

Complete the development and approvals of Mamoref to launch it in the U.S. market.

1.- PROPOSAL DESCRIPTION

Breast cancer is a disease with a high incidence globally: 1 in 8 women will develop the disease. However, 30% of women avoid diagnosis due to contradictory results (especially in individuals with dense tissue), numerous biopsies, high costs, and the use of invasive and painful techniques. As a result, a significant percentage of women receive late-stage breast cancer diagnoses.

To address this issue, Bionirs has developed a groundbreaking optical mammography imaging system specifically designed for women. This system complements traditional methods without the use of radiation or the need for breast compression. It is a simple, fast, non-invasive, effective, and low-cost solution that provides access to diagnosis to large population groups. The estimated market size for this system includes 90 million people in the United States and 6.1 billion worldwide.

2.- BUSINESS MODEL

The company generates revenue from the sale of Mamoref, a mammography imaging device that differentiates itself from other breast cancer diagnostic methods, such as ultrasound, thermography, or optoacoustics, through its portability and affordability. Its accessibility and ease of use make it suitable for installation in various healthcare centers.

3.- FINANCING

The project has successfully secured USD 650,000 in pre-seed funding rounds, which were used for initial development. The company is now seeking an additional USD 1.6 million in seed capital to complete the certification and clinical adoption processes necessary for the market launch in the United States.

4.- IRR AND INVESTOR PROFILE

The company is primarily seeking angel investors and venture capital funds specializing in medical technology.

5.- EXECUTION PLAN

The plan consists of the following phases:

- Validation (partially completed): Between 2021 and 2023, USD 650,000 was invested to develop and patent three (3) prototypes and conduct exploratory clinical trials with 21 participants. Currently (2024), two additional clinical trials are being carried out with 32 patients. Pre-Submission procedures with the U.S. Federal Drug Administration (FDA) have been initiated, and potential customer surveys are underway.
- Evaluation (to be developed in 2025-2026): An additional USD 1.6 million is expected to be used to complete technical testing and clinical trials for FDA product approval, as well as to develop a clinical implementation strategy.
- Commercialization: In this phase, the goal is to scale production and develop marketing channels through strategic partnerships with existing suppliers.

Perfil

Bionirs is an Argentine startup and a technology-based company (in Spanish EBT) from the Argentine National Council of Scientific and Technical Research (CONICET). It was founded by physicists specializing in optics applied to diagnostic technologies. The team is complemented by engineers, AI specialists, and collaborating medical professionals.

The company has international recognition. Its members were acknowledged in 2024 as innovators in the field of medical technology and received awards and mentions for their contributions, including:

- Female Founder Challenge at Vivatech;
- Femtech Awards;
- Innovation Showcase - Women's Health Innovation Summit;
- Burning Heroes.