

Personalized connective tissue treatments.
For patients who deserve better than one-size-fits-all.



smartweave.xyz Cambridge, MA [in](#) [@](#)

Highlights

- 1 One of fifteen startups that were selected by Swiss EPFL affiliated Tech4Eva from 300+ ventures
- 2 \$6.4M in grants and institutional support secured before opening raise
- 3 Key collaborators secured \$12M+ to move enabling R&D toward pre-IND stage.
- 4 Lab-validated technology shown to reduce inflammation, repair tendons, and restore continence.
- 5 150+ years of combined expertise from top institutions in therapeutics, devices, and R&D.
- 6 Generated \$3.5M from IP in 2 years, with product and licensing revenue growing.
- 7 Multiple US patents secured, growing to 50+ across AI, scaffolds, and 3D printing.
- 8 \$100B+ connective tissue restoration market projected by 2030.

Featured Investor



Somesh Surapureddi
Syndicate Lead

Follow

Invested \$30,000 ⓘ

"I met Raj at an investors conference in early 2025. As an emerging fund manager and technologist was intrigued by the idea, I was immediately drawn to his vision for truly personalized surgical solutions.

The validation from Dassault Systems, selecting Smartweave as one of just three startups from over 1,000s applicants globally spoke volumes. But more importantly, the concept of using digital twins to design implants tailored to each patient's unique anatomy felt like the future of personalized medicine finally arriving. After years of one-size-fits-all approaches causing preventable complications, here is a platform that could actually optimize surgical outcomes for individuals, not masses.

What ultimately convinced me to invest, though, went far beyond the software.

Smartweave has built serious clinical and translational depth, collaborating with prestigious teaching hospitals like Stanford Medicine and Cedars-Sinai on regenerative therapeutics for pelvic floor, dental, cardiac, and tendon repair. Between Smartweave and its clinical partners, the underlying science and platforms have already attracted nearly \$20M in competitive, non-dilutive grant funding, which is being used to systematically derisk the tech stack from advanced bioactive gels and tissue-integrating scaffolds all the way through to pre-IND-stage programs. This isn't a pitch-deck biotech; it's an integrated ecosystem of digital twins, personalized implants, and regenerative biologics that have been pressure-tested by top academic centers and funding bodies.

In my view, Smartweave is positioned to transform the surgical implant and regenerative therapeutics market by making truly personalized, biology-aware care accessible at scale. The healthcare industry has been stuck in incrementalism for far too long. This is one of the few teams I've seen that actually has the technical, clinical, and regulatory pieces in place to deliver on the promise of precision surgery and regenerative medicine. I am not just comfortable being an early investor, also excited to help them bring this to patients."

Team



Rajeev Malhotra Founder & CEO

Serial founder with expertise in AI-driven healthcare platforms. Has built and scaled venture-backed companies in global markets. Inventor of surgical technologies and methods.

[linkedin.com](#)



Dr. Mara Domenech Sr. Biomedical Engineer

Professor of Chemical Engineering at the University of Puerto Rico. Board member of the Cellular and Molecular Technologies Study Section at the NIH.



Craig Comiter Surgical Advisor



Advisor Professor of Urology and Obstetrics and Gynecology at Stanford University School of Medicine. Victor A. Politano Award recipient for outstanding achievement in urinary continence. Author of 100+ peer-reviewed articles.



Michael Mack Cardiac Strategic Partnerships

Medical Director of Cardiothoracic Surgery at Baylor Scott & White Health, Vice Chair of the American Board of Thoracic Surgery, Cardiothoracic Surgeon.



David Hetzel Head of Licensing

Technology and IP licensing executive with experience at Intellectual Ventures, Motorola, HP, and McKinsey.



Darryl Tannenbaum Orthopedic Lead

Orthopedic surgeon specializing in complex joint replacement. Former HHMI-NIH Medical Research Scholar with a focus on bone growth factors.



Carlos Rivera Velez Product Operations Lead

Medical device executive with experience spanning early-stage startups to global leaders, including Stryker, Edwards, and Johnson & Johnson. UPR and Wharton alumni.



Bertha Chen, MD Urology Advisor

Co-Chief, Division of Urogynecology and Pelvic Reconstructive Surgery, Stanford Medicine. Recipient of multiple NIH and CIRM grants for regenerative medicine research.



Surya Prabha, JD Compliance

Regulatory compliance specialist for the life sciences and medical device industries.



