INTELLIGENTZIA
CAPITAL MANAGEMENT

CONFIDENTIAL & PRELIMINARY | JUNE 2026

Project ReGenesis

Frozen Shoulder Investment Teaser

A codename investment opportunity focused on a non-surgical, office-based injectable approach to adhesive capsulitis and capsular fibrosis.

~$35B

Global annual gross Frozen Shoulder TAM

source-based midpoint; range ~$23B–$49B

15–20

Planned Phase 1b / pilot patients

GCP-aligned study to support FDA discussions

A$4.0–4.5M

Initial capital requirement

regulatory advice, gap analysis, pilot, IND preparation

Executive Overview & Investment Highlights

Frozen Shoulder is the lead clinical and commercial focus, with platform optionality preserved for later indications.

COMPANY / ASSET OVERVIEW

- Codename for a localized injectable biologic combination designed to soften fibrotic tissue and restore motion.
- Lead focus is Frozen Shoulder / adhesive capsulitis, a high-burden shoulder capsule fibrosis condition.
- Next milestone is independent, GCP-aligned clinical validation of the founder-generated human signal.

Current management materials describe 200+ real-world treatments across fibrotic disorders with no serious adverse events reported; this remains subject to diligence.

TRANSACTION OVERVIEW

A$4.0–4.5M

Initial raise

- Regulatory strategy and formal gap analysis.
- CMC / nonclinical work-up and Phase 1b / pilot study.
- IND-readiness package and larger financing / partnering data room.

Management plan also contemplates up to ~A$20M over three years to reach IND acceptance and pivotal-study readiness.

INVESTMENT HIGHLIGHTS

01 Large, source-based TAM

Annual gross Frozen Shoulder TAM reset to ~$35B midpoint, not unsupported platform TAM.

02 Clear unmet need

Current care is symptomatic or procedural; recovery can take months to years.

03 Measurable lead indication

Shoulder ROM, pain, and function endpoints can be documented objectively.

04 Defined value inflection

Regulatory clarity + independent pilot data create investable next-step optionality.

Frozen Shoulder: High-Burden, Under-Served Fibrosis

Adhesive capsulitis is a painful capsular fibrosis syndrome with prolonged disability and limited disease-modifying options.

2–5%

General-population prevalence

higher in diabetics and middle-aged adults

10–30%

Diabetic population risk range

risk burden amplified by metabolic disease

1.5–3 yrs

Common disease course

pain, sleep disruption and disability

Lead indication: adhesive capsulitis of the shoulder capsule

WHY THE MARKET REMAINS UNDER-SERVED

- Frozen Shoulder is characterized by progressive capsular thickening, fibrosis and restriction of active and passive glenohumeral motion.
- Standard care is largely symptomatic: analgesics, physiotherapy, corticosteroid injections, hydrodilatation and refractory surgical release.
- No approved disease-modifying pharmaceutical therapy specifically targets the underlying fibrotic pathology of Frozen Shoulder.
- Patients often move through a long “freezing–frozen–thawing” course, creating a clear need for a targeted local fibrosis-remodeling intervention.

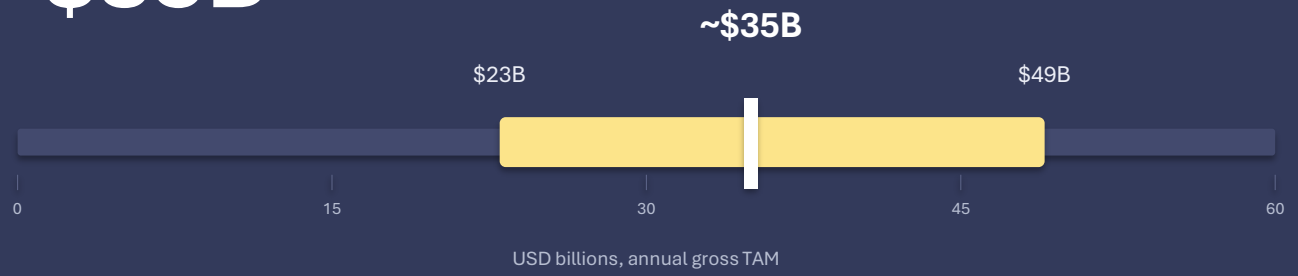
Source-Based Frozen Shoulder TAM

The commercial narrative is now anchored on a transparent annual active-treatment population, not a non-deduplicated platform figure.

GLOBAL ANNUAL GROSS TAM

~$35B

midpoint opportunity



Methodology

- World population: ~8.1B people.
- Annual case-rate range: 1.4–2.4 per 1,000 population.
- Implied annual cases: ~11M–19M.
- Gross TAM range: ~11M–19M cases × $2.0K–$2.5K modeled treatment price = ~$23B–$49B.

Current treated-market context

External treatment-market research estimates the current global Frozen Shoulder / adhesive capsulitis treatment market at roughly ~$1B–$3B, with forecasts reaching ~$2B–$4B by the early-to-mid 2030s.

