GEDEA Biotech

pHyph

White paper | Gedea Biotech | *p*Hyph

Modern, antibiotic free treatment for vaginal infections

European Innovation Council

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1 Introduction

1.1 The Unmet Medical Need in Bacterial Vaginosis

Bacterial vaginosis (BV) is one of the leading causes of vaginal infections globally and a significant unmet need in women's health. The condition is characterized by an imbalance in the vaginal microbiome, where beneficial Lactobacillus species are replaced by anaerobic bacteria, leading to elevated pH, discharge, and a characteristic "fishy" odor. BV is not only distressing for affected women — impacting daily life, intimacy, and self-esteem — but also associated with serious medical risks, including pelvic inflammatory disease, infertility, and pre-term birth.

Current treatment options rely predominately on antibiotics such as metronidazole and clindamycin. While these agents offer rather high initial cure rates more than 50% experience recurrence within one year following treatment, and up to 17% of women develop secondary vulvovaginal Candida infections within a month following antibiotic treatment. Moreover, the use of antibiotics contributes to the growing global challenge of antimicrobial resistance. There is a clear medical and societal need for effective, antibiotic-free therapies that restore and maintain a healthy vaginal environment.

Gedea Biotech's lead product *p*Hyph is a CE-marked antibiotic free vaginal tablet approved for the treatment of bacterial vaginosis, effective symptom relief and maintenance treatment for a healthy vaginal microbiome. **Gedea has run an ambitious clinical program for bacterial vaginosis where 200 patients have used *p*Hyph. Recently *p*Hyph was approved under the new Medical Device Regulation, MDR, in Europe.** The implementation of the MDR is changing the competitive landscape significantly. Products approved under the previous legislation will be withdrawn from the market by the latest at the end of 2027. The recent MDR approval for *p*Hyph poses a major competitive advantage.

2 The Vaginal Microbiome and Its Role in Health and Disease

The vaginal microbiome plays a key role in vaginal health and protection against infections. In women with a healthy microbiome, *Lactobacillus* species dominate, producing lactic acid, hydrogen peroxide, and bacteriocins that create an acidic environment (pH < 4.5) hostile to pathogenic microorganisms. This balance is essential for vaginal health, serving as the first line of defense against infections and maintaining epithelial integrity.

When this equilibrium is disrupted — due to factors such as hormonal changes, sexual activity, antibiotic use, or hygiene practices — *Lactobacillus* levels decline and are replaced by anaerobic species including *Gardnerella vaginalis*, *Fannyhessea Atopobium vaginae*, *Prevotella* spp., and *Mobiluncus* spp. These bacteria increase the vaginal pH and form biofilms that protect them from host immune responses and antibiotic therapy. The result is dysbiosis, inflammation, and the symptoms characteristic of bacterial vaginosis — a thin, greyish discharge with a characteristic "fishy" odour.

Recovery from BV depends on restoring this microbial balance. Evidence shows that sustained resolution is linked to the re-establishment of a *Lactobacillus*-dominated microbiome and normalization of the vaginal pH. However, antibiotic treatment alone rarely achieves this in the long term, as it eradicates both harmful and beneficial bacteria, leaving the environment susceptible to rapid recolonization by pathogens.

A treatment that supports the natural restoration of the vaginal microbiome, rather than indiscriminately suppressing bacterial growth, therefore represents a modern approach to treatment of BV. By promoting reacidification and the regrowth of protective *Lactobacillus* species, such approaches can help strengthen the vaginal ecosystem and increase resilience against new infections — addressing the underlying biological mechanisms that drive recurrence.

