

Quorum Innovations Introductory Pitch Deck

**Protective Biofilm Barriers:
Breakthrough Therapies
Rapidly Enabled by Disruptive
Medical Device Platform**

Presented by: Eva A. Berkes, MD, Co-Founder and Co-CEO



Quorum Innovations: What We Do.



Novel disease target: impaired barriers. Environmental exposures break down protective body barriers, such as our skin and intestinal tract. Breached body barriers result in common and difficult-to-treat diseases.

Novel therapeutics: Barrier protection is what Quorum Innovations does. Quorum Innovations ("QI") is the only biotech company in the world developing microbial biofilms to repair impaired barriers. QI Biofilm Barrier Protectants are breakthrough treatments for common conditions like bacterial vaginosis (BV) and chronic wounds & the orphan disease, eosinophilic esophagitis (EOE).

The problem: Inadequate long-term solutions for barrier diseases

1. Current treatments are symptomatic
2. Underlying pathology - barrier dysfunction - is not addressed
3. Diseases/symptoms recur despite treatment
4. Treatments can involve undesired exposures (immunomodulators, hormones or antibiotics)
5. Patients and care providers are not satisfied
6. Result = areas of high therapeutic need

	US Prevalence	Cost of Treatment	Recurrence Rate	Treatment Risks
Bacterial Vaginosis (BV)	20%-30% of women ages 14-49 ¹	\$-\$\$	Up to 69% in 1 year ⁵	Low
Chronic Wounds (CW)	2% of the total population ²	\$-\$\$\$	40% in 6 months ⁶	Low-Mid
Genitourinary Syndrome of Menopause (GSM)	60% of all women ages 55+ ³	\$-\$\$	Recur if ongoing treatment is stopped	Low-Mid
Eosinophilic Esophagitis (EOE)	0.5-1 per 1,000 people ⁴	\$\$\$\$	Recur if ongoing treatment is stopped	Low-Mid

¹ 2001-2004 National Health and Nutrition Examination Survey Data

² Chandan K. Sen. Human Wound and Its Burden: Updated 2022 Compendium of Estimates. *Advances in Wound Care*. Dec 2023. 657-670. <http://doi.org/10.1089/wound.2023.0150>

³ The NAMS 2020 GSM Position Statement Editorial Panel. The 2020 genitourinary syndrome of menopause position statement of The North American Menopause Society. *Menopause*. 2020 Sep;27(9):976-992. doi: 10.1097/GME.0000000000001609. PMID: 32852449.

https://journals.lww.com/menopausejournal/abstract/2020/09000/the_2020_genitourinary_syndrome_of_menopause.5.aspx

⁴ Moawad FJ. Eosinophilic Esophagitis: Incidence and Prevalence. *Gastrointest Endosc Clin N Am*. 2018 Jan;28(1):15-25. doi: 10.1016/j.giec.2017.07.001. Epub 2017 Aug 25. PMID: 29129296.

⁵ Bradshaw CS, Morton AN, Hocking J, et al. High recurrence rates of bacterial vaginosis over the course of 12 months after oral metronidazole therapy and factors associated with recurrence. *J Infect Dis*. 2006; **193**(11):1478-1486. doi: 10.1086/503780.

⁶ Rosenblum J, Gazes M, Rosenblum S, Karpf A, Greenberg N. A multicenter evaluation of chronic ulcer recurrence with the use of varying mechanical wound healing modalities. *Vasc Med Surg* 2017, 5:3 DOI: 10.4172/2329-6925.1000323

The solution: QI Biofilm Barrier Protectants

Scanning electron microscopy of freeze-dried QI Biofilm Barrier Protectant

QI Biofilm Barrier Protectants resolve barrier weakness and associated disease by forming a physical protective layer.

- QI Biofilm Barriers are sterile preparations of beneficial bacterial biofilms.
- They are selected for their unique adhesion to - and protection of - human body surfaces.
- Non-live QI Protectants have the efficacy of live bacterial drugs, but not their cost, lengthy timeline and significant clinical challenges.
- The proprietary QI biofilm discovery platform ensures a continuous pipeline.



QI Barrier Protectants ... Why now?

Right now, the world is ready for treatments with beneficial microbes.

Consumers/Providers

Regulatory

Insurers

Manufacturers

Investors

Media

Right now, a Medical Device development path for QI technology means huge cost and time savings.

Right now, QI technology has competitive advantage protected by its extensive IP over live bacterial therapeutics.

Annual US Market

QI Barrier Protectant disease targets

Scanning electron microscopy of QI Biofilm Barrier Protectant adhering to vaginal surface characteristic of bacterial vaginosis

Bacterial Vaginosis (BV)

\$1B

Symptoms: vaginal itch, foul smell, discharge.