Nareg Djabrayan, PhD Grants & Academic Partnerships

Formerly Visiting Assistant Professor at Clark University. Expertise in Cellular and Regenerative Biology with grant and fellowship support from NSF and CIRM.



Edward T. Fry, MD Clinical Cardiac Applications Lead

Cardiologist at Ascension St. Vincent, Chair of Ascension National Cardiovascular Service Line, Past President of the American College of Cardiology.



Dmitriy Sheyn, PhD **Regenerative Therapeutics Lead**

Assistant Professor at Cedars-Sinai, Orthopedic Research Lab. Expert in regenerative medicine, particularly tendon regeneration. PhD in Tissue Engineering from the Hebrew University of Jerusalem, Israel.

Pitch Deck



Memo

The Smartweave Story



Smartweave is an AI-powered regenerative therapeutics platform that uses each patient's biological data to design personalized regenerative solutions for soft tissue

repair. We integrate factors including patient-specific inflammation risk, generate individualized therapeutic formulations, and simulate prospective solutions utilizing digital twin techniques as needed. Four product lines leverage this foundational platform: HeraWeave™ for pelvic floor repair, OrthoWeave™ for tendon and ACL reconstruction, CardioWeave™ for cardiac valve replacement, and DentaWeave™ for Periodontal restoration.

\$6.4M

Secured \$6.4M in grants and institutional support

\$12M+

Secured \$12M+ by academic collaborators to support pre-clinical validation

1,000+

Selected by Dassault Systèmes from 1,000+ global ventures for access to the BIOVIA and 3DEXPERIENCE platforms

SMARTS™

Validated the SMARTS™ scaffold system in pre-clinical rodent studies

DS DASSAULT
SYSTEMES

Between key clinical collaborators and the company's own grant funding initiatives, \$18M+ has been secured already for advancing core technologies enabling the company's innovations, including for: pre-clinical validation of SMARTS™ system components, cell-seeded scaffolds, anti-inflammatory biocoatings, and regenerative hydrogels, in rodent models. We were also selected by Dassault Systèmes from more than 1,000 global ventures to access their 3DEXPERIENCE Platform. Our team brings 150+ years of combined expertise from leading medical institutions and innovators such as Stanford Medicine, Cedars-Sinai, Medtronic, and Johnson & Johnson, and has secured multiple US patents that are being evolved to a category-leading portfolio of 50+ patents and trade secrets.

The connective tissue repair market is projected to exceed \$100B by 2030, and documented failure rates across pelvic, orthopedic, and cardiac repair indicate that the current standard of care has not solved the underlying design problem. Smartweave enters that market with pre-clinical data in hand, institutional backing already secured, and a commercialization roadmap that reaches its first revenue milestone by Q2, 2027.

Smartweave's pre-clinical results are based on studies conducted in laboratory and animal models. These studies are preliminary and are not indicative of safety or effectiveness in humans.

Results observed in pre-clinical settings may not be replicated in clinical trials. Further testing, including human clinical studies, will be required to evaluate safety and efficacy.

The Team










Rajeev Malhotra
CEO



Dr. Mara Domenech
MD, PhD



Craig Comiter
MD

<p><i>Founder and CEO</i></p> <p>Serial founder with expertise in AI-driven healthcare platforms. Has built and scaled venture-backed companies in global markets. Inventor of surgical implants.</p>	<p><i>Sr. Biomedical Engineer</i></p> <p>Professor of Chemical Engineering at the University of Puerto Rico. Board member of the Cellular and Molecular Technologies Study Section at the NIH.</p>	<p><i>MD, Surgical</i></p> <p>Serial founder with expertise in AI-driven healthcare platforms. Has built and scaled venture-backed companies in global markets. Inventor of surgical implants.</p>
		
<p>Michael Mack, MD <i>Cardiac Strategic Partnerships</i></p> <p>Medical Director of Cardiothoracic Surgery at Baylor Scott & White Health, Vice Chair of the American Board of Thoracic Surgery, Cardiothoracic Surgeon.</p>	<p>Edward T. Fry, MD <i>Clinical Cardiac Applications Lead</i></p> <p>Cardiologist at Ascension St. Vincent, Chair of Ascension National Cardiovascular Service Line, Past President of the American College of Cardiology.</p>	<p>Dmitriy Sheyn, PhD <i>Regenerative Therapeutics Lead</i></p> <p>Assistant Professor at Cedars-Sinai, Orthopedic Research Lab. Expert in regenerative medicine, particularly tendon regeneration. PhD in Tissue Engineering from the Hebrew University of Jerusalem, Israel.</p>
		
