

# DentoClude F Investment Offering

## Confidential Private Placement Memorandum

Cumberland Biotherapeutics, Inc. – DentoClude F Product Line Tuesday, December 9, 2025

## Executive Summary

### Company Overview

Cumberland Biotherapeutics (CBT) is a commercialization-stage medtech company that received FDA 510(k) clearance for DentoClude F in 2024, a bioactive glass solution engineered for dental restorative, regenerative, and preventive applications. Positioned at the intersection of a growing \$598+ million global dental bioactive glass market (projected to grow at 7.2% CAGR through 2032), DentoClude F is now actively deployed in clinical practice addressing unmet needs in general dentistry and sub specialties: endodontics, periodontics, and restorative.

### The Opportunity

The global bioactive glass dental market was valued at \$342.7 million in 2025 and is expected to reach \$598.4 million by 2032, driven by:

- Increasing adoption of minimally invasive procedures [2]
- Rising demand for biocompatible materials in regenerative dentistry [3]
- Antimicrobial innovations reducing post-surgical infection rates by up to 40% [4]
- Consolidation in dental groups and DSOs creating volume purchasing opportunities [5]

DentoClude F capitalizes on this growth through a clinically validated bioactive glass formulation with enhanced antimicrobial properties, optimized handling for clinical adoption, and a clear go-to-market strategy targeting high-value specialties (endodontics, periodontics, oral surgery).

### Investment Structure

We are raising capital through Regulation **D 506(c) private offering** structured as follows:

Metric	Value
<b>Total Shares Outstanding</b>	100,000,000
<b>Offering Amount</b>	\$10,000,000 USD
<b>Security Type</b>	Series Seed Preferred Stock (1x non-participating liquidation preference)

<b>Post-Money Valuation</b>	\$220,000,000
<b>Investor Ownership</b>	4.55% dilution (per \$10M tranche)
<b>Price Per Share</b>	\$2.20
<b>Minimum Investment</b>	\$250,000
<b>Use of Proceeds</b>	FDA regulatory pathway, clinical trials, manufacturing scale-up, go-to-market launch, international expansion, team build-out

### **Investor Return Profile (Series A, \$10M Investment \$2.20/share)**

Scenario	Exit Valuation (Year 5)	Investor Return (4.55% equity)	Net Multiple	Annualized IRR (5 years)
<b>Conservative</b>	\$600,000,000	\$27.3M	2.7x	~22%
<b>Base Case</b>	\$750,000,000	\$34.1M	3.4x	~27%
<b>Upside</b>	\$1,000,000,000	\$45.5M	4.6x	~36%
<b>Optimistic</b>	\$1,250,000,000	\$56.9M	5.7x	~43%

Exit assumptions include acquisition by a major dental platform (DSO, strategic dental group, or larger medtech), 5–7 year time horizon, and anticipated founder dilution to ~10% by exit through Series A/B rounds.

# **Company Background**

## **Mission & Vision**

DentoClude F (branded product line of Cumberland Biotherapeutics) is engineered to transform dental care by delivering superior clinical outcomes through advanced and first in class bioactive glass technology. Our mission is to make predictable, regenerative dental treatment accessible to practitioners across all specialties and practice sizes.

## **Founders & Leadership**

Cumberland Biotherapeutics is led by a team with deep expertise in:

- Medical device commercialization
- Investor relations and fundraising across medtech platforms
- Regulatory strategy and FDA compliance (506(c), 510(k) pathways)
- Dental practice sales, KOL engagement, and specialty group adoption

## Regulatory Status

- **Current Stage:** Commercial launch phase; FDA 510(k) clearance obtained December 2024 for root canal filling, apical sealing, periodontal bone regeneration, and dentin remineralization indications.
- **US Market Position:** DentoClude F commenced commercial distribution across US dental markets in Q1 2025; establishing adoption among endodontic and periodontal specialists through KOL partnerships and direct sales.
- **International Expansion Timeline:** EU CE Mark application submitted Q4 2026 (expected approval Q2 2026); Canada regulatory clearance planned Q3 2026; Australia TGA approval pathway initiated Q1 2026
- **Geographic Rollout:** US market focus through 2025–2026; EU market entry Q2 2026; Canada/Australia sequential launches through 2026; Asia-Pacific expansion planned 2027+

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## Product & Technology

### DentoClude F: Core Technology

DentoClude F is a bioactive glass formulation optimized for clinical efficacy and ease of use in dental applications:

#### Clinical Applications:

- **Endodontics** – Root canal filling, apical sealing, periapical lesion regeneration
- **Periodontics** – Alveolar ridge preservation, periodontal bone regeneration, graft stabilization
- **Restorative Dentistry** – Dentin remineralization, caries prevention, hypersensitivity treatment
- **Oral Surgery** – Extraction site grafting, implant site preparation, ridge augmentation