3 *p*Hyph: Mode of Action and Clinical Effects on the Microbiome

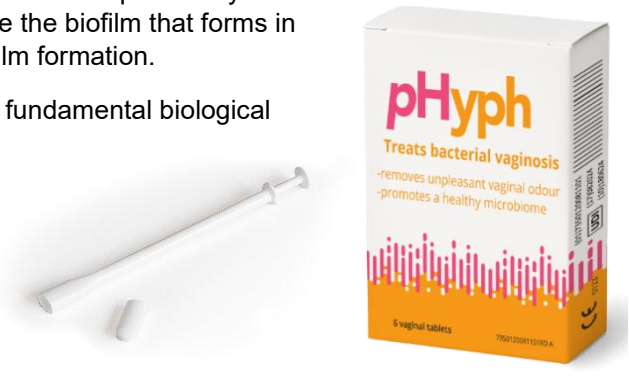
***p*Hyph** is an antibiotic-free vaginal tablet developed by **Gedea Biotech** for the treatment of bacterial vaginosis (BV). The product is based on the active ingredient **glucono-δ-lactone (GDL)**, formulated for controlled local release and gradual pH modulation. *p*Hyph is CE-marked under the EU Medical Device Regulation (MDR, Class IIb), confirming compliance with rigorous standards for safety, efficacy, and quality.

3.1 Mode of Action

*p*Hyph acts locally in the vagina to restore a healthy environment and support the natural balance of the microbiome through two complementary mechanisms:

- **Restoration of physiological pH**
  Upon administration, GDL is hydrolysed to gluconic acid, gradually lowering the vaginal pH to natural levels. This shift inhibits the growth of BV-associated anaerobic bacteria and promotes conditions favourable for *Lactobacillus* species to recolonize and dominate the vaginal microbiota.
- **Support of the natural microbiome**
  By restoring and maintaining the acidic environment without the use of antibiotics, *p*Hyph enables the vaginal microbiome to recover naturally. A balanced, *Lactobacillus*-dominated microbiome is key to protecting against opportunistic pathogens and sustaining vaginal health over time.
- **Biofilm**
  The high recurrence rate in bacterial vaginosis can be explained by the inability of conventional treatments, to eradicate the biofilm that forms in BV. *p*Hyph breaks up biofilm and prevents biofilm formation.

Through these mechanisms, *p*Hyph addresses the fundamental biological imbalance underlying BV rather than merely alleviating its symptoms. This targeted approach supports long-term vaginal health and increased resilience against new infections, without disturbing commensal bacterial populations.



3.2 Effects on the Vaginal Microbiome

Unlike antibiotic therapy, *p*Hyph does not disturb beneficial bacteria or increase the risk of secondary vulvovaginal Candida infections. Its *p*H-based mechanism helps sustain a stable microbial environment that supports long-term vaginal health. This has been supported by microbiological analyses in clinical studies which have shown a strong trend towards restoration of a *Lactobacillus*-dominated flora following *p*Hyph-treatment. The reduction in BV-associated anaerobes such as *Gardnerella vaginalis* and *Fannyhessea vaginae* was accompanied by normalisation of vaginal *p*H.

Clinical investigations have shown that treatment with *p*Hyph leads to:

- Rapid relief of key BV symptoms, such as malodour
- Normalization of vaginal pH following six days treatment.
- Microbiome recovery, characterized by reappearance of *Lactobacillus*-dominated microbiome and reduction of dysbiosis-associated species.

4 Technical and Regulatory Overview

4.1 Product description

*p*Hyph is a slow-release vaginal tablet designed to restore and maintain a healthy vaginal environment by supporting the natural microbiome. The active ingredients are glucono-δ-lactone (GDL) and sodium gluconate (NaG) — both endogenous substances and classified by FDA as Generally Recognized as Safe (GRAS). GDL hydrolyses to gluconic acid, lowering vaginal pH to normal levels), while NaG acts as a mild buffer, stabilizing the pH within this range and creating conditions favorable to Lactobacillus growth.

Table 1:

Technical specifications	
Form	Vaginal tablet (pessary
Weight	~1.0 g
Dimensions	10.1 × 17.9 mm (bullet shape)
Release profile	Controlled dissolution over ~24 hours (in vitro)
Shelf life	48 months
Storage	Room temperature, sealed blister packaging
Packaging	6 pessaries per pack with reusable applicator
Intended users	Adult women in child bearing age with bacterial vaginosis

4.2 Formulation and manufacturing

*p*Hyph is a white, convex, bullet-shaped vaginal tablet (approx. 18 mm, weight 1.0 g) manufactured by direct compression using a dry process without solvents. The tablets are produced under controlled environmental conditions, dried and packed in moisture-protective blister packs, and supplied with a reusable vaginal applicator for hygienic and accurate placement.

