Consolidated Clinical Product Performance Summary

Reported clinical, pilot, observational and preliminary laboratory results | Updated November 2026

Lionheart Health's pipeline centers on a patented bioelectric stimulation platform designed to modulate the expression of targeted proteins involved in tissue repair and regeneration. The company applies this approach across different tissues and body systems. The evidence below also includes combination protocols, cell therapy series and historical cardiac research, identified separately so readers can see which intervention produced each reported result.

Therapeutic Pipeline • Intellectual Property • Investor Materials

BodStim™ | Muscle health mobility and fitness

- Strength improved 15–25%, VO_2 or aerobic capacity improved 10–18%, and lean muscle mass increased 8–14%.
- Six-minute walk distance improved 12.8% and gait performance improved 29.5%. Timed Up and Go completion time fell 19.1%.

SkinStim Plus™ | Skin rejuvenation and collagen

- Reported outcomes included a 20–40% increase in collagen density, 22–38% wrinkle reduction, 18–35% improvement in skin elasticity, 10–22% increase in dermal thickness, 15–30% improvement in skin circulation, and 20–40% reduction in inflammation indicators. Approximately 85–92% of participants showed visible skin improvement.
- Laboratory gene expression increased 35.4% for collagen I, 44% for collagen III, 18% for elastin, and 420% for Klotho.

EyeCell™ | Vision

- In the 16-eye cohort, 11 eyes improved (68.7% as reported), 3 stabilized (18.8%), and 14 improved or stabilized (87.5%). Visual acuity improved by up to four chart lines.
- Earlier observational summaries reported 15–32% improvement in distance vision, 18–35% in near vision, and 12–26% in contrast sensitivity.

OrthoStim™ | Joint health and osteoarthritis

- Joint pain fell 40–65% across summaries. VAS pain scores fell 42–58% and WOMAC pain scores fell 38–52%.
- WOMAC joint function improved 35–50% and range of motion improved 10–18%. Approximately 85% reported moderate to significant improvement.

Clinical Program Outcomes

BladderCell™ | Bladder function

- Urinary symptom scores improved 30–67%. A historical summary reported a 67% response rate among 50 patients.

KidneyCell™ | Kidney function

- Renal function improved 8–20%. A historical summary reported a 50% response rate among 30 patients.

Stem Cell Bra™ | Breast tissue research

- Average breast volume increased 8–18%, upper-pole fullness improved 15–28%, and tissue elasticity improved 18–32%.
- At four weeks, 66% had increased breast volume. A full cup-size increase was reported for 33%. Earlier observational summaries reported visible improvement in 85–92%.

Brain Band™ | Cognitive health

- Memory and cognitive performance improved 12–34%. Mood scores improved 18–35%.

HairCell™ | Hair regeneration

- Hair density improved 16.7% at four weeks. Preliminary summaries reported approximately 30% improvement at 12 weeks with the full HairCell™ Plus regimen of bioelectric stimulation, BioPRF, amniotic fluid, peptides, hair serums, red light and PEMF.

ErectiStim™ | Sexual wellness

- Approximately 89% of more than 100 participants reported significant, lasting improvement in erectile function.

PressureStim™ | Blood pressure

- Average systolic blood pressure fell 11 mmHg and average diastolic blood pressure fell 4 mmHg.

TestiStim™ Plus | Hormonal health

- Total testosterone increased 18–42% in a limited series using multiple modalities.

Klotho-Up™ | Immune health and longevity

- Immune biomarker and inflammation evaluations are underway. A validated percentage improvement in immune function and a consolidated immune-specific percentage for inflammation are pending.
- Earlier company materials reported increases in circulating Klotho. A standardized, independently verified clinical effect size is pending.

Vascular Pilot and Case Series Outcomes

VascuStim™ | Vascular health

- Peripheral tissue perfusion improved 20–40%. A historical summary reported an 80% response rate among 23 patients.

Program	Setting and intervention	Reported outcome
BreatheStim™	California pilot study. Seven patients received BreatheStim™.	All 7 patients (100%) reported easier breathing during testing and reduced snoring.
InStim™	Pilot study. One patient received InStim™.	The patient was reported to have experienced relief of bowel inflammation.
VascuStim™	Czech Republic limb salvage series. Sixteen patients listed for amputation received stromal-derived cells.	12 of 16 legs (75%) were saved from amputation.
VascuStim™	Mexico case series. Eight patients with non-healing leg or foot ulcers received bioelectric therapy alone.	All 8 patients (100%) were reported to have recovered. Recovery criteria and follow-up were unspecified.

How to read the results

Figures are company-reported unless a publication is identified. Percentages describe the cited groups or measurements. Laboratory gene expression, patient-reported outcomes, clinical measures and historical response rates represent different types of evidence. Outcomes from combination protocols are reported for the regimen as a whole.

Historical Cardiac Regeneration Evidence

BioHeart MyoCell™ / BioLeonhardt

Lionheart Health reports an option pathway with U.S. Stem Cell, Inc., the data rights holder, to acquire the associated rights, including rights related to the investigational new drug application for a combination gene and cell therapy. U.S. Stem Cell reports that FDA allowed human trials of MyoCell SDF-1 to begin. The historical results below cover skeletal myoblast research.

- Historical company summary. The reported heart failure response rate was 84% versus 16% for placebo, a 68-percentage-point difference. The underlying cohort and response definition are pending verification.
- Smits and colleagues, JACC, 2003. In five patients, left ventricular ejection fraction (LVEF) rose from 36% to 45% at six months, a 9-percentage-point or 25% relative increase. The six-month result was not statistically significant. Target-area myocardial wall thickening rose from 0.9 mm to 1.8 mm at three months, approximately doubling.
- MYOHEART historical figure. LVEF reportedly rose from 24.3% to 32.2% at 12 months, a 7.9-percentage-point or approximately 32.5% relative increase. Attribution to a specific American Heart Journal publication and cohort remains pending.
- MARVEL randomized trial, American Heart Journal, 2011. Among 23 randomized patients, six-minute walk distance changed by +95.6 m at low dose, +85.5 m at high dose and −3.6 m with placebo. Differences were not statistically significant.
- SEISMIC Phase IIa, EuroIntervention. At six months, six-minute walk distance rose 60.3 m with treatment versus 0.4 m with control, a difference that was not statistically significant. NYHA class improved in 20% versus 14.3% and worsened in 8% versus 28.6%, respectively. Global LVEF did not improve significantly.
- Siminiak Poland Phase I, American Heart Journal, 2004. Regional contractility findings were reported. A review describes an approximately 6.8-percentage-point increase in LVEF in the early surgical cohort, which had no randomized control group.
- Siminiak POZNAN, European Heart Journal, 2005. Improved regional contractility was reported. A review describes improved LVEF in 6 of 9 successfully transplanted patients (66.7%). Controlled efficacy remains unestablished.
- Additional historical research. Exact endpoints and quantitative results are pending verification for PROSPER preclinical research in the European Heart Journal, the Burkhoff and Columbia canine study, and the Brofman Brazil clinical studies.
- JACC rat study, 2004. In infarcted rat hearts, the reported relative change in LVEF was +15 ± 5% with skeletal myoblasts versus −8 ± 4% in controls. This was preclinical evidence.

Selected cardiac references

Smits pilot • MARVEL trial • SEISMIC trial • Siminiak Phase I and POZNAN • POZNAN full publication • JACC rat study • U.S. Stem Cell product and trial status