#### Key Differentiators:

Feature	DentoClude F	Conventional Materials	Clinical Benefit
<b>Bioactivity</b>	Enhanced ion release kinetics	Passive bioactivity	Faster bone/soft tissue regeneration
<b>Antimicrobial Profile</b>	Doped silver/zinc variants available	None (inert)	Up to 40% reduction in post-surgical infections [6]
<b>Handling</b>	Optimized particle size & viscosity	Variable, often difficult	Higher clinical adoption, reduced training burden
<b>Resorbability</b>	Tuned degradation rate	N/A for inert materials	Predictable regeneration timeline
<b>Biocompatibility</b>	Silicate-based, calcium phosphate release	N/A for inert materials	Superior tissue integration, fewer adverse reactions

## COMPARISON OF CLINICAL EFFICACY OF FOUR PROFESSIONALLY APPLIED AGENTS CONTAINING BIOACTIVE GLASS IN TREATMENT OF DENTIN HYPERSENSITIVITY



To compare the efficacy of four agents containing Bioactive glass in treatment of dentin hypersensitivity (DH)

1



2



3



4



### METHODOLOGY

Ten individuals with dentin hypersensitivity in at least one canine or premolar in the four quadrants with VAS score  $\geq 5$  were selected in the study. Each quadrant in an individual was randomly assigned to one of the four agents containing Bioactive glass. Subjects received single application of the assigned agent. Results assessment:

- visual analog scale and
- Schiff cold air sensitivity scale

at baseline, immediately after the treatment, & after 4 week

### RESULTS

Comparison of reduction in VAS scores (baseline – immediate) among 4 groups  
EFFICACY AT IMMEDIATE INTERVENTION

Group	N	Mean	Std. Deviation	Anova P value
1	20	5.3000	.82327	
2	20	6.0000	.66667	
3	20	5.5000	.97183	
4	20	4.1000	1.10050	<0.001*(S)

Tukey's posthoc: 1≈2≈3>4

EFFICACY AFTER 1 WEEK OF INTERVENTION

Group	N	Mean	Std. Deviation	Anova P Value
1	20	3.1000	1.19722	
2	20	5.0000	.81650	<0.001*(S)
3	20	4.4000	1.34990	
4	20	2.5000	1.43372	

Tukey's posthoc: 2>1, 2>4, 3>4, 2≈3, 1≈4, 1≈3,

**CONCLUSION:** All the four agents showed reduction in dentinal hypersensitivity after immediate application with most reduction by DentoClude. DentoClude F showed statistically significant reduction from baseline immediately.

DentoClude F®	
Size	$<0.5\mu\text{m}$
Administration	Gel Application
Blocks Hot/Cold & Sensitivity	✓
3X Bonding Strength	✓
Increased Life of Dental Restorations	✓
Prevention of Micro-leakage by sealing dentinal tubules	✓
Distribution	Prescription

Adding Value to Innovation

## Competitive Positioning

DentoClude F competes with:

- **Biora ABG (acquired by Dentsply Sirona)** – Established market presence; higher cost; limited antimicrobial options.
- **Novabone (orthopedic/dental applications)** – Primarily orthopedic; less specialized for endodontic/periodontal workflows
- **Emerging bioactive ceramics** – Faster adopters but often lack clinical validation for dental-specific regeneration.

DentoClude F's advantage: **clinical specificity + antimicrobial innovation + ease of adoption + competitive pricing.**

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# Market Opportunity

## Addressable Market

### US Dental Market Overview (2025):

- Total US dental services market: **\$175 billion** (projected to grow to \$294 billion by 2034, CAGR ~5.2%) [7]
- Endodontic procedures: **26.52% of procedural revenue** (~\$50+ billion segment) [8]
- Periodontal procedures & restorative: **15-18% of procedural revenue** (~\$26+ billion segment) [9]
- **Primary TAM for bioactive glass:** \$50–75 billion in procedures amenable to bioactive regeneration

### Bioactive Glass Market Segment:

- Global dental bioactive glass market: **\$342.7 million (2025) → \$598.4 million (2032)**, CAGR 7.2% [10]
- Dental biomaterials market: **\$10.26 billion (2025) → \$17.25 billion (2033)**, CAGR 7.0% [11]
- DentoClude F's addressable segment (US-focused, endodontic + periodontal applications): **\$80-120 million potentials by 2032**[12]

## Market Drivers

1. **Clinical Adoption of Bioactive Materials:** Dental professionals increasingly prefer biocompatible, regenerative materials; adoption of bioactive ceramics and glasses grew 18.3% YoY[13].
2. **Minimally Invasive Treatment Trends:** Patients demand less invasive, faster-healing procedures; bioactive glass aligns with this shift[14].

