JAYCOX & CO.

Business Plan — Confidential

JXC-001: A Modified Peptide Analog for Rotator Cuff Repair

Seed-Stage Investment Memorandum

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1. EXECUTIVE SUMMARY

Jaycox & Co. is a single-asset biotech company developing JXC-001, a modified peptide analog designed to reduce re-tear rates after rotator cuff surgery. We are raising $1.5–2M in seed capital to synthesize, screen, and validate a lead analog candidate. If successful, the company exits via acquisition after Phase 2 clinical data, targeting $200–500M.

The Investment Thesis

Every year, 450,000 Americans undergo rotator cuff repair. One in four of those repairs fails. Failed repairs cost the U.S. healthcare system $3.9 billion annually and leave patients worse off than before surgery. No FDA-approved peptide therapeutic exists to address this. The parent compound behind JXC-001 — BPC-157 — has over 200 preclinical studies demonstrating tissue repair activity, but its half-life is under 30 minutes. That makes it clinically useless in its native form.

We solve the half-life problem using modification technologies already validated by the FDA in multiple approved drugs. Lipidation extended semaglutide's half-life from 2 minutes to 165 hours. PEGylation, D-amino acid substitution, and cyclization have each produced FDA-approved therapeutics. These are engineering problems, not science-fiction. The real question — will the modified analog retain the parent compound's biological activity? — is exactly what seed capital answers.

What We Are Not

We are not a platform company. We are not pursuing multiple indications simultaneously. We are not claiming BPC-157 is a miracle drug. We are a single-indication, single-asset company making a disciplined bet that a well-characterized peptide can be engineered into a real therapeutic. Platform expansion comes after — and only after — we validate the core asset.

Key Metrics

Metric	Value
Target Indication	Rotator cuff repair (post-surgical)
U.S. Procedures / Year	~450,000
Re-Tear Rate	13–94% (size-dependent); 20–40% in patients >50
Annual Cost of Failed Repairs	$3.9B (AAOS 2025)
Seed Round	$1.5–2M
Primary Exit	Acquisition post-Phase 2: $200–500M
Timeline to Exit	5–7 years

At seed stage, investors are not funding a company. They are funding evidence — packaged as opportunity. This plan details what evidence we will generate, what it costs, and why it matters.

2. THE PROBLEM

Rotator cuff tears are the most common shoulder injury treated surgically in the United States. Approximately 450,000 repair procedures are performed annually, making it one of the highest-volume orthopedic surgeries. The procedure itself is well-understood. The problem is what happens after.

Re-tear rates range from 13% for small tears to 94% for massive tears, depending on the study and tear classification. The American Academy of Orthopaedic Surgeons reported in 2025 that one in four rotator cuff repairs fails to heal. In patients over 50 — the largest demographic for this surgery — re-tear rates run 20–40%, according to Arcuro Medical's 2025 FDA filing data. These are not edge cases. These are the typical patient.

Three Pillars of Failure

Patient Suffering.

A failed rotator cuff repair means months of rehabilitation wasted, return to chronic pain, and often a second surgery with worse prognosis. Revision repairs have higher complication rates and lower success rates than primary repairs. For many patients — particularly older adults — a failed repair means permanent functional limitation.

Physician Frustration.

Orthopedic surgeons have refined their technique for decades. The mechanical repair is excellent. What they lack is a reliable biologic augment that promotes tendon-to-bone healing at the cellular level. Current options — platelet-rich plasma (PRP), scaffolds, dermal matrices — show inconsistent results. Acellular dermal matrices have demonstrated a 42% reduction in re-tear risk in some studies, and Medicare reimburses an additional $1,500 per case for their use. But outcomes remain variable, and no single product has become standard of care.

Payer Burden.

Failed rotator cuff repairs cost the U.S. healthcare system $3.9 billion over two years, per AAOS 2025 estimates. This includes revision surgeries, extended rehabilitation, imaging, pain management, and lost productivity. A therapeutic that reduces re-tear rates by even 15–20% would generate hundreds of millions in savings — and payers know it.

Why No Peptide Therapeutic Exists

The orthopedic biologics market has grown without a peptide-based therapeutic because no one has solved the delivery problem. Peptides are fragile. They degrade in minutes. The most promising tissue-repair peptide in the literature — BPC-157 — has a half-life under 30 minutes. You cannot build a clinical program around a molecule that disappears before it can act. That pharmacokinetic barrier, not a lack of biological evidence, is why this space remains open.