Complications: premature labor and birth, uterine infection, STDs.

<https://www.futuremarketinsights.com/reports/vaginitis-treatment-drugs-market>

Genitourinary Syndrome of Menopause (GSM)

\$1.6B

Symptoms: vaginal dryness, itching, painful sex, urinary urgency, painful urination, UTIs, sexual dysfunction.

Complications: Decreased quality of life, urosepsis, loss of relationships and intimacy.

<https://www.delveinsight.com/report-store/atrophic-vaginitis-market>

Chronic Wounds (CW)

\$3B

Symptoms: chronic, non-healing wound.

Complications: Decreased quality of life, scarring, sepsis, loss of limb, mortality.

<https://www.precedenceresearch.com/advanced-wound-care-market>

Eosinophilic Esophagitis (EOE)

\$150M

Symptoms: difficulty swallowing, acid reflux.

Complications: esophageal scarring, food impaction, perforation, malnutrition.

<https://www.globaldata.com/store/report/eosinophilic-esophagitis-market-analysis/>

Atopic Dermatitis/Skin Barrier Dysfunction (CPG)

\$200M

Symptoms: itchy, dry skin, rash.

Complications: recurrent bacterial infections, decreased quality of life.

QI Barrier Protectants: Pipeline

1

Bacterial
Vaginosis
(BV)

Regulatory
pathway:
Device

2

Chronic
Wounds
(CW)

Regulatory
pathway:
Device

3

Genitourinary
Syndrome of
Menopause
(GSM)

Regulatory
pathway:
Device

4

Eosinophilic
Esophagitis
(EOE)

Regulatory
pathway:
Device or Drug

5

Atopic
Dermatitis/Skin
Barrier Deficiency
(AD/CPG)

Regulatory
pathway:
Cosmetic/CPG

Program	Indication	Funding	MOA	Pre-Clinical	CMC	Pre-Sub	Pilot Study	Efficacy Study	Rights
Qi601	BV		Barrier	→			2024	2025	QI/Pharma Partner
Qi611	CV	DARPA	Barrier	→			510k	510k	QI
Qi601	GSM		Barrier	→			2024	2025	QI
Qi6/Qi601	EOE		Barrier	→			2025	2025	QI
Qi601	AD/CPG		Barrier		CPG Commercialized				QI

Pre-Sub = FDA Pre-Submission

CMC = Chemistry, Manufacturing & Controls

CPG = Consumer Package Goods

First QI Product: QI BV Barrier Protectant

Clinical indication: Bacterial Vaginosis (BV)

What It Is:

- Vaginal Gel
- Class II Medical Device
- Treatment Indication:
Bacterial Vaginosis

How It Works:

- QI Lactobacillus Biofilm Tissue Protectant adheres to and protects vaginal tissues
- Resolves tissue barrier dysfunction
- Resolves abnormal bacterial colonization in bacterial vaginosis

Why It's Needed:

- High recurrence rate (~70%) in 1 year despite use of antibiotics
- Safer than current standard-of-care treatments
- Treats the underlying problem - vaginal barrier compromise