<p>David Hetzel <i>Head of Licensing</i></p> <p>Technology and IP licensing executive with experience at Intellectual Ventures, Motorola, HP, and McKinsey.</p>	<p>Darryl Tannenbaum <i>Orthopedic Lead</i></p> <p>Orthopedic surgeon specializing in complex joint replacement. Former HHMI-NIH Medical Research Scholar with a focus on bone growth factors.</p>	<p>Carlos Rivera Velez <i>Product Operations Lead</i></p> <p>Medical device executive with experience spanning early-stage startups to global leaders, including Stryker, Edwards, and Johnson & Johnson. UPR and Wharton alumni.</p>
		
<p>Bertha Chen, MD <i>Urology Advisor</i></p> <p>Co-Chief, Division of Urogynecology and Pelvic Reconstructive Surgery, Stanford Medicine. Recipient of multiple NIH and CIRM grants for regenerative medicine research.</p>	<p>Nareg Djabrayan, PhD <i>Grants & Academic Partnerships</i></p> <p>Formerly Visiting Assistant Professor at Clark University. Expertise in Cellular and Regenerative Biology with grant and fellowship support from NSF and CIRM.</p>	<p>Surya Prabha, JD <i>Compliance</i></p> <p>Regulatory compliance specialist for the life sciences and medical device industries.</p>

The Problem

Connective tissue devices are designed before a patient's biology is ever considered, and the failure rates show it.

The
Problem

Re-injury and failure

Problem



Up to 50% of women develop urogynecological conditions requiring surgical repair.

rates in orthopedic repair remain high



No current solution incorporates the patient's biology at the design stage.

- **Up to 50% of women develop urogynecological conditions requiring surgical repair.** Post-operative complication rates from current devices reach 45%. Current solutions have not meaningfully changed this outcome.
- **Re-injury and failure rates in orthopedic repair remain high.** ACL reconstruction carries re-injury rates of 10-30%. Rotator cuff repair fails in 10-50%+ of cases. Generic materials do not match the biomechanical properties of native tissue.
- **No current device incorporates the patient's biology at the design stage.** Most devices are designed before the patient's data is considered. The body's inflammatory response is treated as an unpredictable variable rather than a solvable design input.

The tissue repair industry generates tens of billions of dollars annually by selling the same products to every patient. The cost in complications, revision surgeries, and patient suffering falls elsewhere.

Statements regarding limitations of existing medical devices and treatment approaches are based on published studies, reported outcomes, and industry observations. While Smartweave believes there are opportunities for improvement, existing treatments may be effective for many patients, and clinical outcomes can vary widely based on individual circumstances.

Our Solution



Smartweave Inside™ Biocoatings

AI-designed anti-inflammatory coatings convert passive synthetic meshes into active healing platforms. Regenerative agents can be loaded to recruit the patient's own stem cells.



SMARTS™ System

A composite scaffold incorporating collagen, sulfated glycosaminoglycans (structural proteins found in connective tissue), and stem cell-derived proteins. Pre-clinical rodent model data validate pelvic tissue regeneration and tendon repair.



HeraWeave™

addresses stress urinary incontinence and pelvic organ prolapse through hydrogels and AI-biocoated slings. Targets a condition affecting up to 50% of women.



OrthoWeave™

uses bioprinted patches with tendon cell alignment for ACL and tendon reconstruction. Designed to match native tissue biomechanics.



CardioWeave™

delivers custom-printed cardiac valve replacements matched to each patient's individual heart function.



DentaWeave™

addresses periodontal restoration through a light-curable gel that conforms to and regenerates damaged oral tissue, with formulation tuned to each patient's inflammatory profile.

Smartweave's platform integrates each patient's biological data at every stage of the therapeutic design process. The AI we are building seeks to classify patients by their risk of inflammation and to select a formulation matched to their individual biology. We can then generate virtual replicas of patient disorders using the Dassault Systèmes' 3DEXPERIENCE Platform and other digital twin technology providers. This enables surgeons to simulate and refine therapeutic solutions to enhance patient outcomes.

The result is a therapeutic solution engineered to work with the body rather than against it. We design each product to reduce chronic inflammation, accelerate tissue integration, and support the body's own regenerative response.

The SMARTS™ System

The SMARTS™ (Specific Matrix Assisted Regenerative Tissugenic Scaffold) system is the engine behind every Smartweave product. Using each patient's digital twin, SMARTS™ determines the right therapeutic combinations for that individual, which could include injectable gels, anti-inflammatory agents, biocoated scaffold composites seeded with cells and/or regenerative factors. The patient's biology drives the design, not the other way around.