The formulation ensures controlled release of the active ingredients over approximately 24 hours, providing a gradual and sustained therapeutic effect.

4.3 Dosage and administration

Treatment regimen: One vaginal tablet **once daily for six consecutive days**.

Maintenance regimen: Two tablets per week for **six weeks** following initial treatment, to support long-term microbiome balance and vaginal health.

5 Market and Partnering Opportunity

Bacterial vaginosis (BV) represents one of the most common vaginal infections globally, with a prevalence estimated to 20–30% of women of reproductive age. Despite its high prevalence, there has been a striking lack of innovation in treatment over the past decades.

5.1 Europe

Current products for the treatment of bacterial vaginosis fall into two main categories: antibiotic prescription treatments and OTC medical devices or biotherapeutic products aimed at symptom relief. The European market for non-fungal vaginal conditions is valued at approximately €200 million (~$220 million) annually, within the OTC segment only. Prescription drugs based on metronidazole or clindamycin dominate in terms of clinical acceptance but carry drawbacks such as high recurrence rates and increased risk of Candida infections.

5.2 MDR is changing the landscape

The Medical Device Regulation (EU 2017/745) replaced the previous Medical Device Directive (MDD). Most vaginal products on the European market are still approved under the MDD and will no longer be allowed after 2027, unless they undergo MDR approval process. pHyph is approved under the MDR which poses a major competitive advantage.

This regulatory shift opens a significant commercial window for new, MDR-approved products with validated clinical performance and strong safety profiles — a position where *p*Hyph is well placed.

5.3 OTC treatment for Bacterial Vaginosis

According to Gedea's Patient Survey (Sweden, 2020), almost half (46%) of women experiencing vaginal symptoms do not seek care, mainly because they prefer to try self-care first (49.9%) or find it embarrassing or difficult to seek help for intimate conditions (39.5%). This means that around 50% of women refrain from seeking help for intimate problems, highlighting a major need for safe and effective OTC alternatives.

We therefore see two main pathways for marketing *p*Hyph on the European market:

1. Direct-to-consumer (OTC) – Available in pharmacies and online for women who prefer self-care.
2. Healthcare-recommended – A product that can be recommended by healthcare professionals during counselling or when in-person visits are not possible.

*p*Hyph represents a non-antibiotic alternative in situations where antibiotics are not an option — whether the patient does not want to take antibiotics, lacks access to a doctor, feels uncomfortable seeking care for intimate symptoms, or considers self-care a preferred first-line choice. With established manufacturing, validated shelf life (48 months), and an MDR-approved clinical evidence package, *p*Hyph is launch-ready.

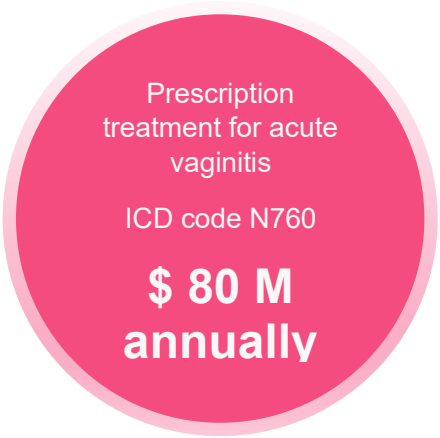
5.4 Partnering opportunity in Europe

A commercial partner can enter the market rapidly with minimal additional regulatory work, leveraging both the CE-mark and existing marketing assets. Gedea is currently looking for a partner for sales and marketing of *p*Hyph in Europe.

5.5 United States

*p*Hyph will be considered as a prescription drug by the FDA and next step is phase 3 studies in the US for treatment of BV.

In the United States, the market for treatment of acute vaginitis (ICD code N760) — including both branded and generic drugs — exceeded $80 million (~€73 million) in 2024 *(source: IQVIA MIDAS database*). *p*Hyph will be classified as a pharmaceutical product by the FDA and will enter Phase 3 clinical development prior to market approval.