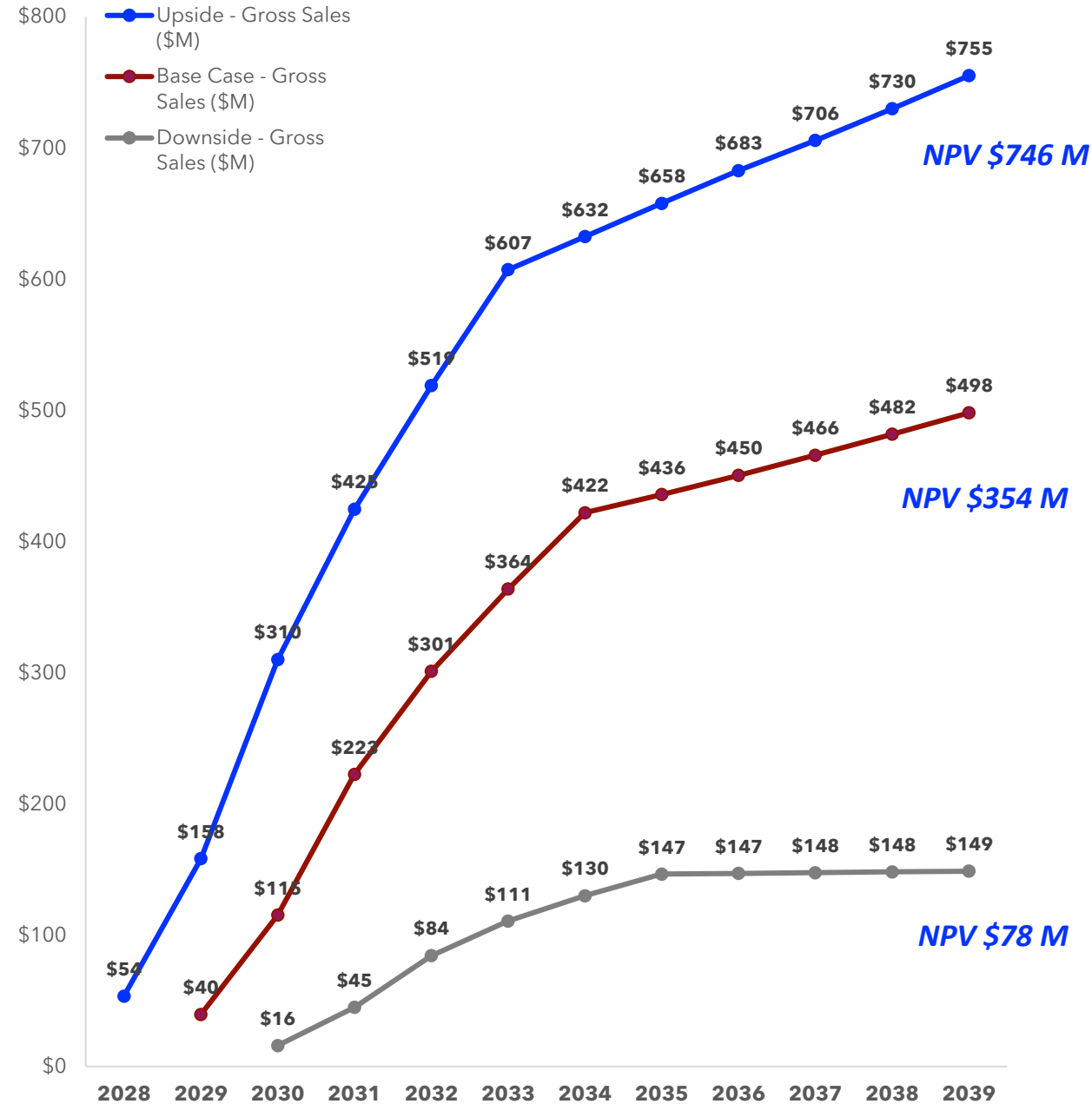
Business Model: License

BV

Bacterial Vaginosis

Figure. QI BV Barrier Protectant US Gross sales Forecast (\$M). Upside (NPV: \$746 M): launch 2027, women ages 14-89, Qi601 peak share = 20%; Base Case (NPV: \$354 M): launch 2028, women ages 14-69, Qi601 peak share = 15% of treated cases and 3.5% of affected women; Downside (\$78 M): launch 2029, women ages 14-69, Qi601 peak share = 10%. NPV calculated with a 12% discount rate through the forecast period.

QI BV Barrier Protectant U.S. Gross Sales Forecast (\$M)



Financials

QI BV Barrier Protectant

Estimated FDA Clearance Date :
Q1 2028

Regulatory Strategy

- Medical Device: Pre-Submission (mid-2024), 510(k) clearance in early 2028
- De-Novo Application with Breakthrough Status anticipated
- **Cost: ~ \$0.5M**

Formulation

- Novel formulation development in-house
- Outsourced to CMO in 2024 for clinical trial formulation, commercial scaling
- **Cost: \$1M**

Medical Device Performance Testing & Manufacturing Design

- CMO final design development and verification and validation testing in preparation for commercial production; completion by 2027
- **Cost: \$2M**

Clinical Trials

- Feasibility clinical trial design, execution and analysis; completion by 2027
- **Cost: \$0.5M**

TOTAL: \$4M

Competition BV

QI: the only biotech company developing tissue barrier device treatments

CURRENT TREATMENTS

Lupin Pharmaceuticals

secnidazole (oral)

Dare Biosciences

clindamycin (vaginal gel)

Manufacturers of generic antibiotics

metronidazole, clindamycin

DRUGS UNDER DEVELOPMENT

LUCA Biologics

L. crispatus

Osel

L. crispatus

Nexbiome

Live bacterium

Ferring/Rebiotix/Mybiotix

Live consortia

Intralytix

Phage

DEVICE UNDER DEVELOPMENT

Quorum Innovations

QI Barrier Protectant

QI ADVANTAGES:

EFFICIENCY & IP PROTECTION

Speed to market

Device mechanism

Intellectual Property

Global and broad, to 2040'

