC compliance
Prevail-FX™	CareFusion	Povidone-Iodine (8.3%) + IPA (72.5%)	OTC Monograph	Yes (bottle with sponge tip)	Surgical site antisepsis	Lower-cost alternative; OTC labeling; no NDA claims

Strong & Defensible IP Position for Foam Antimicrobial Platform

- Broad composition-of-matter protection covering core foam formulation
- Claims **span all major antiseptic actives** (CHG, PVI, BAC, octenidine, PHMB, quats)
- Method-of-use claims **block any expanding, non-running foam achieving ≥ 3 -log kill**
- Dispenser/device claims protect **controlled-volume, non-aerosolizing foam delivery**