The prescription market for bacterial vaginosis is currently dominated by various antibiotic formulations. Key Opinion Leaders in the U.S. have confirmed a strong patient demand for antibiotic-free alternatives, citing adverse effects, secondary yeast infections, and growing concerns regarding antibiotic resistance.

Over the past seven years, several single-dose antibiotic reformulations have been launched for treatment of BV. Their market performance has been weaker than expected. However, all represent incremental updates of existing antibiotics rather than true innovation — highlighting the need for new therapeutic mechanisms that restore the vaginal microbiome rather than disrupt it.

5.6 Partnering opportunity in the US

Gedea is seeking partnership for phase 3 studies in the US for *p*Hyph, for registration as a prescription treatment for bacterial vaginosis by the FDA.

5.7 Competitive Advantage

The combination of **strong regulatory position**, **robust clinical evidence**, and **commercial readiness** differentiates *p*Hyph from both traditional antibiotic therapies and competing OTC products.

Table 2:

Competitive overview of *p*Hyph versus typical BV treatments				
Feature	*p*Hyph	Typical OTC BV product	Antibiotic Rx treatment	Dequalinium
Regulatory status	MDR Class IIb (CE-marked)	MDD, phase-out by 2027	Drug, Rx only	Drug, Rx in most countries/OTC in Sweden and Germany
Active principle	Glucono-δ-lactone (GDL)	Various, often unproven	Metronidazole / Clindamycin	Dequalinium chloride
Antibiotic-free	✅	✅	❌	✅
Microbiome-promoting	✅	Variable / unproven	❌	❌
Risk of recurrence	Low (supports microbiome recovery)	Variable	High	Not studied
Candida risk	No increased risk	Variable	Increased	Not studied

5.8 Antimicrobial Resistance

The WHO has identified antimicrobial resistance (AMR) as a global threat to public health, referring to it as ”the silent pandemic,” with approximately 30,000 people in the EU dying each year as a result of AMR. It is crucial to have access to effective antibiotics when they are truly needed to treat serious infections. A significant amount of antibiotics is prescribed for treating bacterial vaginosis, in Sweden accounting for 2,3% of total antibiotic prescriptions. Clinical Evidence and Safety

5.9 Study Overview

The clinical performance and safety of *p*Hyph have been evaluated in a stepwise clinical development program comprising three studies in BV: CL2, CL3, and CL3-2.

Table3:

Study overview

Study	Number of patients	Design
CL2	24	Single arm Active treatment
CL3	152	Two arms Active treatment/placebo group Ratio 4:1
CL3-2	61	Two arms Active treatment/untreated control group Ratio 1:1

Study CL2 was an early proof-of-concept trial in 24 women with bacterial vaginosis, testing an earlier version of the vaginal tablet containing glucono-δ-lactone (GDL). The study confirmed the concept of acidification, symptom improvement, and microbiome restoration, establishing the foundation for further product development.

Studies CL3 and CL3-2 were randomised controlled trials investigating the final MDR-approved formulation of *p*Hyph in women with confirmed BV according to Amsel criteria. Participants self-administered one vaginal tablet daily for six days using a vaginal tablet applicator.
Clinical and microbiological assessments were performed at baseline, at Day 7 and 25. All studies were conducted in accordance with ISO 14155 and EU MDR requirements for Class IIb devices.