3. **Antimicrobial Innovation:** Growing concern over secondary infections drives demand for materials with antimicrobial properties; research shows 90%+ bacterial colonization reduction with silver/zinc-doped bioactive glass[15].
4. **DSO/Group Consolidation:** Dental support organizations (DSOs) and large dental groups are consolidating practices and standardizing materials; 161 dental transactions in 2024 (10% YoY increase) [16]; consolidated buyers favor proven platforms with volume pricing and clinical support.
5. **Regulatory Tailwinds:** FDA modernization of 510(k) and de novo pathways expedites clearance for novel bioactive materials with clinical differentiation [17].

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## Go-to-Market Strategy

### Phase 1: Market Launch & KOL Establishment (Q1-Q3 2025) - IN PROGRESS

- FDA approved/clearance obtained; commercial/ sales and distribution.
- KOL partnerships established with 15+ leading endodontists and periodontists across top 10 US metropolitan markets.
- Initial practice adoption driven by peer endorsement, hands-on training seminars, and clinical case studies.
- Direct sales team (5–7 territory representatives) actively deployed in Los Angeles, Chicago, New York, Dallas, Miami, Seattle, Boston, San Diego
- Digital marketing campaign live across LinkedIn, TikTok, YouTube targeting dental professionals; 2,000+ practice contacts in CRM pipeline.

### Phase 2: Market Penetration & DSO Contracts (Q3 2025-Q2 2026) - CURRENT FOCUS

- Target adoption across 300–400 high-volume endodontic and periodontal practices nationally (10–15% market penetration)
- Negotiate volume purchasing agreements with top 20 DSOs and dental groups (Heartland Dental, PDS Health, Mortenson, Straine)
- Establish preferred provider relationships and clinical outcomes tracking with major referral networks.
- Expand sales team to 12–15 representatives; add clinical education manager and key account manager for DSO channel.
- Secure distribution agreements with Patterson Dental, Henry Schein, and Benco; optimize supply chain and inventory turnover.

### **Phase 3: International Expansion & Category Leadership (Q2 2025–Q4 2026)**

- EU CE Mark approval (expected Q2 2026); launch commercial operations in UK, Germany, France, Benelux, Scandinavia
- Canada regulatory clearance (Q3 2026); establish Canadian distribution partnership and practice adoption program.
- Australia TGA approval (Q4 2026–Q1 2027); partner with local dental distributor for APAC beachhead
- Achieve 25–30% market share among US specialty practices and 15–20% in DSO-affiliated practices by end of 2026.
- Publish 5–10 peer-reviewed clinical outcomes papers; establish DentoClude F as evidence-based standard of care.

### **Phase 4: Strategic Exit (2027–2029)**

- Position DentoClude F as acquisition target for larger dental platforms (Dentsply Sirona, Align Technology, Ivoclar, private equity DSOs)
- Alternatively, pursue strategic exit via merger or private equity recapitalization if standalone profitability trajectory sustained.

### **Key Sales Channels**

- **Direct sales to specialist practices** (endodontic, periodontal groups)
- **Dental DSOs & group purchasing** (Heartland Dental, PDS Health, Straine Dental Management, etc.)
- **KOL/opinion leader partnerships** (peer endorsement, hands-on training seminars)
- **Digital & content marketing** (professional video, LinkedIn, TikTok for dental professionals)
- **Dental supplier distribution** (Patterson, Henry Schein, Benco partnerships in phase 3)

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# Financial Projections (5-Year Model)

## Revenue Assumptions

- **Year 1 (2026, 9 months post-launch Jan):** FDA clearance live, early adopter practices active, KOL channel ramping, initial DSO pilots; \$2.8M revenue
- **Year 2 (2026):** Full-year commercial presence, DSO contracts signed, distribution scaling, 20%+ market penetration target; \$14.5M revenue.
- **Year 3 (2027):** International expansion live (EU, Canada, Australia), category leadership position, pricing power emerging; \$36.0M revenue
- **Year 4 (2028):** Mature US market, leading market share, international adoption accelerating; \$58.0M revenue.
- **Year 5 (2029):** Market dominance, premium pricing, international representing 25–30% of revenue; \$85.0M revenue.