25 patents issued

Advanced Development Stage

In formulation lab trials

Team

Quorum Innovations



Nicholas T. Monsul, MD.
Co-CEO & Co-Founder

- QI IP estate co-developer & serial entrepreneur
- Oculofacial and anterior skull-base surgeon
- Drexel University, Yale University College of Medicine, The Johns Hopkins Hospital, Wilmer Institute (Fellowships and Assistant Professor)



Eva Berkes, MD
Co-CEO, CSO & Co-Founder

- QI IP estate co-developer & serial entrepreneur
- Physician, Allergy, Asthma & Immunology
- Clinical Professor, FSU College of Medicine
- Williams College, University of Florida College of Medicine, Scripps Clinic & Green Hospital



Jim Self, MBA
CBO

- 30+ years global business development (Merck)
- Various BD and Operational roles
- Wharton, MBA
- Founder, Probiopharm Consulting



Chris Gardner
Director, R & D

- 14+ years clinical research project management
- 20+ publications in peer-reviewed journals
- 10+ years senior biological scientist
- University of Florida (BS, microbiology)
- Microbiome therapeutics development experience



David Whitwell, CPA, MBA
CFO

- 30+ years finance & accounting (Merck)
- Founder, Whitwell CFO, LLC
- Partner, B2B CFO Partners, LLC
- CFO for IWT and Clean Diesel



David Salinwanchik, JD
Patent Attorney/ Advisor

- Partner, Salinwanchik, Lloyd & Eisenschenk
- Adjunct Professor Univ of Florida Law School
- University of Michigan (JD), University of Florida (BS, chemistry, environmental science)



Ankur Ghandi
Regulatory Strategy/Product Development

- 18+ years, regulatory & product development
- Founder, SKG RegenMed Consulting
- VP, Americord; Director, Integrity LifeSciences
- PhD, Biomedical Engineering (NJIT/UMDNJ)



Katie MacFarlane, PharmD
Market Expert / Advisor

- Managing Partner, SmartPharma
- CCO, Agile Therapeutics
- VP Marketing, Warner-Chilcott
- Regional Sales Director, Pfizer

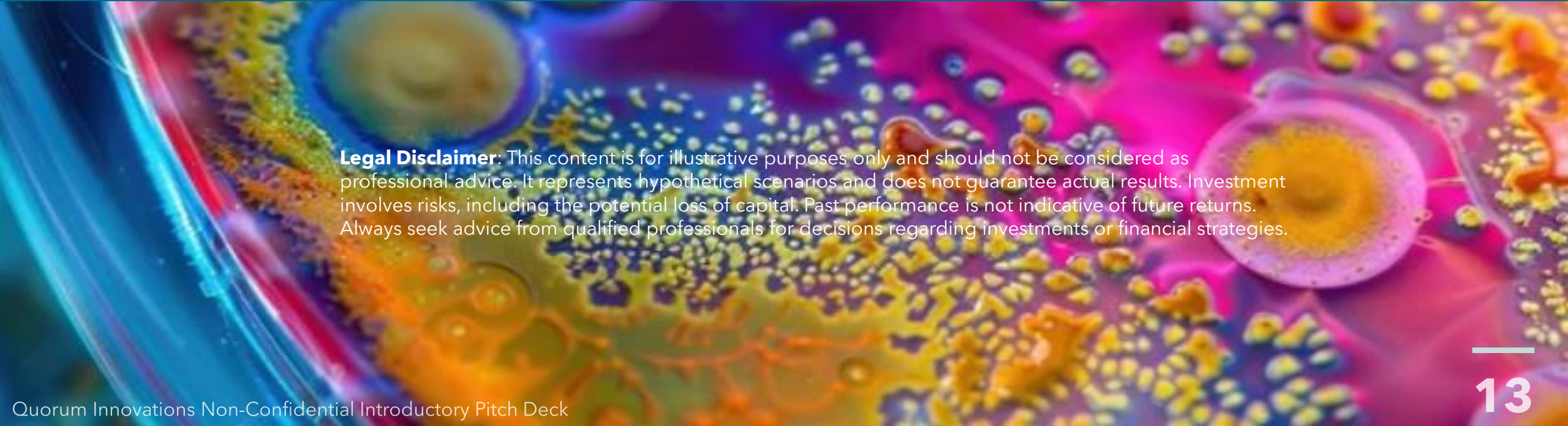
contact info

Eva Berkes, MD, Co-Founder

941-951-0126

evaberkesmd@quoruminnovations.com

www.quoruminnovations.com

A vibrant, multi-colored microscopic image of cells, likely from a tissue sample. The cells are stained in various colors including blue, green, yellow, orange, and pink, highlighting different cellular structures and components. The background is a mix of these colors, creating a complex, textured appearance.

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