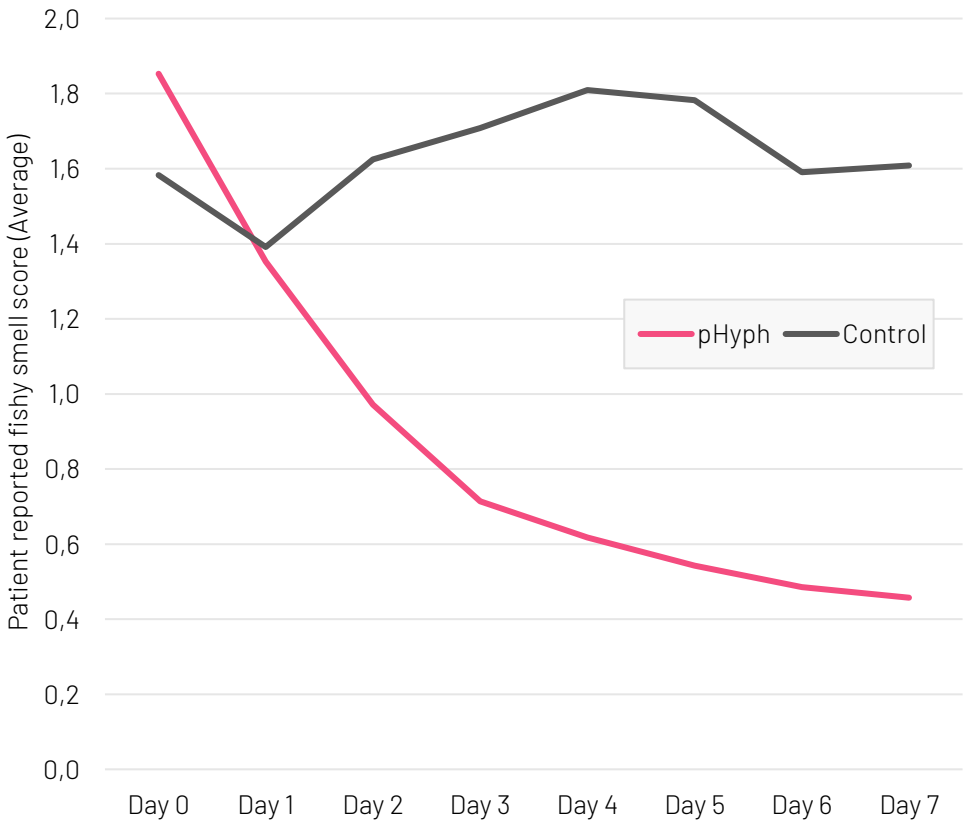
5.10 Treatment of Bacterial Vaginosis

Bacterial vaginosis is very limiting for women. The most common symptom of BV is an unpleasant odour from the increased vaginal discharge. The odour can be very intense and causes immense stress and suffering for women with BV. According to our own survey of 1,000 women (2020), 95% of women worry about smelling bad when they have vaginal symptoms, and 57% cannot exercise and stay active as they usually do.

The graph below shows patients' own symptom assessment on day 0 and day 7, average symptom score.

Figure 2

Patient reported fishy smell score between days 0-7



Effective symptom relief is crucial for the treatment of bacterial vaginosis. At day 7, 77-89%* see reduction in fishy smell and absence of fishy smell is seen by 63-66%.

*p*Hyph provides symptom relief from the first day for most women. The bothersome odor decreases after just one day, and after 7 days, almost 90% report decrease in symptoms. The malodour is completely resolved in nearly 70% of patients after completing a treatment course with *p*Hyph, of 6 tablets with assessment on day 7.

