

AGEless Biomedical, Inc.
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 W: AGElessBiomedical.com (Under Construction)



**AGEless
 Biomedical**

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Industries: Medical Device

Management:

Antonio Frasca, PhD (Biomedical Science), Founder, CEO

Board: Pending

Scientific Advisory Board:

Giovanni Ferrari, PhD, Associate Professor of Surgery & Biomedical Engineering (Columbia University)

David A. Spiegel, PhD, Professor of Chemistry (Yale University)

Seeking additional advisors

Number of Employees: 1

Finance:

Accounting/Tax: TBD

Funding to Date:

Columbia University BiomedX Accelerator (\$100k)

Financing Sought: \$4.0M

For:

- Continued tech refinement & long-term de-risking
- Multiple beachhead market pre-FDA testing (in vitro & animal)
- R&D for IP expansion
- IP & licensing fees
- Corporate overheads

Intellectual Property:

- PCT/US20/27698: Anti-Glycation Modification for Bioprosthetic Tissue
- PCT/US20/27619: Methods for Improved Bioprosthetic Valve Performance/Durability Testing

Legal:

AGEless: WSGR
 Columbia University IP: Dentons

Business Description / Company Background:

AGEless Biomedical is founded and led by a duo of Columbia University scientists who discovered that advanced glycation end product (“AGE”) formation, which is well known to instigate bodily disease, is also a key cause of biomaterial degeneration. We have developed a method for protecting protein-based biomaterials against AGE formation. This offers to improve outcomes for millions of patients yearly by enhancing durability & performance for implantable medical devices with biological components, such as bioprosthetic heart valves, and injectable proteins, such as collagen and albumin. AGEless also provides a platform for new discoveries & interventions related to these mechanisms.

Market Opportunities / Unmet Needs:

Bioprosthetic heart valve degeneration (BHV) causes repeat heart failure and necessitates device replacement for ~200,000 devices implanted every year within 10 years on average. Fibrotic remodeling, inflammation, & reduced clearance limit performance & utilization for bioprosthetic patches, conduits, scaffolds, and injectable proteins. Reagents to study glycation are also of great interest to biomedical research. The cumulative current market size for implantable devices with biomaterial components is ~\$7.5B + >10% CAGR. The cumulative injectable protein market is currently ~\$18B + ~8% CAGR. Market expansion opportunities are estimated at an additional \$10B. The novel research product market is estimated at \$15M.

Products / Services – Launched & Pipeline:

AGEless will provide integration-ready process for manufacturers to incorporate in various production pipelines (AGEless Biomaterial Treatment for Manufacturers). For products consisting only of bioprosthetic tissue or protein, we will proceed towards manufacture of our own products with concomitant generation of new IP (AGEless Tissue Patch, AGEless Serum Albumin, AGEless Collagen).

Commercial/Technical Milestones:

Achieved: >50% reduction of glycation (Q1 2020); treatment timescale (<1 week) & conditions (compatible buffer conditions, etc.) amenable for manufacturing integration (Q4 2020).

Forthcoming: Complete tech refinement & de-risking (Q4 2021); Primary beachhead market (patches): complete testing (Q3 2022), FDA 510(k) Submissions (Q3 2022), market entries (Q2 2023); Lab product partnerships (mid 2022), market entry (Q2 2023); BHV: complete testing (Q1 2023), market entry (mid 2025); Injectable proteins: market entry (2026).

Competition/Competitive Advantages/Customer Benefits:

AGEless is the first-mover in biomaterial anti-glycation. Competing technologies target auxiliary mechanisms, such as calcification & inflammation, but have not achieved significant clinical benefits. Edwards’ Resilia & Thermafix, Medtronic’s Linx AC, Abbott’s T6, and Integra’s Surgimend are exemplars. AGEless can be layered on these techs, obviating mutual exclusivity.

Financial Projections (Unaudited, time from first market entry):

Projections through Year 4 from first clinical market entry consider only sublicensing-driven revenue from single-product exclusivity agreements yielding AGEless 2% royalty, using an S-curve adoption model based on the recent experience of Edwards Resilia. Year 5 Projection adds first self-manufactured product market entry, with 50% initial margin.

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue	\$450K	\$1.5M	\$6.4M	\$30.9M	\$67M
Growth Rate		333.3%	426.7%	482.8%	216.8%
Gross Profit	\$450K	\$1.5M	\$6.4M	\$30.9M	\$65M
Gross Margin	100%	100%	100%	100%	97%