



Company: Gyntools | CEO: Nimrod Lev | Tel: +052-750-2747
Submission Category: Women's health - Medical Devices

Investment Rational

GynTools offers GYNI™, a point-of-care AI-powered microscopy system that diagnoses the 7 major causes of vaginitis within 5 minutes from a single swab. Addressing a \$4B+ market with tens of millions affected annually, GYNI is already in clinical use, supported by European distributors and endorsed by KOLs. The leadership team brings strong med-tech, regulatory, AI, biz-dev and clinical expertise in women's health.

We are currently seeking investment partners for a \$5M Series A round, to allow for market expansion and US FDA clearance.

Business Strategy

Near-term revenue is driven by B2B2C sales of disposables. Long-term growth includes global expansion and data-driven decision support tools.

Core Technology

GYNI combines fully automated microscopy with deep learning-based image analysis to deliver lab-quality diagnosis in-clinic. Uniquely, it also diagnoses non-infectious conditions such as the common vaginal atrophy in menopause. Diagnostic accuracy is 85%-90%, allowing effective treatment prescription on first clinic visits. GYNI supports self sample collection and can be operated by a clinic Nurse or Assistant to improve the clinic workflow efficiency.

Product Profile/Pipeline

The flagship product, GYNI, is CE-marked and in use in multiple EU clinics as well as in Israel (approved by AMAR). Upcoming milestones include a wide FDA requested clinical trial followed by a 510(k) + CLIA waiver submission. Pilots are also underway with Israeli HMOs.

What's Next?

We plan to enhance clinical utility by launching a decision support extension that recommends further diagnostics or treatment protocols. Patents have been granted for two additional products – GYNI Home enabling patient self-testing with remote physician consultation and a low price-per-test GYNI ECO tailored for developing countries.