3. THE SOLUTION: JXC-001

JXC-001 is a modified analog of BPC-157, a 15-amino-acid peptide with over 200 preclinical studies demonstrating activity in tissue repair, angiogenesis, and anti-inflammatory pathways. The parent compound's biological profile is unusually broad and unusually consistent across models. What it lacks is pharmacokinetic viability. JXC-001 is designed to fix that.

The Half-Life Problem

Native BPC-157 has a plasma half-life of less than 30 minutes. For a tissue-repair application requiring sustained exposure over days or weeks, this is a non-starter. Frequent dosing is impractical. Continuous infusion is impractical. The molecule needs to last longer in the body, period.

The Modification Approach

We are applying four established modification technologies to extend the half-life of BPC-157 while preserving its biological activity. Each of these technologies has produced FDA-approved drugs. None of them is experimental.

Lipidation.

Attaching a fatty acid chain enables the peptide to bind serum albumin, shielding it from enzymatic degradation and renal clearance. This is the technology behind semaglutide. Native GLP-1 has a half-life of approximately 2 minutes. Novo Nordisk attached a C18 fatty diacid via a gamma-glutamic acid/2xOEG linker and extended the half-life to approximately 165 hours — enough for once-weekly dosing. Published in the Journal of Medicinal Chemistry (2015) and validated in PMC (2019). Other FDA-approved lipidated peptides include liraglutide, insulin detemir, insulin degludec, and somapacitan. A 2024 PNAS paper established that lipidation has a practical ceiling of approximately one week for peptide half-life — which is exactly the dosing interval we target.

PEGylation.

Conjugating polyethylene glycol (PEG) polymers increases hydrodynamic radius and reduces renal clearance. Multiple FDA-approved PEGylated therapeutics exist across oncology, hematology, and hepatology. PEGylation is the most widely used half-life extension technology in biologics.

D-Amino Acid Substitution.

Replacing select L-amino acids with their D-enantiomers renders the peptide resistant to protease cleavage. This is a well-established approach in peptide drug design, used in approved therapeutics including desmopressin and leuprolide.

Cyclization.

Forming intramolecular bonds constrains the peptide backbone, reducing enzymatic access. Cyclic peptides have demonstrated dramatically improved stability and oral bioavailability in multiple clinical-stage programs.

The Real Scientific Risk

We are not inventing new chemistry. We are applying proven technologies to a new target. The engineering risk — can we extend the half-life? — is low, because these technologies have worked on dozens of peptides. The biological risk — will the modified analog retain the parent compound's tissue-repair activity? — is real, and it is the central question our seed program answers. Structure-activity relationship (SAR) studies will tell us which modifications preserve function and which do not. That is the entire purpose of the $1.5–2M seed raise.

Preclinical Evidence: Parent Compound

Study Area	Key Finding	Model	Source
Tendon Healing	Accelerated Achilles tendon repair, increased collagen organization	Rat transection	Staresinic et al., J Orthop Res (2003)
Ligament Repair	Enhanced MCL healing with increased biomechanical strength	Rat MCL transection	Chang et al., J Orthop Res (2014)
Muscle Healing	Accelerated recovery after crush injury, reduced fibrosis	Rat quadriceps	Novinscak et al., J Physiol Pharmacol (2008)
Angiogenesis	Promoted new blood vessel formation in ischemic tissue	Rat/chick CAM	Seiwerth et al., J Physiol Pharmacol (2018)
Anti-Inflammation	Reduced TNF-α, IL-6; modulated NO pathway	Multiple rodent	Sikiric et al., Curr Pharm Des (2018)
Bone Healing	Accelerated fracture repair, increased callus formation	Rat segmental defect	Krivic et al., J Orthop Res (2006)
GI Cytoprotection	Protected against NSAID-induced gut damage, promoted mucosal healing	Rat	Sikiric et al., Life Sci (1993)

200+ preclinical studies. Consistent activity across tissue types and injury models. Zero approved therapeutics. The gap is not evidence — it is engineering.

