

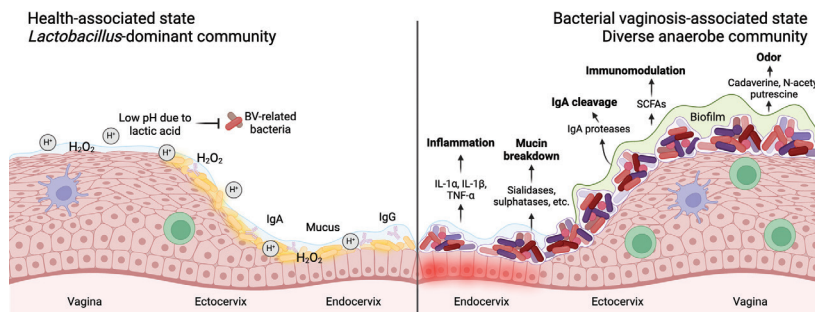


Figure 1.



Figure 2: LC-106 Vaginal LBP Tablet



Figure 3: LCFA-01 Vaginal Capsule

Restoring Vaginal Health: Next-Generation Live Biotherapeutics and Microbial-Modulating Metabolites for Bacterial Vaginosis and Reproductive Health



Douglas Kwon, MD, PhD

Director of Clinical Operations, Ragon Institute of MGH, MIT and Harvard;
Associate Professor of Medicine, Harvard Medical School
dkwon@mgh.harvard.edu



Bacterial vaginosis (BV), a common disruption of the vaginal microbiome, affects 20–30% of women worldwide and is associated with a range of adverse health outcomes—including spontaneous preterm birth, infertility, increased risk of sexually transmitted infections (including HIV), and cervical dysplasia. Despite billions of dollars in annual healthcare costs, the standard-of-care antibiotic, metronidazole, fails to deliver durable responses in over 50% of cases. It has been almost 40 years since a new class of intervention for BV has been developed, resulting in a significant unmet need that impacts the health of women globally.

Our approach directly addresses this gap by developing precision microbial and small-molecule therapies that work together to re-establish a healthy *Lactobacillus crispatus*-dominant microbiome. Unlike standard antibiotics, which indiscriminately disrupt microbial communities, our strategy seeds beneficial, protective bacteria and supports their robust colonization across diverse patient populations. Our lead program, LC-106, is a live biotherapeutic product comprising a genomically selected geo-diverse consortium of *L. crispatus* strains, formulated for vaginal administration. In parallel, we are advancing LCFA-01 and LCFA-02, two novel microbiota-modulating metabolites designed to selectively promote the colonization of the health-associated bacteria found in LC-106.

In a Phase 1 clinical study in women with Nugent-score-defined BV, LC-106 reduced BV recurrence to 24% (95% CI: 10%–48%) compared to 66% with placebo (95% CI: 36%–88%) at five weeks post-treatment. Preclinical development of LCFA-01 and LCFA-02 has demonstrated favorable safety and selectivity profiles, with a first-in-human study expected to launch in Q1 of next year.

Together, these complementary programs represent new classes of interventions designed to restore microbial balance, reduce recurrence, and address the downstream reproductive health risks associated with BV. By shifting from symptom control to targeted and durable microbiome restoration, this approach has the potential to transform women's health outcomes on a global scale.