SmartCoating™. AI-designed anti-inflammatory coatings convert passive synthetic meshes and slings into active healing platforms. Anti-inflammatory properties are tuned to each patient's profile, and regenerative agents can be loaded to enlist healing effects from the patient's own stem cells.

SmartScaffold™. A cell-seeded scaffold engineered to support structural repair and tissue integration. Pre-clinical rodent models validate two distinct components: stem cell-derived regenerative proteins that restore pelvic tissue as part of HeraWeave™, and a cell-seeded scaffold that demonstrates tendon repair as part of OrthoWeave™.

Product Lines

HeraWeave™ addresses stress urinary incontinence and pelvic organ prolapse through hydrogels and AI-designed biocoated slings. Targets a condition affecting up to 50% of women.

OrthoWeave™ uses bioprinted patches with tendon-cell-aligned architecture for ACL and tendon reconstruction. Designed to match native tissue biomechanics.

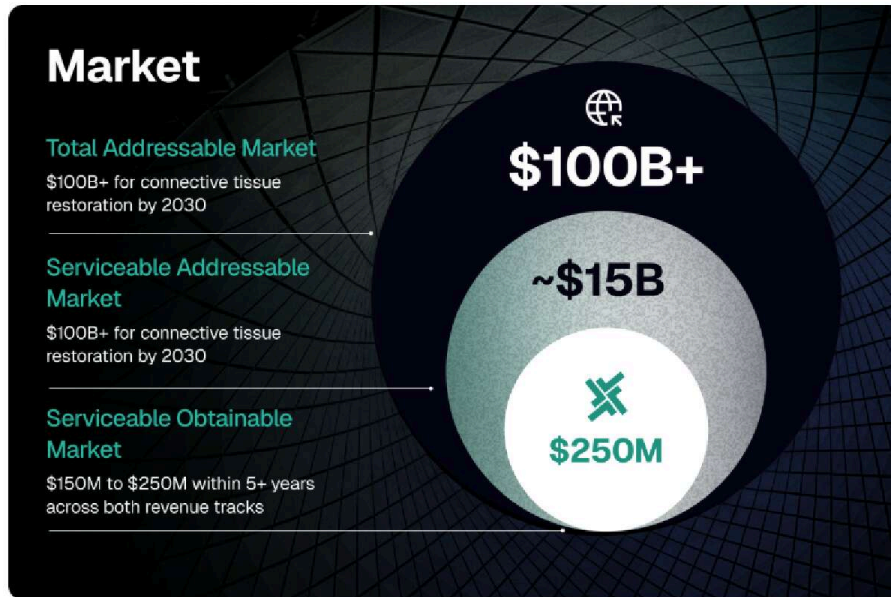
CardioWeave™ delivers custom-printed cardiac valve replacements matched to each patient's individual heart function.

DentaWeave™ addresses periodontal restoration through a light-curable gel that conforms to and regenerates damaged oral tissue, with formulation tuned to each

patient's inflammatory profile.

Smartweave's technologies are currently in the pre-clinical stage of development. Statements regarding potential performance characteristics—including reduced inflammation, improved tissue integration, or regenerative outcomes—are based on early-stage research, design objectives, and pre-clinical data, including animal models. These findings have not been validated in human clinical trials.

There is no assurance that these technologies will demonstrate similar results in humans or receive regulatory approval. Actual product performance, if commercialized, may differ materially from current expectations.



The connective tissue restoration market is one of the largest and most underserved in medicine. Aging populations are driving surgical volume across all three of Smartweave's clinical domains, and advances in AI, biofabrication, and cell therapy are expanding what is clinically achievable.

Urogynecological repair, orthopedic reconstruction, and cardiac valve replacement each represent large, established markets where published complication and failure rates signal that the current standard of care has a design problem.

- **Total Addressable Market:** \$100B+ for connective tissue restoration by 2030
- **Serviceable Addressable Market:** ~\$15B across technology licensing and direct product applications
- **Serviceable Obtainable Market:** \$150M to \$250M within 5+ years across both revenue tracks

Market size estimates and growth projections are based on third-party reports, industry publications, and internal assumptions. These estimates are inherently uncertain and subject to change.

Smartweave's ability to capture any portion of the identified market is dependent on numerous factors, including regulatory approval, clinical outcomes, commercialization execution, competition, and market adoption. There can be no assurance that the company will achieve meaningful market penetration.

