Regentis Biomaterials Ltd.
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Company Overview

Pioneering a restorative, off-the-shelf, solution for durable cartilage regeneration

Regentis Biomaterials Ltd. (NYSE American: RGNT) is a regenerative medicine company dedicated to developing innovative tissue repair solutions that restore health and enhance quality of life. With an initial focus on orthopedic treatments, Regentis' Gelrin™ platform technology, based on synchronized, degradable hydrogel implants, regenerates damaged or diseased tissue including inflamed cartilage and bone. Regentis' lead product GelrinC®, is a cell-free, off-the-shelf hydrogel that is eroded and resorbed in the knee, allowing the surrounding cells to regenerate durable and healthy cartilage in a controlled and synchronous process with sustained results. GelrinC® aims to address an estimated $3 billion annual U.S. market of approximately 470,000 cases for cartilage knee repair annually, where no off-the-shelf treatment is available. It has CE Mark approval for commercialization in Europe and has completed >50% enrollment in its pivotal Phase III study for U.S. FDA approval. Several value-driving upcoming catalysts include completion of the U.S. pivotal trial, commercialization in Europe, and submission for FDA approval in the U.S.

Investment Highlights

Positioned as Potentially First Off-the-Shelf Product for Knee Cartilage Repair in U.S.

GelrinC is uniquely positioned to redefine the standard of care as a first-in-class, off-the-shelf solution for knee cartilage repair in the U.S., where no comparable ready-to-use product currently exists that is supported by prospective clinical data. Unlike legacy approaches, GelrinC is a cell-free hydrogel delivered in a single, ~10-minute procedure, eliminating the need for cell harvesting, lab processing, and surgeries. This simplicity directly addresses a key bottleneck in orthopedic adoption: procedural complexity and workflow disruption. Today's standard treatments, particularly microfracture and autologous cell-based procedures like MACI, either suffer from limited durability or require costly, multi-stage interventions. GelrinC bridges this gap with a single-step, minimally invasive, immediately available implant, offering surgeons a practical alternative that fits seamlessly into existing arthroscopic workflows. This combination of off-the-shelf accessibility, procedural simplicity, and the ability to generate durable, healthy cartilage, positions GelrinC as a category-defining product capable of displacing both microfracture and complex cell-based therapies.

Clinical Efficacy Advantages Compared to Current Procedures

With ~100 procedures performed to date, GelrinC has demonstrated compelling clinical efficacy with durability and no adverse events through both patient-reported and objective quantified outcomes, differentiating it from existing cartilage repair approaches, with statistically significant outcomes. In clinical studies, GelrinC achieved approximately 100% greater improvement in KOOS pain scores versus microfracture at two years, with sustained benefits observed over multi-year follow-up. This level of improvement addresses one of the biggest limitations of current care: short-term symptom relief without long-term durability. MRI-based MOCART scores, a clear quantified measure, exceeded 80 at 24 months, indicating near-complete, hyaline-like cartilage repair, which is widely regarded as the gold standard for functional recovery. This dual validation—patient reported and structurally quantified—strengthens confidence that outcomes are durable over time.

Improved Healthcare Economics Support Market Adoption Upon Approval

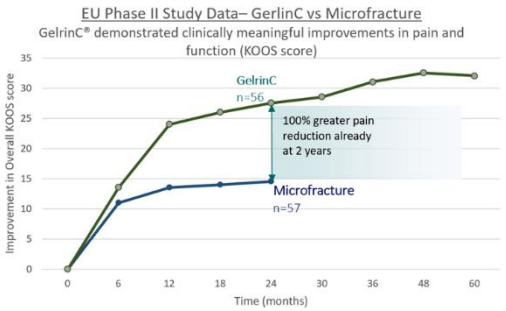
Beyond efficacy, GelrinC offers clear procedural and economic advantages: a single minimally invasive , ready-to-use intervention, faster recovery of ~2 weeks vs. ~6 weeks for cell-based therapies, and significantly lower cost compared to procedures like MACI which range ~$38K–$45K. The result is a solution that is clinically superior, simpler, faster, and more scalable, aligning with both surgeon and payer incentives while delivering lasting results to patients.

Targeting Substantial Underpenetrated Markets in Europe and U.S.

GelrinC targets a large and underpenetrated market, with approximately 750,000 knee arthroscopies annually in the U.S., of which ~470,000 involve cartilage damage. This translates into a ~$3 billion annual U.S. addressable market, even before considering expansion into adjacent indications such as osteoarthritis and other joints. In Europe, GelrinC is already CE Mark approved, significantly de-risking global regulatory pathways, and enabling a partner-led commercialization strategy in the EU. The U.S. represents the larger long-term opportunity, with an FDA IDE-approved pivotal trial that is >50% enrolled and a targeted PMA submission by 2027, positioning the Company for entry into a reimbursement-driven, high-value market. From a financial perspective, GelrinC combines attractive unit economics, with expected pricing under $10K per procedure with strong gross margins, and a scalable, repeatable surgical workflow.

Equity Overview (as of 04.02.26)

NYSE American: RGNT
Price Per Share: $3.11
52-Week Price Range: $2.04-$8.35
Market Cap: $16 M
Shares Outstanding: 5.15 M
Average Daily Trading Volume: 19 K



Disclaimer: Except for historical information contained herein, the statements in this fact sheet are "forward looking" within the meaning of the Private Securities Litigation Act of 1995. This fact sheet includes estimates and projections and, as such, reflects only management's current expectations. A fuller discussion of Regentis Biomaterials' risks and uncertainties are described in the Company's filings with the Securities and Exchange Commission, which should be reviewed in conjunction with this overview.