DentoClude™ F
Dentin Tubule Agent

Cumberland Biotherapeutics

SECTIONS

- **Company and Product Overview**
- **Executive Summary for Venture Capital Investors**
- **North America represents the largest market for dental hypersensitivity solutions and tooth desensitizers**
- **Updated Unit Sales Projections**
- **Dental channels: general dental practices, periodontal specialists, and dental group networks**
- **DentoClude™ FRevenue Forecast (Global)**
- **The Cumberland Biotherapeutics team** https://cumberlandbio-therapeutics.com/
- **Study Summary:** Bioactive glass is widely applied across multiple dental specialties due to its regenerative, antibacterial, and remineralizing properties.
- **Study Summary:** The studies demonstrated that DentoClude™ F occludes dentinal tubules, reduces sensitivity, promotes hydroxyapatite formation, and provides a protective seal superior to other marketed treatments, with consistent safety and tolerability.

DentoClude™ F by Cumberland Biotherapeutics is an innovative, FDA-approved dental device leveraging bioactive glass with fluoride and botanicals to treat dentin hypersensitivity and enhance periodontal regeneration, supported by robust clinical evidence and uniquely positioned for market growth in the dental therapeutics sector.

Company and Product Overview

Cumberland Biotherapeutics is focused on integrating science and Ayurvedic medicine to develop advanced, bioceutical solutions for patient well-being. DentoClude F, its flagship product, is designed to safely and effectively block dentin tubules, reducing tooth sensitivity and promoting both periodontal and implant bone regeneration.

Key Clinical Studies

Multiple peer-reviewed studies and trials have validated DentoClude™ F's efficacy:

- A double-blind comparative trial (n=30) found DentoClude™ F outperformed standard agents (Stannous Fluoride Gel, Gluma) in decreasing dentinal hypersensitivity, inflammation, and pain, as measured by both VAS and facial rating scales across multiple time points (immediate, 1 and 4 weeks post-application).
- A separate randomized, double-blind split-mouth study (n=20) confirmed significant reductions in VAS pain scores at test sites versus controls over 45 days, with clear safety and clinical improvement in patients with moderate to severe dentin hypersensitivity.

Competitive Advantage

- **Differentiation:** DentoClude™ F is the only FDA-cleared device in its class that incorporates <1 μm bioactive glass, fluoride, and botanical extracts with proven anti-inflammatory and anti-infective properties, targeting the root causes of sensitivity and supporting tissue healing.
- **Regulatory Securing:** Approved by both the FDA (USA) and DCGI/AYUSH (India), enabling straightforward adoption by dental professionals in multiple key markets.

Market Opportunity

- An estimated tens of millions of Americans and global patients experience dentin hypersensitivity, especially post-periodontal procedure; current solutions are often inadequate or temporary.

- DentoClude™ F is available exclusively through licensed dental professionals, targeting a sizable addressable market in both dental practices and specialist settings.

Commercial Traction and Outlook

- Cumberland has launched DentoClude™ F in the US and India, with studies indicating not just symptomatic relief, but regenerative benefits—a message strongly supported by clinical evidence and practitioner feedback.
- As dental professionals seek more effective and differentiated treatment options, DentoClude™ F's combination of scientific rigor, natural actives, and clinically demonstrated outcomes positions it for substantial commercial adoption.

Summary Table

Feature	DentoClude™ F	Key Competitor Products
Core Technology	Bioactive glass + fluoride + botanicals	Stannous Fluoride, Gluma
FDA Clearance	Yes	Yes
Clinical Efficacy	Superior, multi-study proven	Variable, standard
Regenerative Benefits	Yes (bone/periodontal tissue support)	No/limited
Clinical Availability	Licensed dental professionals	OTC and professional

Investment Rationale

DentoClude™ F represents a disruptive opportunity in dental therapeutics, with strong clinical validation, scalable regulatory approvals, and a compelling commercial model for practitioners and patients, making Cumberland Biotherapeutics an attractive candidate for venture capital support in the growing dental device sector.

DentoClude™ F, developed by Cumberland Biotherapeutics, is a next-generation FDA- and DCGI-approved dental device that delivers rapid, sustained relief from dentin hypersensitivity and addresses micro-leakage after restorative procedures. Leveraging proprietary bioactive glass (<1µm) with fluoride and botanicals, DentoClude™ F not only blocks dentinal tubules but also promotes remineralization and supports tissue regeneration.