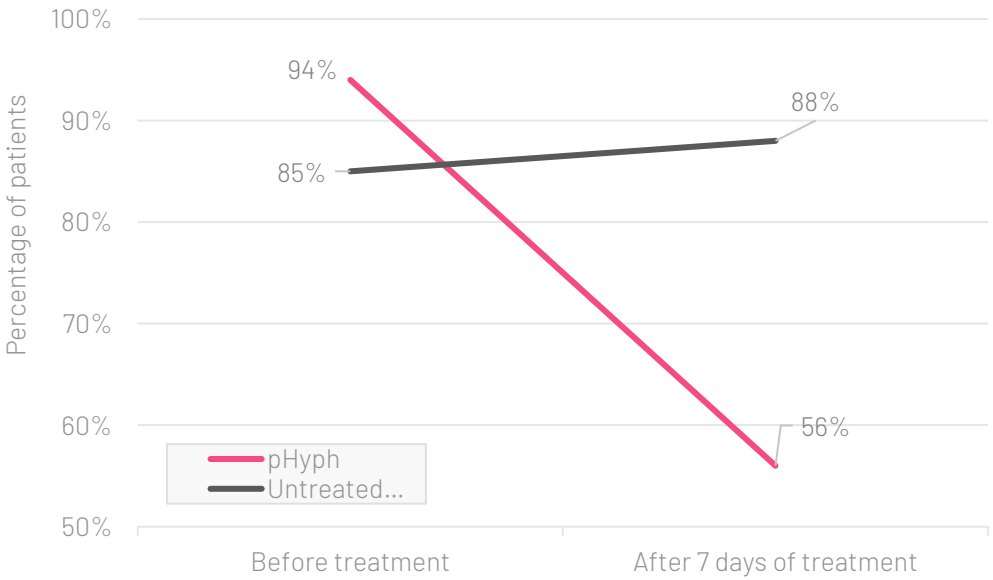
5.11 Improvement of the microbiome

As a modern treatment for bacterial vaginosis, *p*Hyph strengthens the vaginal microbiome to treat the infection and to boost resilience to recurrent infections. Conventional antibiotic treatment for bacterial vaginosis (BV) negatively affects the vaginal microbiome and therefore recurrences are very common. After treatment with antibiotics, the recurrence rate for bacterial vaginosis is 23-46%.

During the first week of treatment with one tablet per day for six consecutive days, the abundance of lactobacilli significantly increases.

Figure 3

Decrease in dysbiosis after treatment with *p*Hyph



At day 0, around 90 % of patients in both groups (no significant difference) have dysbiosis. At day 7, the treated group show a significantly lower level of dysbiosis than the untreated group. Patients with a healthy microbiome at day 7 that continued with the maintenance treatment with 2 tablets a week for 6 additional weeks kept a healthy microbiome.

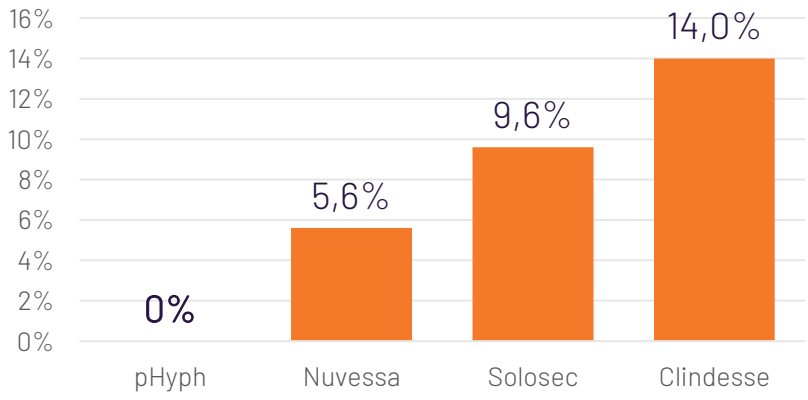
*CL3-2, 61 patients and CL3, 152 patients

5.12 No secondary yeast infection

Current treatment with antibiotics give a secondary vaginal fungal infection in 5,6-17% of patients within 30 days from start of treatment compared to treatment with *p*Hyph where there are no secondary fungal infections.