Traction

Smartweave has built substantial validation across science, funding, IP, and team credentials before opening this public raise under Regulation Crowdfunding.

Company has generated

Company has generated

\$1.6M in revenue

over past 2 years from its IP assets and expects to continue to build both product and licensing revenue

Smartweave has leveraged its patent portfolio to generate \$1.6 MM in IP revenue over the past 2 years. It expects to build both product and licensing revenue as it scales.

Scientific and Pre-Clinical Validation

Pre-clinical rodent model data for the SMARTS™ system have demonstrated pelvic tissue regeneration and tendon repair, with FDA engagement now scheduled. The regulatory pathway for biocoatings suggests that Class II device clearance may be achievable within approximately one year of that engagement.

Smartweave's products are subject to review and approval by the U.S. Food and Drug Administration (FDA) or comparable regulatory authorities outside the United States. Any discussion of potential regulatory pathways, classifications, or timelines reflects current expectations only.

There can be no assurance that Smartweave will obtain FDA clearance or approval within any anticipated timeframe, or at all. Regulatory processes are inherently uncertain, may require extensive additional testing or clinical trials, and can result in significant delays, increased costs, or failure to commercialize.

Institutional Recognition and Funding

We were selected by Dassault Systèmes from more than 1,000 ventures worldwide, making us one of only 3 startups globally to access BIOVIA and the 3DEXPERIENCE Platform for constructing virtual patient replicas.

Alongside that recognition, we secured \$6.4M in grants and institutional support before opening this raise. Our clinical collaborators secured an additional 12M+ to advance key enabling technologies to a pre-IND stage, further de-risking the platform ahead of FDA engagement.

Intellectual Property

Smartweave has secured multiple patents and filed multiple applications, with a portfolio actively growing toward 50+ filings and trade secrets spanning scaffold designs, AI algorithms, regenerative formulations, and 3D printing methods.

Commercialization Roadmap



Commercialization Roadmap



Q4 2026	Q2 2027	Q4 2027
SMARTS™ System (bioengineered connective tissue scaffolds) - proof of concept complete	SmartCoating™ (HeraWeave™) - market entry for AI-tuned anti-inflammatory biocoatings	HeraWeave™ expansion - SmartGel™ for stress urinary incontinence enters market

- ▶ Q4 2026: SMARTS™ System (bioengineered connective tissue scaffolds) - proof of concept complete
- ▶ Q2 2027: SmartCoating™ (HeraWeave™) - market entry for AI-tuned anti-inflammatory biocoatings
- ▶ Q4 2027: HeraWeave™ expansion - SmartGel™ for stress urinary incontinence enters market

All development milestones and commercialization timelines represent current goals and expectations. These timelines are subject to significant risks and uncertainties, including but not limited to regulatory review, clinical validation, technical feasibility, manufacturing constraints, and funding availability.

Actual timing of product development, regulatory clearance, and market entry may differ materially from current projections or may not occur at all.

How We Make Money

Direct Product Commercialization

HeraWeave™, OrthoWeave™, and CardioWeave™ advance through FDA regulatory pathways toward direct market entry.

Smartweave Inside™ (B2B Licensing)

Smartweave licenses its IP, biomaterial formulations, AI algorithms, and training modules to existing device manufacturers.

Smartweave generates revenue through two parallel tracks that reinforce each other.

Smartweave Inside™ (B2B Licensing)

Smartweave licenses its IP, biomaterial formulations, AI algorithms, and training modules to existing device manufacturers. Manufacturers gain access to next-generation regenerative capabilities.