4. MARKET OPPORTUNITY

We size our market bottom-up, from the procedure we target, not top-down from global healthcare spending. Top-down math is lazy. It tells investors nothing about whether anyone will actually buy the product.

Bottom-Up: Rotator Cuff Repair

Approximately 450,000 rotator cuff repairs are performed annually in the United States (Mordor Intelligence). Current biologic augments — dermal matrices, PRP preparations — are reimbursed at $1,000–2,000 per case on top of the surgical procedure. Medicare already reimburses an additional $1,500 per case for acellular dermal matrices that demonstrate re-tear reduction.

At a price point of $1,000–2,000 per treatment, the U.S. rotator cuff augmentation market represents $450M–$900M in addressable revenue. We do not assume 100% penetration. At 10–15% market share — a realistic target for a first-in-class biologic — annual U.S. revenue would be $45M–$135M. This is the number that matters for a potential acquirer's DCF model.

Market Context

Market Segment	Size (2024)	Growth	Source
Rotator Cuff Repair Devices	$899M	7.58% CAGR → $3.69B by 2033	Grand View Research
Orthobiologics	Subset of above	8.36% CAGR through 2031	Grand View Research
Biologic Patches & Meshes	Fastest-growing category	9.24% CAGR	Grand View Research
Global Soft Tissue Repair	$15.6B	Growing	Industry reports
Global Peptide Therapeutics	$141B (Grand View 2025)	High single-digit CAGR	Multiple sources

Why This Market, Why Now

Three forces converge. First, the orthobiologics segment is the fastest-growing category in orthopedic surgery, driven by surgeon demand for better healing outcomes. Second, the FDA's 2023–2025 crackdown on unregulated peptide compounding pharmacies has created market demand for an FDA-approved peptide therapeutic — patients who experienced benefits from compounded BPC-157 now have no legal source. Third, the aging population ensures that rotator cuff repair volumes will grow, not shrink. The demographic tailwind is permanent.

The broader peptide therapeutics market validates the commercial viability of peptide drugs. Semaglutide alone generated over $20 billion in 2024 revenue. The market understands peptides. What it does not yet have is an FDA-approved peptide for musculoskeletal repair.

5. COMPETITIVE LANDSCAPE

The competitive landscape for BPC-157-based therapeutics is thin. Despite 200+ preclinical publications, only two entities are pursuing clinical development, and neither is developing a patentable modified analog.

Direct Competitors

Entity	Approach	Stage	Limitation
Hudson Biotech	Native BPC-157 (unmodified)	Phase 2 (est. 2027)	No composition-of-matter IP; half-life constraint remains
Diagen (Croatia)	Patent holder; licensing native peptide	Preclinical / licensing	Patents cover salt forms only; not pursuing analogs

Adjacent Competition

The broader orthobiologics space includes products that augment rotator cuff repair without using peptide therapeutics. Platelet-rich plasma (PRP) has mixed evidence and no standardized preparation protocol. CONMED's BioBrace is an absorbable implant that provides mechanical reinforcement but does not deliver biologic signaling. Acellular dermal matrices (e.g., from Stryker, Integra) provide scaffolding and have demonstrated re-tear reduction, but are not pharmacologically active.

None of these products addresses the underlying cellular biology of tendon-to-bone healing. JXC-001 is designed to be complementary — it could be used alongside scaffolds or matrices — not as a replacement. This is an expansion of the market, not a displacement.

Our Competitive Advantage

No entity is developing a composition-of-matter-patentable modified analog of BPC-157 for orthopedic indications. Hudson Biotech's approach uses the native peptide, which cannot be patented as a new composition. Diagen's patents cover salt forms, not novel sequences. We have a clear freedom-to-operate window to file composition-of-matter patents on modified analogs — the strongest form of pharmaceutical IP.

Potential Acquirers

Company	Strategic Fit	Orthobiologics Revenue	Acquisition Logic
Johnson & Johnson (DePuy Synthes)	Dominant in orthopedics	>$8B sports med / ortho	Fill biologics gap in shoulder portfolio
Stryker	Sports medicine leader	>$3B sports med	Complement existing scaffold products
Smith+Nephew	Active acquirer in biologics	>$2B orthopedics	Recently acquired CartiHeal ($180M upfront + $150M milestones); building portfolio
Novo Nordisk	Peptide engineering expertise	N/A (peptide focus)	Leverage lipidation platform into musculoskeletal

Zimmer Biomet	Orthopedic pure-play	>$7B total	Biologics category expansion

6. INTELLECTUAL PROPERTY STRATEGY

Intellectual property is the single most important asset in a preclinical biotech company. Without strong IP, there is no acquisition premium, no licensing revenue, and no barrier to competition. Our IP strategy is designed to secure composition-of-matter protection on novel analog sequences — the gold standard in pharmaceutical patents.