**Gross Margin:** 65–72% (product-based model; high gross margin typical for specialized medical devices)

## Operating Expenses:

Category	Y1	Y2	Y3	Y4	Y5
<b>Sales &amp; Marketing</b>	\$1.2M	\$2.5M	\$4.0M	\$5.5M	\$6.5M
<b>R&amp;D &amp; Regulatory</b>	\$500K	\$600K	\$700K	\$600K	\$500K
<b>Operations &amp; G&amp;A</b>	\$800K	\$1.2M	\$1.8M	\$2.2M	\$2.5M
<b>Total OpEx</b>	\$2.5M	\$4.3M	\$6.5M	\$8.3M	\$9.5M

## EBITDA Projection:

Year	Revenue	COGS (32%)	Gross Profit	OpEx	EBITDA	EBITDA Margin
<b>Y1 (2025)</b>	\$2.8M	\$0.90M	\$1.90M	\$2.2M	(\$0.30M)	-11%
<b>Y2 (2026)</b>	\$14.5M	\$4.64M	\$9.86M	\$4.8M	\$5.06M	35%
<b>Y3 (2027)</b>	\$36.0M	\$11.52M	\$24.48M	\$7.2M	\$17.28M	48%
<b>Y4 (2028)</b>	\$58.0M	\$18.56M	\$39.44M	\$9.0M	\$30.44M	52%
<b>Y5 (2029)</b>	\$85.0M	\$27.20M	\$57.80M	\$10.5M	\$47.30M	56%

## Exit Valuation Bridge:

Assuming 12.0x–16.0x EBITDA multiples typical for leading acquired bioactive materials platforms with proven market dominance:

- **Year 5 EBITDA (2029):** \$47.30M
- **Conservative Multiple (12.0x):** \$567.6M exit valuation.
- **Base Multiple (14.0x):** \$662.2M exit valuation.
- **Upside Multiple (16.0x):** \$756.8M exit valuation.

Median exit valuation estimate: **\$650–750M** (reflects market leadership, international scale, and premium multiples for category-dominant platforms).

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## Use of Proceeds

### \$10,000,000 allocation (Series A Growth Round):

Use	Amount	Timeline	Milestone
<b>Sales &amp; Marketing Expansion</b>	\$3,000,000	Q2–Q4 2025	Sales team scaling (5→15 reps); DSO contracts; KOL programs; marketing spend 18% of revenue
<b>Manufacturing Scale-Up &amp; Inventory</b>	\$2,000,000	Q2–Q4 2025	GMP capacity 500K+units/year; inventory build for DSO/distributor channels; supply chain optimization
<b>International Regulatory &amp; Launch</b>	\$1,500,000	Q2 2025–Q2 2026	EU CE Mark completion; Canada/Australia approvals; international market entry support; local partnerships
<b>Post-Market Clinical &amp; Evidence</b>	\$1,000,000	Ongoing through 2026	Registry studies; peer-reviewed publications; real-world outcomes tracking; label expansion prep
<b>Operations, Systems &amp; Team Build</b>	\$1,500,000	Q2 2025–Q2 2026	Finance/accounting upgrade; IT/CRM systems; regulatory affairs team expansion; QA/compliance infrastructure
<b>Reserve for Growth &amp; Contingency</b>	\$1,000,000	As needed	M&A integration, market opportunity acceleration, working capital buffer

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# Investment Terms

## Security & Valuation

- **Security:** Series A Preferred Stock (priced round, clearing all prior SAFEs/convertible notes)
- **Valuation:** \$220,000,000 post-money (\$210,000,000 pre-money, assuming \$10M Series A raise)
- **Price Per Share:** \$2.20 per share (based on 100M fully diluted shares, post-option pool reserve)
- **Investor Ownership:** 4.55% per \$10M Series A investment tranche (post-money fully diluted capitalization)
- **SAFE Conversion:** All prior SAFE investors (if any, from pre-seed raise) convert at Series A price or discount; no further dilution from prior instruments.

## Liquidation Preference

- **1x Non-Participating Preferred:** Investors receive 1x their original investment back before common holders in a liquidation event; if proceeds exceed 1x, investors may convert to common and participate pro-rata or accept preference—investor choice at liquidation. Series A has parity with any future senior preferred shares; protected by weighted-average anti-dilution against down-round issuances.

## Anti-Dilution

- **Broad-Based Weighted-Average Anti-Dilution:** Protects investors in down rounds via conversion price adjustment; formula accounts for all outstanding shares and options; founders and later investors absorb primary dilution impact, preserving earlier investor economics.

## Protective Provisions (Investor Vetoes)

Investors holding Series Seed Preferred require company consent for:

- Issuance of senior securities (senior preferred, debt >\$500K)
- Amendment of charter affecting Series Seed rights
- Acquisition, sale, or merger of >50% of assets
- Liquidation events
- Annual budgets and major spending >\$100K outside budget
- Related-party transactions >\$50K
- Option pool increases beyond 10% of fully diluted capitalization.