Figure 4

No secondary yeast infection with *p*Hyph

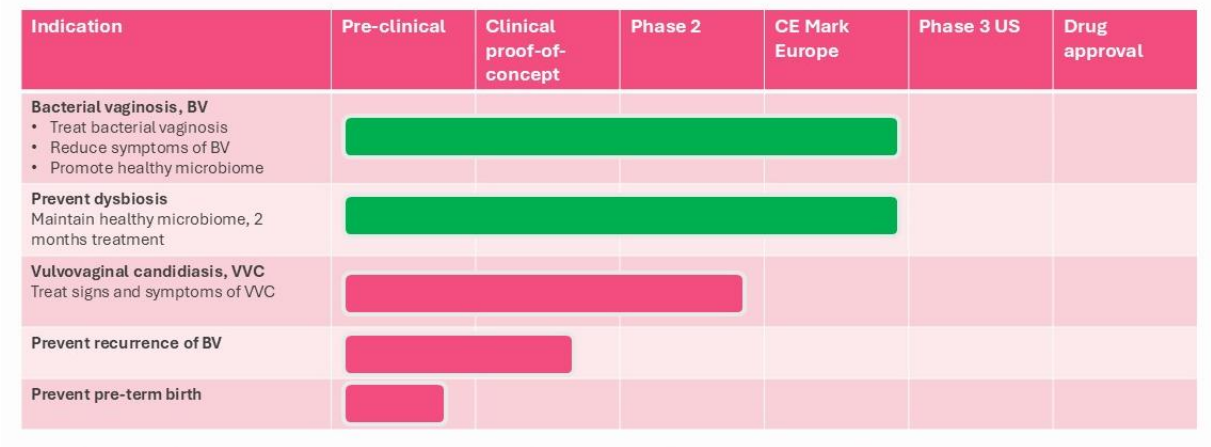


5.13 Safety and Tolerability

Across both clinical studies CL3 and CL3-2, *p*Hyph demonstrated an excellent safety and tolerability profile.
Importantly, no increase in Candida infections or other adverse microbiological effects was observed.

6 Pipeline

*p*Hyph is further developed for the treatment of vulvovaginal candidiasis symptoms (vaginal fungal infections) and for prevention of pre-term birth.



6.1 Vulvovaginal candidiasis

Proof-of-concept has been established for *p*Hyph in treatment of vulvovaginal candidiasis (VVC) in the phase 2-trial (E*p*Hect, CL4).

Gedea's strategy is to extend the CE marking of *p*Hyph to also include the treatment of symptoms associated with VVC.

Given the difficulty for patients to distinguish between the symptoms of BV and VVC infections, the conditions are often misdiagnosed and many women use over-the-counter medications for yeast infections to treat bacterial vaginosis. This often results in repeated treatments for vaginal infections without achieving a long-term solution.

6.2 Pre-term birth

It is known that bacterial vaginosis and other imbalances in the vaginal microbiome during pregnancy are associated with preterm birth, whereas if a pregnant woman's microbiome is dominated by beneficial Lactobacilli, she has a higher likelihood of giving birth full-term. An effective treatment that reduces the risk of preterm birth would have a tremendous impact on obstetric and neonatal care worldwide.

In research collaboration with Karolinska Institutet, *p*Hyph has been shown to improve the vaginal microbiome, especially by increasing the presence of the beneficial vaginal Lactobacilli and reducing vaginal dysbiosis. Next step is to find a collaboration partner to develop the product further for possible prevention of pre-term birth.

7 Executive Summary

***p*Hyph** is an innovative, antibiotic-free treatment for bacterial vaginosis (BV) developed by **Gedea Biotech**. The product is based on the active ingredient **glucono-δ-lactone (GDL)**, which restores the vaginal pH to physiological levels and supports recovery of a **Lactobacillus-dominated microbiome** and prevents biofilm formation— addressing the root cause of BV rather than merely suppressing symptoms.

BV affects up to one in three women of reproductive age and is associated with discomfort, reduced quality of life, and increased risk of reproductive complications. Despite its prevalence, **treatment innovation has been minimal** for decades, and recurrence after antibiotic therapy remains common.

Clinical studies (CL2, CL3, and CL3-2) of over 200 patients demonstrate that *p*Hyph provides **rapid and sustained symptom relief**, with most patients reporting improvement already on Day 1 and normalisation of vaginal pH by Day 7. In addition, a significant improvement of the microbiome balance has been shown. *p*Hyph was well tolerated, with **no increase in Candida infections** or other adverse effects.

*p*Hyph is **CE-marked under MDR (Class IIb)** and fully ready for launch in Europe. This certification provides a lasting regulatory advantage as many competing MDD-approved products lose market access by 2027. In the U.S., *p*Hyph will be developed as a **prescription drug**, addressing an $80 million (~€73 million) market currently dominated by antibiotics.

Beyond BV, Gedea Biotech is exploring new indications, including **vaginal Candida infections** and **prevention of preterm birth**, reflecting the product's broader potential as a **microbiome-promoting therapeutic platform** in women's health.

With validated clinical data, MDR approval, and strong commercial readiness, *p*Hyph offers partners and investors a **unique opportunity to enter the women's health market** with an evidence-based, sustainable innovation that meets clear medical and societal needs.

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