Freedom to Operate

Diagen holds patents on BPC-157 salt forms (e.g., the acetate and chloride salts of the native 15-amino-acid sequence). These patents do not cover modified analogs with altered amino acid sequences, lipidated variants, PEGylated conjugates, or cyclized forms. Our preliminary FTO analysis indicates a clear path to file without infringing existing claims. Formal FTO opinion will be completed prior to provisional filing.

Patent Strategy

- **Core Claims:** Composition-of-matter claims on novel modified sequences (strongest protection)
- **Method Claims:** Method-of-use claims for rotator cuff repair and tendon healing applications
- **Formulation Claims:** Formulation and delivery-specific claims (sustained-release, injectable depot)

Filing Timeline

Milestone	Timing	Purpose
Provisional patent (U.S.)	Q1 2027	Secure priority date on lead analog(s)
Additional provisionals	Q3 2027	Cover backup analogs and formulations
PCT international filing	Q1 2028	International protection (150+ countries)
National phase entry	H2 2029	File in key markets: U.S., EU, Japan, China

Patent Life and Exclusivity

Base patent term is 20 years from filing date. As a new chemical entity (NCE), JXC-001 would qualify for 5 years of NCE exclusivity under the Hatch-Waxman Act, independent of patent status. Patent term extension (PTE) of up to 5 years is available to compensate for time spent in FDA review. Combined, this creates approximately 16 years of protected commercial exclusivity — more than sufficient to support acquisition valuations and licensing terms.

7. REGULATORY PATHWAY

We are honest about what the regulatory pathway requires. JXC-001 is a new chemical entity. There is no shortcut to approval. This section describes the full pathway, the timeline, the cost, and the designations we will pursue to accelerate it.

NDA Pathway

JXC-001 will require a full New Drug Application (NDA) via the 505(b)(1) pathway — or potentially 505(b)(2) if we can reference existing published data on the parent compound to support portions of the safety profile. The 505(b)(2) pathway could reduce clinical development costs by 30–40%, but eligibility depends on how the FDA views the relationship between the modified analog and the native peptide. We will seek a pre-IND meeting to clarify this.

Development Timeline

Phase	Duration	Estimated Cost	Key Activities
Preclinical / IND-enabling	2–3 years	$5–15M	GLP tox, GMP manufacturing, PK/PD, IND filing
Phase 1 (safety)	1–1.5 years	$10–20M	First-in-human, dose escalation, safety/tolerability
Phase 2 (efficacy)	2–3 years	$30–60M	Proof-of-concept in rotator cuff repair patients
Phase 3 (pivotal)	3–4 years	$100–200M+	Large multicenter RCT, NDA submission
TOTAL	8–12 years	$150–250M+	From IND to approval

The total cost of $150–250M to FDA approval is consistent with industry averages for a new molecular entity in a surgical indication. This is not capital we are raising now. This is capital that an acquirer or licensing partner brings to the table after we deliver validated preclinical and early clinical data.

FDA Designations to Pursue

- **Fast Track Designation:** JXC-001 addresses a serious condition with unmet medical need. If granted, provides increased FDA engagement and rolling NDA review.
- **Orphan Drug Designation:** If rotator cuff repair failure can be defined as affecting <200,000 patients annually (subset of total procedures), orphan designation would provide 7 years of market exclusivity, tax credits, and reduced filing fees.

Regulatory Tailwind

The FDA's ongoing crackdown on compounding pharmacies selling unregulated BPC-157 creates a structural tailwind. Patients who experienced benefits from compounded peptides now have no legal access. Physicians who observed clinical effects have no FDA-approved product to prescribe. An FDA-approved BPC-157 analog would fill a regulatory vacuum that the FDA itself created.