Interpretation: ReGenesis is a latent market-creation opportunity, not a claim that current spend is already $35B.

Why not use total prevalence as annual TAM?

A prevalence pool of ~160M+ people worldwide is useful for understanding disease burden, but multiplying total prevalent cases by price overstates an annual TAM. The deck uses annual active / incident-treatment logic.

Source-based annual TAM: ~$23B–$49B; deck midpoint: ~$35B.

Core-Market Launch Model

Management's current plan narrows commercialization to Frozen Shoulder first and models a conservative core-market ramp.

Modeled revenue ramp: Frozen Shoulder lead indication

Illustrative revenue is based on the updated plan's core geographies and is not the global TAM.

Key plan assumptions

Target markets	USA / Canada, EU, UK and Japan
Annual incidence	0.5% of adult population; plan notes accepted range of 0.3%–0.7%
Injection treatment share	39% of adhesive capsulitis patients receive injections
ReGenesis share	25% preferred treatment five years after launch
WAC	$1,500 North America; $1,200 other countries
COGS	30% of WAC, pending manufacturing validation

Financial table in updated plan: revenue reaches ~A$548M in 2034 and ~A$564M in 2035 under the core-market launch case.

Product Concept & Mechanism

The proposed kit is positioned as an office-based injectable biologic approach targeting capsular fibrosis at the source.

PROPOSED REGENESIS KIT

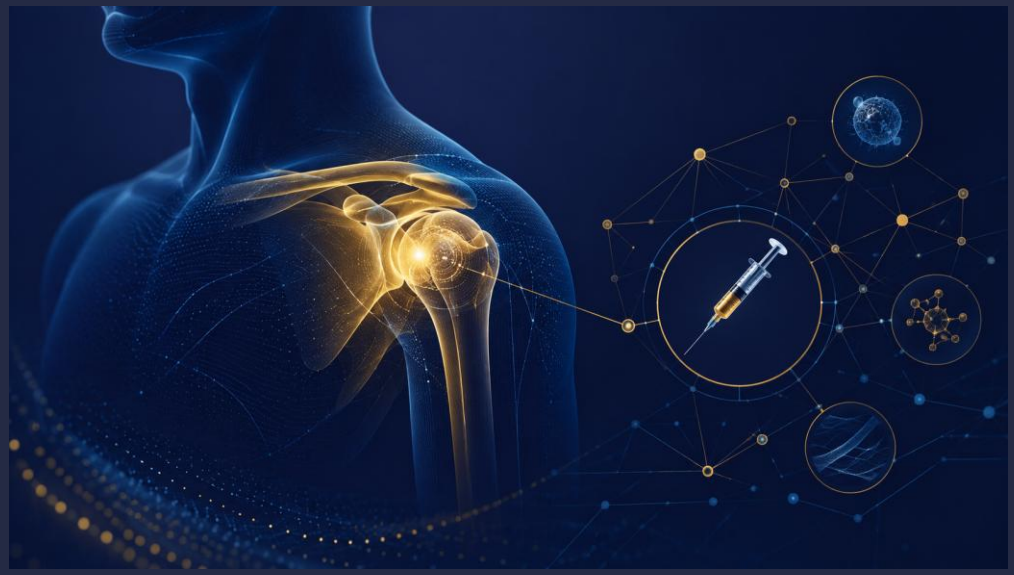
- Clinically-ready syringe kit: lyophilized drug combination, sterile water and anesthetic needle.
- Injection is intended to soften the thickened shoulder capsule and stiffened ligaments.
- Designed for appropriate outpatient use without operating-room escalation.

01 **tPA activates plasminogen**
Converts endogenous plasminogen to plasmin locally.

02 **Plasmin activates collagenase cascade**
Promotes controlled remodeling of collagen-rich fibrotic tissue.

03 **Hyaluronidase improves tissue diffusion**
Reduces extracellular-matrix resistance and enhances penetration.

04 **Goal: restored mobility**
Reduce capsular stiffness, improve ROM and function.



Designed to “dissolve what surgery cuts” by activating endogenous tissue-remodeling pathways.

Why Frozen Shoulder First?

Lead-indication selection reflects patient availability, clear endpoints, and strategic relevance to orthopedic care.

01 Large patient pool

Frozen Shoulder is common, under-served and visible to primary care, orthopedics, sports medicine and pain clinics.

02 Objective documentation

Range of motion, pain and function scores can be measured reproducibly; outcomes are less subjective than hand-opening assessment.

03 No disease-modifying drug

Current treatments generally reduce pain or mechanically stretch/release the capsule, without targeting fibrosis biology directly.

04 Commercial wedge

A successful shoulder proof point creates strategic relevance to orthopedic and specialty-pharma buyers while preserving platform optionality.

Proposed frozen shoulder endpoints to validate with advisors: external rotation / abduction ROM, pain score, SPADI / DASH-like functional scores, rescue therapy, safety and durability.