Executive Summary for Venture Capital Investors

Company Overview

Cumberland Biotherapeutics integrates advanced science with Ayurvedic principles to create bioceutical solutions, specializing in dental and musculoskeletal health innovations. DentoClude™ F is their flagship technology, targeting a critical unmet need in dental care.

Problem and Solution

Dentin hypersensitivity affects tens of millions globally, especially after periodontal therapy and restorative dental work. Existing products often offer only transient relief and do not address the underlying causes. DentoClude™ F's bioactive composition uniquely remediates sensitivity by sealing tubules, minimizing inflammation, and promoting new hydroxyapatite formation—delivering superior, longer-lasting outcomes.

Clinical Evidence

Independent, double-blind clinical trials validate DentoClude™ F's safety and efficacy:

- In a 30-patient comparative study versus Gluma® and Stannous Fluoride, DentoClude™ F yielded the greatest reductions in pain and inflammation at every assessment (VAS, FRS, up to 4 weeks post-application).
- In a randomized split-mouth study (n=20), patients had statistically significant and sustained improvement in hypersensitivity indicators, with no adverse effects recorded.
- Further studies comparing four bioactive glass products confirmed DentoClude™ F provided the most substantial and persistent pain relief, outperforming international market leaders.

Competitive Advantage

- First-in-class device with <1µm bioactive glass, fluoride, and anti-inflammatory botanicals, offering a multi-modal solution beyond traditional desensitizing agents.

- Demonstrated reductions in root sensitivity and micro-leakage, plus potential for regenerative outcomes.
- Exclusively professional channel sales, capturing a specialty and recurring-use market.

Market and Commercial Traction

The global dental restorative and desensitizing market offers robust growth opportunity, with rapid professional adoption driven by clinical results and a unique mechanism of action. DentoClude™ F is now available in the US and India, supported by strong clinical endorsements and regulatory approvals.

Investment Opportunity

Cumberland Biotherapeutics is positioned for accelerated growth as dental professionals seek advanced, proven solutions that offer clinical differentiation and real patient benefit. Backing this team provides entry to the scalable, high-growth dental therapeutics sector, with potential to expand into adjacent oral and regenerative markets.

For more detailed clinical documentation, regulatory status, and commercial milestones, materials are available upon request.

North America represents the largest market for dental hypersensitivity solutions and tooth desensitizers, with the region valued at roughly $272.5 million in 2024 and accounting for about 38.5% of the global market share. Projections show the total North American tooth desensitizer segment will exceed $300 million by 2026 as demand for advanced in-office therapies like DentoClude™ Fgrows.

Globally, the dental desensitizer market is estimated at $1.5 billion for 2025 and is forecast to expand at approximately 7% compound annual growth rate (CAGR), reaching over $2.5 billion by 2033. DentoClude™ F, positioned as a premium, professional-only solution, targets substantial value-capture through both patient-pay and insurance channels, especially as adoption in emerging markets increases.

Sample Revenue Projections

North America (2025–2028)

- Market Size 2025: ~$275 million
- Projected CAGR: ~6–7%
- Estimated 2028 Value: $325–345 million [based on linear growth]
- If DentoClude™ F secures even a 10% share (via professional channel adoption and clinical advocacy), the North American annual run-rate could exceed $30 million within 3 years.

Global (2025–2030)

- Market Size 2025: $1.5 billion
- Projected CAGR: ~7%
- Estimated 2030 Value: $2–2.1 billion
- Achieving a 5% global share could generate $75–100 million annual revenue for DentoClude™ F, with upside if clinical adoption and payer coverage accelerate in new geographies.

DentoClude™ F's first-in-class, FDA-cleared technology and strong clinic-driven market strategy position Cumberland Biotherapeutics to capture significant value in both North America and worldwide, underpinned by growing clinical demand for advanced dental desensitizers.

With a revised **average price per unit of $49**, the updated North America revenue model and unit sales assumptions are as follows:

Pricing Assumption

- **Average Price/Unit:** $49
  This aligns with the upper range for innovative, clinically applied dental desensitizers in the professional channel.

Updated Unit Sales Projections

Year	Revenue Projection	Units Sold	Avg. Price/Unit
2028	$23.3 million	475,510	$49
2030	$37.7 million	769,948	$49

Calculation:

- **2028 (Year 3):** 23,253,030÷49≈475,51023,253,030 \div 49 \approx 475,51023,253,030÷49≈475,510 units/year
- **2030 (Year 5):** 37,677,383÷49≈769,94837,677,383 \div 49 \approx 769,94837,677,383÷49≈769,948 units/year

Market Size (for Reference)

- **2028 North America Market:** ~$332 million
- **2030 North America Market:** ~$377 million

These scenarios assume premium positioning, ongoing exclusive sale to dental professionals, and clinical advocacy to support gradual penetration at a higher price point.