8. TEAM

Seed-stage biotech companies are built on small teams with outsized commitment. The founding team handles operations, fundraising, and strategic direction. The science is driven by hired expertise — a Chief Scientific Officer and a Scientific Advisory Board. That is the model. Here is where we stand.

Founding Team

Jonathan Jaycox — Chief Executive Officer & Founder

Business and economics background. Former law enforcement — a career that selects for discipline under pressure, decision-making with incomplete information, and zero tolerance for cutting corners. Brings operational execution, fundraising leadership, and the strategic vision behind JXC-001. Identified the opportunity gap between BPC-157's preclinical evidence base and the absence of any FDA-approved analog. Built the company's research thesis, business model, and investor materials from the ground up.

Addison West — Executive Assistant & Operations

Manages day-to-day operations, investor relations coordination, scheduling, and administrative infrastructure. As the company scales, this role expands into investor communications and board support.

Critical Hire: Chief Scientific Officer

The CSO hire is the single most important decision this company will make before Series A. This person will design the analog synthesis program, select CRO partners, interpret PK and activity data, and represent the company's science to investors and regulators. The wrong CSO wastes the seed round. The right one makes JXC-001 real.

CSO Profile:

- PhD in medicinal chemistry, peptide chemistry, or pharmacology
- 5+ years in drug development (industry or academic translational research)
- Experience with peptide modification technologies (lipidation, PEGylation preferred)
- Track record of IND-enabling studies
- Compensation: $150–200K base + 1–2% equity (vesting over 4 years)

Scientific Advisory Board (Planned)

We will assemble a 3–5 member SAB upon closing the seed round. Target composition:

Role	Expertise	Compensation	Purpose
Peptide Chemist	SAR, modification technologies, formulation	0.1–0.3% equity	Guide analog design and synthesis strategy
Orthopedic Surgeon (KOL)	Rotator cuff repair, clinical trial design	0.1–0.3% equity	Clinical relevance, trial endpoint selection, credibility
Regulatory Expert	FDA interactions, IND strategy, 505(b)(2)	0.1–0.3% equity	Regulatory pathway optimization

Pharmacologist	PK/PD modeling, preclinical development	0.1–0.3% equity	Data interpretation, CRO oversight

At seed, the team is not the team that takes a drug to market. It is the team that generates the data to attract the team that takes a drug to market.

9. FINANCIAL PLAN

We are raising $1.5–2M in seed capital. Every dollar has a job. The purpose of this round is not to build a company — it is to generate a single, fundable data package: a validated lead analog with extended half-life and retained biological activity. That package enables a $10–15M Series A. Everything else is sequenced after.

Use of Funds

Category	Budget	Detail
Analog Synthesis (5–10 candidates)	$200–300K	CRO-based synthesis of modified sequences (lipidated, PEGylated, D-amino, cyclic variants)
In Vitro Activity Screening	$150–250K	Cell-based assays: proliferation, migration, angiogenesis, anti-inflammatory markers
PK Validation	$50–100K	Plasma stability, half-life measurement in rodent models, albumin binding studies
Lead Candidate Selection	Included above	SAR analysis to identify 1–2 candidates with optimal activity/PK profile
Provisional Patent Filing	$15–25K	File composition-of-matter provisionals on lead analog(s)
CSO & SAB Recruitment	$50–100K	CSO salary (partial year) + SAB engagement fees
Consultants (Regulatory, Legal)	$30–50K	Pre-IND strategy, FTO opinion, corporate counsel
Operations & Overhead	$100–200K	Rent, insurance, travel, investor relations, accounting
Contingency (10%)	$100–150K	Buffer for unexpected CRO costs or additional assays
TOTAL	$1.5–2.0M	18–24 month runway

Burn Rate and Runway

Projected monthly burn rate: $60–80K. At $1.5M raised, runway is approximately 18 months. At $2.0M raised, runway extends to 24 months. We budget conservatively because seed-stage biotech companies that run out of cash before generating data are worth zero. Runway is survival.

Success Criteria for Seed Round

The seed round succeeds if we deliver three things: (1) at least one modified analog with a half-life exceeding 4 hours — ideally 24+ hours; (2) demonstrated retention of biological activity in validated in vitro assays; and (3) a provisional patent filed on the lead sequence. These three deliverables constitute a de-risked data package sufficient to raise a Series A.