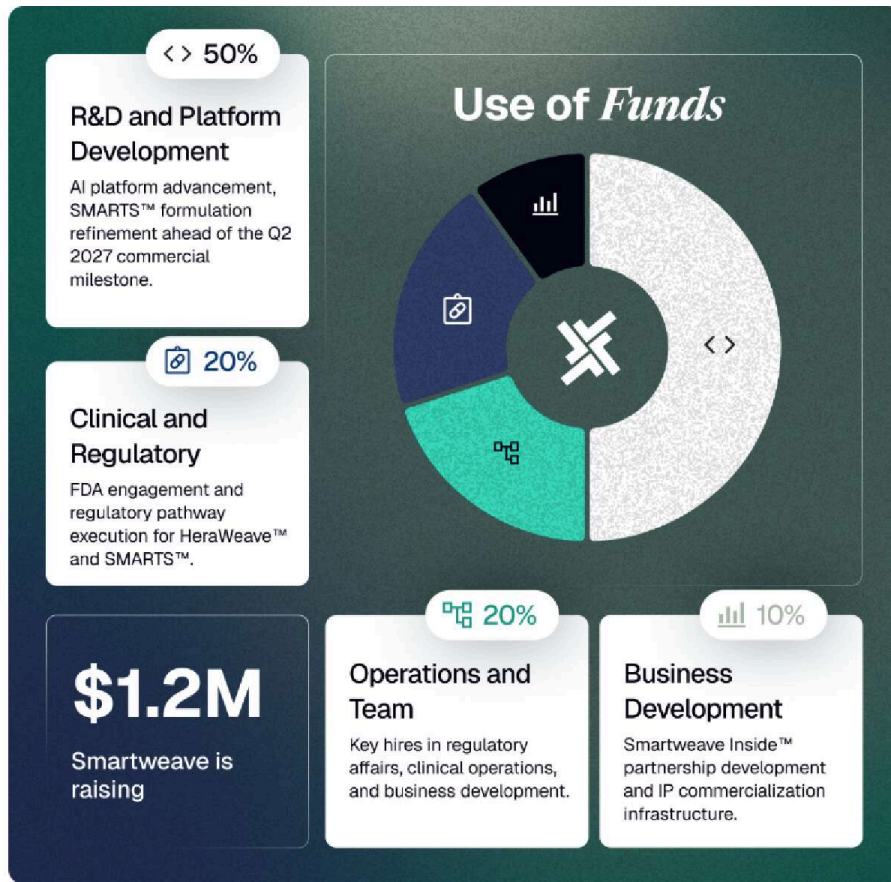
Smartweave earns licensing fees and royalties without carrying a full direct commercial infrastructure. This track generates recurring revenue and builds a commercial track record ahead of direct product launches.

Direct Product Commercialization

HeraWeave™, OrthoWeave™, and CardioWeave™ advance through FDA regulatory pathways toward direct market entry. Clinical data from these products strengthen the licensing portfolio. Licensing revenue funds continued product development. Both tracks operate from the same AI platform and IP portfolio.

Use of Funds

Smartweave is raising \$1.2M to advance from pre-clinical validation to first commercial revenue. Funds are allocated across four areas:

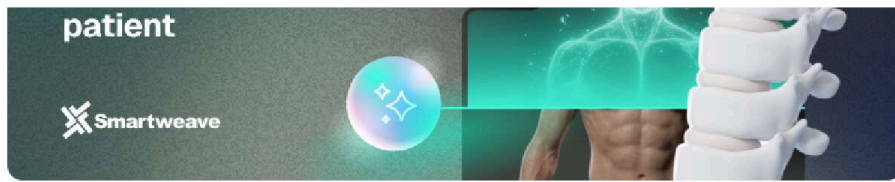


- **R&D and Platform Development (50%):** AI platform advancement and SMARTS™ formulation refinement.
- **Operations and Team (20%):** Key hires in regulatory affairs, clinical operations, and business development.
- **Clinical and Regulatory (20%):** FDA engagement and regulatory pathway execution for HeraWeave™ and SMARTS™.
- **Business Development (10%):** Smartweave Inside™ partnership development and IP commercialization infrastructure.

This raise advances Smartweave to its first commercial revenue milestone: Q4 2026 (SMARTS™ System), Q2 2027 (SmartCoating™ (HeraWeave™)), and Q4 2027 (HeraWeave™ expansion).

Own a piece of the regenerative medicine platform built for the individual patient.





The connective tissue repair market generates tens of billions of dollars annually, and documented failure rates across pelvic, orthopedic, and cardiac repair procedures indicate that the current standard of care has a design problem.

We're building Smartweave to address it.

Pre-clinical validation is complete for some of our initial products, \$18M in institutional backing has been secured toward derisking key technologies, and our team, advisors, and clinical collaborators bring credentials, expertise, and almost 150+ years of experience from industry leaders such as Stanford Medicine, Cedars-Sinai, Medtronic, and Johnson & Johnson. We are raising capital to advance from pre-clinical validation to first commercial revenue.

Invest in Smartweave

This content is prepared for Regulation Crowdfunding (Reg CF) purposes. Forward-looking statements, including financial projections and commercialization timelines, involve risks and uncertainties and are not guarantees of future results. Pre-clinical data from animal models do not guarantee equivalent outcomes in humans. Smartweave has not received FDA approval or clearance for any product as of this date. Investing in early-stage companies involves significant risk, including the possible loss of your entire investment. Nothing herein constitutes financial, legal, or investment advice.