

# A New Drug for Improved Healing Following Pelvic Floor Reconstructive Surgery

## Background and Unmet Need

Millions of women worldwide suffer from pelvic floor disorders (PFDs). PFDs include pelvic organ prolapse (POP), urinary incontinence, and sexual dysfunction. POP, which is often referred to as the "hidden epidemic", involves the descent of pelvic structures into the vagina due to ligament or muscular weakness. It impairs women's quality of life and is associated with limited physical and social activity, leading to poor self-image and depression. As the women population ages, the prevalence of POP is expected to increase, further highlighting the need to address POP as a significant public health concern. Current surgical treatments for POP using the patient's own tissue are frequently ineffective due to diminished age-related healing, leading to weak scar tissue. Hence, developing a new drug for enhanced healing following surgery is expected to change the quality of life of millions of women worldwide.

## Our Solution

Dr. Ofra Zidon discovered that vaginal epithelial Arginase 1 (Arg-1) is a key mediator of age-associated delayed healing. Most significantly, treatment with a small molecule transcriptional inducer of Arg 1 (SM1) was sufficient to rebuild and repair the vaginal tissue in aged rats. However, so far, the utilization of SM1 as a drug was challenging due to its poor water solubility and bioavailability. Together with Prof. Shlomo Magadassi, a formulation chemist from the Hebrew University of Jerusalem, while using only FDA-approved materials, they developed a new SM1 formulation with significantly improved solubility.

## Future Objectives

After achieving good solubility in water, we next aim to form a gel/ointment/suppositories formulation that will be appropriate for vaginal use.

## Market Potential

The market size for Pelvic Organ Prolapse Repair is projected to achieve 1 USD billion by the conclusion of 2036, with a compound annual growth rate (CAGR) of 5% between 2024 and 2036. The upswing in this market is attributed to the escalating incidence of POP among women worldwide. Across the globe, POP affects over 35% of the female population, driving the demand for related medical interventions. The new compositions will open the way to additional drug products, beyond post-operation vaginal treatment, that can be applied in the general field of wound healing.

Dr. Zidon brings over a decade of expertise in investigating the role of advanced age and estrogen deficiency in the impaired healing outcomes following POP surgery. Her groundbreaking research revealed epithelial Arginase-1 as a critical factor in age-related delayed healing in vaginal tissue. Notably, her work showed that a small molecule transcriptional inducer of arginase 1 expedited vaginal wound closure in aged rats. Her future focus is on designing a platform for clinical translational experiments to develop small molecule compounds that promote vaginal tissue regeneration. This platform holds promise for broader applications in human wound healing processes.