Cap Table (Post-Seed)

Stakeholder	Ownership	Notes
Founder (Jonathan Jaycox)	~96%	Full dilution pending option pool creation
Seed Investors	~4%	Based on $1.5M raise at $5M post-money cap (SAFE)
Employee Option Pool	To be created at Series A	Standard 10–15% pool

Future Financing

Series A ($10–15M) is targeted 18–24 months after seed close, contingent on successful lead validation. Series A funds IND-enabling studies: GLP toxicology, GMP manufacturing, and IND filing. Beyond Series A, the capital-efficient path is partnership or acquisition — not further dilutive fundraising. The financial plan assumes exit at Phase 2, not full commercialization.

Funding Environment Context

We are raising in a difficult market. Biotech seed funding in Q1 2026 was nearly absent: only 2 deals totaling $4M across the entire sector (BiotechTube). VCs are overwhelmingly favoring de-risked, later-stage assets (Alacrita 2025). This is the environment we operate in. We are not pretending otherwise. Our response is disciplined capital allocation, milestone-gated spending, and a seed round sized to deliver a specific, fundable result — not to sustain a burn rate.

10. EXIT STRATEGY

We build to exit. The most probable and most capital-efficient path is acquisition after Phase 2 clinical data. We are not building a commercial-stage pharmaceutical company. We are building a validated asset that a larger company can take through Phase 3 and commercialization using their existing infrastructure.

Primary Exit: Acquisition (Phase 2 Data)

Target exit window: 5–7 years from seed close. Valuation range: $200–500M. The orthopedic and biologics space has consistent M&A activity, and mid-stage assets with clinical proof-of-concept command significant premiums.

Comparable Transactions

Acquirer	Target	Value	Stage	Relevance
Smith+Nephew	CartiHeal	$180M + $150M milestones	Clinical-stage cartilage repair	Orthobiologics M&A precedent; up to $330M total ($180M upfront + $150M milestones)
BMS	Karuna Therapeutics	$14B	Phase 3 CNS	Premium for validated clinical data
Stryker	Wright Medical	$5.4B	Commercial	Orthopedic portfolio expansion
J&J	Abiomed	$16.6B	Commercial cardiovascular	MedTech biologics precedent

The $200–500M range for our exit is anchored in early-to-mid clinical stage orthobiologics precedents, not in the blockbuster pharmaceutical deals listed above. We include the larger deals to demonstrate that validated clinical assets command premiums across therapeutic areas.

Secondary Exit: Licensing

An alternative to outright acquisition is licensing the asset to a larger company for continued development and commercialization. Typical terms: $10–30M upfront payment, $50–200M in development and regulatory milestones, and 5–10% royalties on net sales. Licensing preserves optionality — the company retains rights for other indications or geographies.

Tertiary Exit: Full Commercialization

Building a fully integrated pharmaceutical company to commercialize JXC-001 independently would require $250M+ in additional capital, a commercial sales force, and 10+ years. This is the highest-reward path and the highest-risk one. We mention it for completeness. It is not our plan.

11. RISK FACTORS

Every seed-stage biotech investment carries the risk of total loss. We are not going to minimize that. Instead, we describe each major risk honestly, explain why it exists, and detail how we mitigate it. Investors who cannot tolerate these risks should not invest. Investors who understand them will recognize that each risk has a plan.

1. Scientific Risk: Analog May Not Retain Activity

Modifying a peptide's structure can reduce or eliminate its biological activity. This is the central scientific risk of the program. There is no guarantee that a lipidated, PEGylated, or otherwise modified BPC-157 will retain the tissue-repair properties of the parent compound.

Mitigation: Structure-activity relationship (SAR) studies across 5–10 analogs maximize the probability of identifying a functional candidate. The modification technologies we employ have successfully preserved activity in dozens of other peptide programs (GLP-1, insulin, growth hormone). The risk is real but addressable through systematic screening.

2. Translational Risk: No Controlled Human Data on Parent Compound

BPC-157 has never been evaluated in a controlled, peer-reviewed human clinical trial. The 200+ preclinical studies are entirely in animal models. Preclinical results frequently fail to translate to humans — the historical success rate from preclinical to FDA approval is under 10%.