Current Treatment & Competitive Landscape

Existing care pathways create a wide gap between symptom management and invasive release procedures.

Approach	Role in care	Key limitation	ReGenesis positioning
NSAIDs / analgesics + PT	First-line symptom control and mobility maintenance	Variable outcomes; recovery may take months to years	Potential earlier local fibrosis intervention
Corticosteroid injection	Short-term pain reduction in inflammatory phase	Often temporary; not disease-modifying; weaker in diabetics	Designed to address fibrotic pathology directly
Hydrodilatation	Capsular distension to improve motion	Procedural; variable durability and repeat-treatment burden	Office-based injectable without mechanical distension thesis
MUA / arthroscopic release	Reserved for refractory or severe cases	Invasive, costly, rehab burden and procedural risk	Non-surgical pathway before operating room escalation
PRP / biologics / cell therapies	Investigational adjunct approaches	Inconsistent evidence; no established disease-modifying standard	Mechanism-based remodeling with established components

Investor takeaway: the target market has meaningful treatment activity today, but lacks a validated, office-based, disease-modifying pharmaceutical option for capsular fibrosis.

Regulatory & Clinical Strategy: De-Risk Before Scaling

The near-term objective is to confirm classification, product configuration and FDA-usability of early evidence.

Pre-RFD / classification

Clarify combination-product status, PMOA and lead review center.

Pre-IND meeting

Confirm CMC, nonclinical, protocol and foreign-data strategy.

Phase 1b / pilot

15–20 patient independent, GCP-aligned Frozen Shoulder study.

Pivotal alignment

Randomized design, endpoints, durability and safety package.

BLA strategy

Likely biologics framework; existing data may support portions of dossier.

Regulatory logic

Because the program includes a biologic component and may be a combination product, the formal route should be confirmed with FDA early. The plan should avoid over-reliance on a simple 505(b)(2) narrative and frame prior approvals as supportive, not determinative.

Frozen Shoulder pilot design considerations

Independent investigator, ethics approval, GCP documentation, baseline-to-follow-up ROM / pain / function assessment, local tolerability, rescue therapy and data capture suitable for FDA discussions under foreign-clinical-data expectations.

Development Timeline & Use of Proceeds

The updated plan positions the first financing around regulatory clarity, Phase 1b validation and IND-readiness.

Initial round: A$4.0–4.5M

Intended to fund regulatory advice, gap analysis, Australian Phase 1b / pilot study, FDA engagement and IND preparation.

Management plan also references ~A$20M over three years to reach IND acceptance and pivotal-study readiness.

Value inflection from this round

Clear classification, defined product configuration, independent human pilot data and a data-room package suitable for larger financing, strategic partnering or licensing discussions.

Investment Highlights

A focused Frozen Shoulder proof point can unlock orthopedic, specialty-pharma and platform-expansion optionality.

Large market, corrected TAM

Source-based annual TAM midpoint of ~$35B with current treated-market spend far smaller.

Human signal to validate

200+ real-world treatments across fibrotic disorders with no serious adverse events reported in management materials.

Unmet medical need

No approved disease-modifying pharmaceutical therapy for the fibrotic pathology of Frozen Shoulder.

Low-friction care setting

Office-based kit concept may reduce operating-room burden and patient downtime if validated.

IP / exclusivity narrative

Management materials cite patents granted in key markets and protection through 2042.

Strategic exit paths

Orthopedic, sports medicine, pain, biologics and specialty-pharma buyers can all underwrite a successful shoulder asset.

Core thesis: ReGenesis is built on a credible ~$35B gross annual TAM, a conservative core-market launch model, and near-term regulatory / clinical milestones — not inflated prevalence-based market math.

Sources, Methodology & Teaser Caveats

All partner-identifying source material has been sanitized; this deck uses the Project ReGenesis codename throughout.

Primary management materials used

- Updated confidential business plan focused on Frozen Shoulder first, dated May 2026 / uploaded June 2026.
- Intelligentzia Capital Management investment teaser template and logo assets.
- Previously prepared Project ReGenesis sanitized materials and regulatory strategy notes, with codename-only language retained.
- All instances of the partner/company name were intentionally excluded from the presentation.

Internal management claims used in the deck, including human-treatment experience, IP status, financial projections and capital requirements, remain subject to diligence and legal / regulatory verification.

Frozen Shoulder TAM source basis

- U.S. Census Bureau International Database projection: world population ~8.1B in 2025.
- Rangan et al. / BMJ: annual prevalence estimate of 1.4 per 1,000 patients in a UK study.
- Swiss Medical Weekly burden study: 2.4 per 1,000 / year incidence cited for adhesive capsulitis.
- Annual cases calculated as ~11M–19M globally; TAM range calculated using $2.0K–$2.5K gross treatment price.
- Precedence Research and Zion Market Research used only as current treated-market context, not as full latent TAM.

Teaser caveat: This presentation is confidential and preliminary; it is not an offer to sell securities. Clinical, regulatory, CMC, patent, market-size and financial claims require independent diligence.