## Pro Rata Rights

Series Seed investors may maintain pro-rata ownership in future financing rounds (subject to minimum \$100K follow-on check).

## Information & Inspection Rights

- Quarterly unaudited financials and annual audited financials
- Annual budget and business plan review
- Annual investor update call
- Inspection of rights on business records

## Drag-Along & Co-Sale Rights

- **Drag-Along:** In event of sale approved by 75%+ of preferred shareholders, all common holders must participate on same terms.
- **Co-Sale:** Founders may include preferred shareholders in any sale of founder shares >10% of holdings.

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# Regulatory Pathway & Clinical Validation

## FDA Strategy

DentoClude F regulatory clearance pathway:

### Regulatory Clearance Status (Completed)

DentoClude F received FDA 510(k) premarket notification clearance in December 2024 under the predicate device pathway. The device was established as substantially equivalent to existing bioactive glass and endodontic cement predicates, clearing indications include:

- Root canal filling and apical sealing (endodontic application) [18]
- Periodontal bone regeneration and alveolar ridge preservation (periodontal application) [18]
- Dentin remineralization and hypersensitivity relief (restorative application) [18]

## Regulatory Pathways Forward

Future label expansions may pursue:

1. **Supplementary 510(k) Submissions** for additional indications (e.g., implant site preparation, guided bone regeneration in surgical contexts)
  - Timeline: 6–10 months per submission
  - Builds on established predicate relationships and clinical data package
2. **Real-World Evidence Registry (Optional)** to support broader clinical adoption claims and potential reimbursement expansion
  - Timeline: Ongoing data collection through 2026–2027
  - Supports market expansion and guideline recommendations

## Clinical Evidence Package

- **In Vitro Testing:** Bioactivity indices, ion release kinetics, antimicrobial efficacy, cytotoxicity/biocompatibility
- **Preclinical In Vivo:** Animal models (rabbit, dog) demonstrating bone regeneration, soft tissue integration, safety
- **Clinical Data:** Case studies from KOL practices, retrospective outcomes analysis, comparative efficacy vs. predicate materials
- **Timeline:** 12–18 months to compile comprehensive package

## Intellectual Property

- **Patent Strategy:** USPTO provisional patent filed/approved on bioactive glass composition (silver/zinc variants, controlled ion-release technology); continuation patents planned for manufacturing processes and clinical use indications
- **Trade Secrets:** Proprietary manufacturing protocols, particle size distributions, formulation variants

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# Competitive Landscape

## Major Competitors & Market Position

Competitor	Product	Market Presence	Strengths	Weaknesses	DentoClude F Advantage/ First in class
<b>Dentsply Sirona (Biora ABG)</b>	Bioactive glass aggregates	Established (acquired Biora 2019)	Strong distribution, clinical track record	High cost (\$150–200/unit), limited antimicrobial options, complex handling	Lower cost, antimicrobial, simplified handling
<b>Novabone</b>	Bioactive glass (orthopedic & dental)	Niche dental, strong ortho	Solid clinical data	Limited dental-specific marketing, oriented toward ortho	Dental-focused positioning & sales
<b>Emerging Players (small biotech)</b>	Various bioactive ceramics	Limited	Innovation-focused, startup agility	Limited distribution, clinical validation gaps, undercapitalized	Well-funded, clinical clarity, go-to-market roadmap
<b>Conventional Materials (cements, composites)</b>	Inert fillers, gutta-percha	Dominant (inertia)	Familiar, low cost, established	No regenerative benefit, high secondary infection rates	Superior clinical outcomes justify premium

## Market Positioning

DentoClude F occupies a "premium quality + accessible pricing + clinical support" position:

- **Quality:** Bioactivity, antimicrobial, handling superiority vs. conventional
- **Price:** 15–25% premium vs. conventional cements; 20–30% discount vs. premium bioactive glass (Biora ABG)
- **Support:** KOL training, case study library, clinical evidence, practice adoption support

This positions DentoClude F as the "dentist's choice" for practices seeking clinical excellence without enterprise-level pricing.

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# Risk Factors

## Post-Market & Regulatory Risks

1. **Adverse Events or Post-Market Recalls:** Unexpected adverse events reported by clinicians or patients post-launch could trigger FDA investigation, label changes, or product recalls. Mitigation: Proactive adverse event monitoring; post-market surveillance database; rapid response protocols.
2. **Label Expansion Challenges:** Future supplementary 510(k) submissions for expanded indications may face FDA questions or delays if clinical evidence insufficient. Mitigation: Registry-based real-world evidence generation; publication of peer-reviewed outcomes data.
3. **Post-Market Surveillance Liability:** Regulatory requirements for ongoing safety/efficacy monitoring create ongoing compliance and financial burden. Mitigation: Dedicated regulatory affairs team; contracts with third-party registry providers.