Mitigation: Hudson Biotech's Phase 2 trial (expected 2027) will provide the first controlled human data on native BPC-157. Positive results would dramatically de-risk the translational hypothesis for all BPC-157-derived programs, including ours. Negative results would be a significant setback. We monitor this trial closely.

3. Single-Lab Concentration

Approximately 80% of the published preclinical data on BPC-157 originates from a single research group (Sikiric et al., University of Zagreb). When the majority of evidence comes from one lab, publication bias and methodological consistency concerns are legitimate.

Mitigation: Independent validation studies are emerging from groups in the U.S., Japan, China, and South Korea. Early results are consistent with the original findings. Additionally, our own in vitro screening program will generate independent data on the analog's activity — data that either confirms or contradicts the preclinical record.

4. Regulatory Risk: Full NDA Required

JXC-001 is a new chemical entity requiring a full NDA. This means 8–12 years of development, $150–250M in total capital, and no guarantee of approval. The FDA may require larger or longer trials than anticipated. Endpoints for rotator cuff repair (imaging-based re-tear assessment) may not satisfy the agency.

Mitigation: FDA designations (Fast Track, potentially Orphan) can accelerate review. The 505(b)(2) pathway may reduce clinical requirements if the FDA accepts reference to published parent compound data. Pre-IND meeting will clarify expectations before significant capital is committed to clinical development.

5. Capital Risk: $150–250M to Approval

The total capital required to take JXC-001 from seed to FDA approval exceeds $150M. This capital must come from subsequent financing rounds, partnership deals, or an acquirer. If the funding environment deteriorates further — and biotech seed funding in Q1 2026 was historically low — the company may not be able to raise subsequent rounds on acceptable terms.

Mitigation: Our exit strategy does not require FDA approval. Acquisition or licensing at Phase 2 data ($200–500M) is the primary exit. The seed round is sized to deliver a specific data package, not to sustain indefinite operations. Milestone-based exits are available at every stage of development.

6. Key Person Risk

The company currently has a two-person team. Loss of the founder or failure to recruit a qualified CSO would materially impair operations. At seed stage, there is no depth on the bench.

Mitigation: CSO recruitment is the #1 operational priority post-close. SAB members provide scientific continuity independent of any single hire. Key-person insurance will be obtained. CRO-based execution model means the science does not depend on in-house lab capabilities.

7. Competitive Risk

A well-funded competitor — a large pharma with peptide engineering capabilities, or a well-capitalized startup — could enter this space and outpace us. The competitive moat is narrow at seed stage.

Mitigation: Speed to patent is our primary defense. Composition-of-matter filings on lead analogs will be made as soon as data supports them. First-mover advantage in this specific niche — modified BPC-157 analogs for orthopedic indications — is real but perishable. We treat the filing timeline as a competitive race.

12. MILESTONES & TIMELINE

The following timeline assumes seed close in Q3 2026 and maps the critical path from analog synthesis through a Phase 2 exit window. Each milestone is a decision gate: proceed, pivot, or return capital.

Year	Quarter	Milestone	Gate Decision
2026	Q3	Seed round closes ($1.5–2M)	—
2026	Q4	CSO hired; CRO contracts executed	Proceed / adjust scope
2027	Q1	First analog candidates synthesized (5–10)	—
2027	Q2–Q3	In vitro activity screening complete	Activity retained? → Proceed No activity? → Redesign or halt
2027	Q3	PK validation: half-life measurement	Half-life >4 hrs? → Proceed <4 hrs? → Iterate modifications
2027	Q4	Lead candidate selected; provisional patent filed	Seed round success criteria met
2028	Q1–Q2	Series A raise ($10–15M)	—
2028	Q3–Q4	IND-enabling studies begin (GLP tox, GMP mfg)	—
2029	H1	PCT international patent filing	—
2029	H2	IND submission to FDA	FDA feedback → proceed to Phase 1
2030	Full year	Phase 1: safety, dose escalation	Safe? → Proceed Safety signal? → Halt or redesign
2031–2032	Full period	Phase 2: efficacy in rotator cuff patients	Efficacy signal? → Exit window opens No signal? → Halt or pivot
2032–2033	—	EXIT WINDOW: Acquisition or licensing	Target: $200–500M

Every gate has a 'halt' option. We do not spend the next dollar until the last dollar proved it was worth spending. That is how seed investors are protected in high-risk programs.

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