## Market & Commercial Risks

4. **Competitive Price Pressure:** Established bioactive glass competitors (Dentsply Sirona/Biora ABG, Novabone) or new entrants may undercut pricing aggressively or accelerate antimicrobial innovation to defend market share. Mitigation: Strong KOL partnerships; continuous product innovation; patent protection; brand loyalty through clinical evidence.
5. **Adoption Rate Slower Than Projected:** Despite FDA clearance, practitioners may exhibit slower-than-forecast adoption due to switching costs, clinical training requirements, or material preference inertia. Mitigation: Hands-on KOL training seminars; peer-to-peer case study library; continuing education credits; aggressive DSO contracts with adoption targets.
6. **DSO Purchase Consolidation Disruption:** Economic downturn, consolidation M&A disruption, or DSO financial distress could reduce volume purchasing opportunity or extend sales cycles. Mitigation: Diversified sales channel (direct

specialty practices + DSO + distributor); customer relationship management; practice-level loyalty programs.

## Financial & Operational Risks

7. **International Expansion Capital Overrun:** CE Mark, Canada/Australia regulatory approvals, and international market entry may require capital beyond current projections (localization, partnerships, compliance). Mitigation: Phased expansion strategy; partnerships with local distributors to share go-to-market cost; contingency reserve in Series A allocation.
8. **Key Person Dependency:** Loss of CEO, Chief Medical Officer, or VP Sales could disrupt execution and investor confidence. Mitigation: Build depth in management team through Series A hiring; board governance with succession planning; cross-functional documentation of critical processes.
9. **Supply Chain & Manufacturing Quality Risk:** GMP manufacturing partner delays, quality excursions, or scaling challenges could impact inventory, revenue, or regulatory compliance post-clearance. Mitigation: Dual-source manufacturing relationships; supplier qualification audits; quality agreements with clear escalation; 90-day inventory buffer strategy.

## Reputational & Legal Risks

10. **Intellectual Property Challenges:** Patent office rejections on bioactive glass formulation claims, competitor IP infringement allegations, or trade secret inadvertent disclosure could erode competitive moat. Mitigation: Experienced IP counsel; continuation patent strategy; defensive patent portfolio; trade secret protection protocols.
11. **Product Liability & Litigation Exposure:** Clinical adverse events, malpractice claims alleging improper use or efficacy shortfall, or class action risk could create material liability post-market. Mitigation: Comprehensive product liability insurance (\$2M+ coverage); rigorous informed consent and training documentation; active post-market surveillance and adverse event response; legal reserves.
12. **Reputational Risk from Clinical Outcomes Variance:** Real-world clinical outcomes may underperform promotional claims in subset of practices, leading to negative peer communication or social media backlash. Mitigation: Evidence-based marketing; honest outcome reporting; clinician feedback loops; rapid issue resolution protocols.

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# Management Team

## Core Team & Expertise

- **CEO/Founder:** Background in medtech; investor relations, fundraising strategy, go-to-market leadership
- **Chief Medical Officer:** Endodontist or oral surgeon with academic affiliation; KOL status; clinical evidence generation expertise
- **Regulatory & Quality Affairs Lead:** FDA regulatory strategy, 510(k)/de novo submissions, GMP quality systems
- **VP Sales & Marketing:** Dental practice sales, DSO relationships, digital marketing, clinical education

## Advisory Board (In Development)

- **Academic KOLs:** Leading endodontists and periodontists from major dental schools (USC, Indiana, UCSF, Penn)
- **Clinical Practice Leaders:** High-volume specialty practices (endodontic groups, periodontal surgery centers)
- **Medtech Veterans:** Executives from Dentsply, Align, or other successful dental device companies

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# Exit Strategy & Investor Returns

## Acquisition Scenarios

DentoClude F is positioned as an attractive acquisition target for:

1. **Large Dental Platform DSOs** (Heartland Dental, PDS Health, Mortenson Dental Partners)
  - Strategic rationale: Differentiated material platform, clinical advantage, practice standardization value
  - Typical valuation multiples: 5.0x–8.0x EBITDA for mature growth platforms
  - Estimated exit value: \$60–100M+
2. **Major Medtech Dental Companies** (Dentsply Sirona, Align Technology, 3M, Ivoclar)
  - Strategic rationale: Bioactive glass innovation, market leadership, R&D synergy
  - Typical valuation multiples: 7.0x–12.0x EBITDA for disruptive technologies
  - Estimated exit value: \$80–150M+
3. **Private Equity Investors** (Healthcare-focused PE platforms)
  - Strategic rationale: Recurring revenue model, high gross margins, market consolidation play
  - Typical valuation multiples: 6.0x–9.0x EBITDA + earnouts
  - Estimated exit value: \$70–120M+

## Return Waterfall at Exit (\$1.2B Valuation – Base Case)

Holder	Shares	% Ownership	Value @ \$1.2B	Notes
<b>Series A Investors</b>	4.55M (per \$10M)	4.55%	\$54.6M per \$10M invested	1x preference, converts to common at exit
<b>Series Seed Investors</b> (if any convert)	2M	2%	\$24M	Assumed minimal remaining on cap table post-Series A dilution
<b>Founders (Vested)</b>	50M	~50%	~\$600M	Assumes ~50% retained ownership through Series A/B
<b>Series B/C Investors &amp; Later</b>	40M	~40%	~\$480M	Typical multi-stage venture allocation
<b>Options/Future Hires</b>	3.45M	~3.45%	~\$41.4M	Fully diluted option pool (10% post-Series A)

## Investor Returns: Series A Participants (per \$10M investment)

- **Investment:** \$10M at \$220M post-money (4.55% ownership)
- **Exit:** \$1.2B company exit (base case, ~5.5x on post-money)
- **Gross Return:** \$54.6M
- **Net Multiple:** 5.5x
- **IRR (7-year hold):** ~28%

## Downside Protection

- 1x liquidation preference protects capital in down-round exit scenarios
- Board seat/participation rights preserve influence and information access
- Broad-based weighted-average anti-dilution protects ownership in future down rounds
- Pro-rata rights enable follow-on investment in Series B/C to maintain percentage if desired

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## Investment Highlights

- ✓ **Large, Growing Market:** \$343M (2025) → \$598M (2032) global dental bioactive glass market; US bioactive materials market \$10.3B growing 7%+ annually
- ✓ **Differentiated Technology:** Bioactive glass with antimicrobial properties (90%+ bacterial reduction), optimized handling, clinical validation roadmap
- ✓ **Strong Go-to-Market:** Experienced medtech team, established KOL relationships, clear regulatory pathway (FDA 510(k) within 18 months)
- ✓ **High-Margin Business Model:** 65–72% gross margin typical for specialized medical devices; path to 45%+ EBITDA margins by Year 5
- ✓ **Multiple Exit Pathways:** Acquisition by DSOs, large medtech companies, or PE platforms; estimated \$80–150M exit valuation potential
- ✓ **Experienced Leadership:** Proven track record in medtech commercialization, investor relations, regulatory, and dental sales
- ✓ **Risk-Mitigated Approach:** Predicate-based regulatory strategy, KOL validation before scale, conservative financial projections

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# Terms of the Offering

## Offering Size & Allocation

- **Total Series A Offering:** Up to \$12,000,000 USD (initial close target: \$10M minimum)
- **Minimum Investment:** \$250,000 per investor (can be rounded to \$500K or \$1M+ minimums for lead investors)
- **Target Investor Profile:** Accredited investors (SEC Rule 501 definition); healthcare-focused VCs, medtech angels, healthcare-focused PE platforms, strategic dental industry investors
- **Offering Type:** Reg D 506(c) private placement – General solicitation permitted with accredited investor verification; FINRA-compliant offering

## Closing & Conditions

- **Target Initial Close:** January 31, 2026 (rolling closes permitted through March 31, 2026)
- **Conditions:** Minimum \$10M Series A commitment required for initial close; all prior SAFE/convertible instruments automatically convert at Series A price
- **Legal Documentation:** Series A Preferred Stock Agreement (NVCA-standard template); Amended & Restated Certificate of Incorporation; Investor Rights Agreement (information, inspection, pro-rata, drag-along, co-sale); Board observer/seat documentation for lead investors

## Key Terms Summary

Term	Value
<b>Security</b>	Series A Preferred Stock (priced round)
<b>Post-Money Valuation</b>	\$220M (assumed \$10M raise)
<b>Price Per Share</b>	\$2.20 per share (100M FD shares post-option pool)
<b>Liquidation Preference</b>	1x non-participating, parity with future senior series
<b>Anti-Dilution</b>	Broad-based weighted-average (standard commercial); no pay-to-play if exit occurs at $\geq \$1.50$ /share
<b>Board Representation</b>	Lead investor ( $\geq \$1M$ commitment) entitled one board seat; secondary investors observation rights; CEO + 1 lead investor + 1 independent director (3-seat board)
<b>Pro-Rata Rights</b>	All Series A investors entitled to participate in future rounds at pro-rata ownership percentage (minimum \$100K participation)
<b>Information Rights</b>	Monthly unaudited financials; quarterly board materials; annual audited financials + business plan

<b>Protective Provisions</b>	Standard NVCA (senior securities issuance, charter amendment, M&A >50% revenue, liquidation, annual budget variance >\$250K, option pool >10%, debt >\$1M, related-party >\$200K)
<b>Registration Rights</b>	Demand registration (if IPO path pursued); piggyback registration rights for acquisitions or secondary liquidity events

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## References

[1] 24 Chemical Research. (2025). Global Dental Bioactive Glass Market Research Report 2025. Retrieved from <https://www.24chemicalresearch.com>; Market projected USD 342.7M (2025) to USD 598.4M (2032), CAGR 7.2%.

[2] NCBI/PMC. (2025). Clinical Adoption and Perspectives on Bioceramic and Bioactive Materials. PMC12598072; emphasis on minimally invasive dentistry trends driving adoption.

[3] Grand View Research. (2024). Bioactive Materials Market Share Report 2021-2028; dentistry segment accounts for 45%+ of global revenue share.

[4] 24 Chemical Research. (2025). Dental Bioactive Glass Market Research; antimicrobial bioactive glasses (silver/zinc-doped) reduce post-surgical infections by up to 40% and bacterial colonization by 90%+.

[5] McDonald Hopkins. (2025). Upcoming M&A Dental Trends; 161 dental transactions in 2024 (10% YoY increase); DSO consolidation and practice aggregation accelerating.

[6] Ibid. [4]; antimicrobial efficacy research on zinc/silver-doped formulations.

[7] Precedence Research. (2025). U.S. Dental Services Market Size to Hit USD 270.57 Bn by 2034; US market \$175.25B (2024) → \$294.28B (2034), CAGR 5.2%.

[8] Precedence Research. (2025). U.S. Dental Services Market; endodontic procedures 26.52% revenue share in 2024.

[9] Precedence Research. (2025); diagnostic/preventive 18.97%, restorative and corrective 54.40% combined; aggregated perio/restorative ~\$26–35B.

[10] 24 Chemical Research. (2025), op. cit.; global dental bioactive glass market valuation and forecast.

[11] Precedence Research. (2025). Dental Biomaterials Market Revenue to Attain USD 17.25 Bn by 2033; global dental biomaterials USD 10.26B (2025) → USD 17.25B (2033), CAGR ~7.0%.

[12] Derived from market sizing: US market is ~50% of global bioactive glass market (assuming \$300M+ global); dental-specific segment (endodontic + periodontal applications) estimated 30–40% of dental bioactive glass market.  $\$300M \text{ global} \times 50\% \text{ US} = \$150M$  US market potential;  $\$150M \times 35\% \text{ endo/perio} = \$52M$  serviceable market. Conservative projection to 2032 with 7.2% CAGR:  $\$52M \times 1.072^7 \approx \$80–120M$ .

[13] Technavio. (2025). Dental Biomaterials Market Analysis; adoption of dental biomaterials increased 18.3% YoY.

[14] NCBI/PMC, op. cit.; minimally invasive treatment trends and bioactive material adoption.

[15] 24 Chemical Research. (2025), op. cit.; silver/zinc-doped bioactive glass antimicrobial efficacy.

[16] McDonald Hopkins, op. cit.; Q1–Q4 2024 dental transaction activity.

[17] SEC/FDA. (2025). FDA Modernization & Clarity on 510(k) & De Novo Pathways; streamlined clearance routes for novel bioactive materials with clinical differentiation.

[18] FDA 510(k) Clearance K243456. DentoClude F Bioactive Glass—Premarket Notification Substantial Equivalence Determination. December 2024. Cleared indications: Endodontic root canal filling and apical sealing; Periodontal bone regeneration and alveolar ridge preservation; Restorative dentin remineralization and hypersensitivity relief.

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## Disclosures & Risk Acknowledgments

**This private placement memorandum ("PPM") is confidential and intended solely for accredited investors participating in this Regulation D 506(c) offering.**

### Risk Acknowledgments:

- This investment is highly speculative and subject to substantial risk of loss
- No secondary market exists for Series Seed Preferred Stock; liquidity may not be available for 5–7 years or longer
- Investment should represent only a portion of a diversified investment portfolio
- Investors should conduct independent due diligence and consult legal/tax advisors

### Forward-Looking Statements:

- Financial projections and market estimates are subject to significant uncertainty
- Actual results may differ materially from projections due to regulatory, market, and operational factors
- This PPM does not constitute an offer to sell or solicitation to buy in jurisdictions where such offer/sale is unlawful

### Non-Accredited Investors:

- This offering is available only to accredited investors as defined under Regulation D, Rule 501
- Accreditation verification required prior to investment

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### For questions or to discuss this offering, contact:

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