With an average unit price of $49, revenue can be segmented by primary North American dental channels: general dental practices, periodontal specialists, and dental group networks. Below is a standard breakdown reflecting likely sales distribution for a professional-use desensitizer like DentoClude™ F .

Per-Channel Revenue Splits (2030 Projection Example)

Assumptions:

- General Dental Practices: 60% of total units
- Periodontal Specialists: 25% of total units
- Dental Group Networks (DSOs/large chains): 15% of total units

Total 2030 Units: 768,825
Total 2030 Revenue: $37,677,383
Avg. Unit Price: $49

Channel Breakdown

Channel	Units Sold	Revenue	Percentage
General Dental Practices	461,295	$22,602,455	60%
Periodontal Specialists	192,206	$9,417,094	25%
Dental Group Networks (DSOs)	115,324	$5,657,834	15%

- General Dental Practices: 768,825×0.60=461,295 / 768,825×0.60=461,295 units; 461,295×49=$22,602,455461,295×49=$22,602,455
- Periodontal Specialists: 768,825×0.25=192,206768,825×0.25=192,206 units; 192,206×49=$9,417,094192,206×49=$9,417,094
- Dental Group Networks: 768,825×0.15=115,324768,825×0.15=115,324 units; 115,324×49=$5,657,834115,324×49=$5,657,834

This per-channel revenue segmentation highlights the importance of tailored marketing and clinical education strategies across all dental channels to maximize adoption and recurring sales of DentoClude™ F in North America.

Global dental desensitizer market projections indicate strong, sustained growth driven by aging populations, expanding middle classes, and rising awareness of oral sensitivity solutions. The worldwide market is estimated at **$1.5 billion in 2025**, forecast to expand at a **CAGR of ~7%** to reach **$2.5 billion by 2033**.

DentoClude™ F Revenue Forecast (Global)

Assuming DentoClude™ Ftargets a premium professional market and captures a conservative **2% global share** by year 5, scaling up to **5% share** (aggressive scenario) as adoption grows with clinical advocacy, channel expansion, and new regulatory approvals:

Year 3 (2028)

- **Market size:** ~$1.84 billion
- **DentoClude™ F revenue (2% share):** $36.8 million

Year 5 (2030)

- **Market size:** ~$2.1 billion
- **DentoClude™ F revenue (5% share):** $105 million

Key Inputs and Assumptions

- Premium average price per unit (aligned to North American levels) for professional/in-office use.
- Growth driven by dental practices, specialist channels, and emerging markets (Asia-Pacific fastest-growing, North America largest overall segment).
- Upside potential with insurance reimbursement, global DSO/group network adoption, and regulatory expansion.

Year	Global Market Size	DentoClude™ F Share	Revenue Projection
2028	$1.84 billion	2%	$36.8 million
2030	$2.1 billion	5%	$105 million

These global forecasts reflect robust sector growth and position DentoClude™ Ffor significant revenue scaling as the company expands professional adoption worldwide. nal channel exclusivity, driving both value and manageable unit volume scaling as adoption rises in North America.

The Cumberland Biotherapeutics team brings decades of proven leadership in drug development, regulatory navigation, and market expansion—with specialized strengths in forging international partnerships and integrating science with market realities.

Team Experience

- **Executive Leadership:** The company's executive team collectively offers over 70 years of pharmaceutical management experience, including deep expertise in scaling hospital and practice-channel products, regulatory strategy, and establishing commercial field forces.
- **Track Record of Execution:** Cumberland's team has driven successful collaborations, FDA launches, and integration of specialty pharmaceuticals with clinical practice channels, demonstrating consistent ability to translate science into scalable therapies.

India Relationships

- **Operational HQ:** Cumberland maintains a strong India headquarters in Hyderabad, positioned to support research, manufacturing, and regulatory interfacing with DCGI/AYUSH authorities.
- **Global Regulatory and Commercial Reach:** DentoClude™ F and other Cumberland therapies are approved and distributed in India, leveraging direct relationships and regulatory experience for product launch and scaling in one of the world's fastest-growing health markets.
- **Cross-Border Partnerships:** The company's ability to secure regulatory clearance and commercial traction in both the US and India highlights robust international capabilities and established local relationships.

Cumberland's North America-India dual base enables efficient product development, regulatory management, and sales execution across geographies, amplifying the impact and reach of innovations like DentoClude™ F.

Cumberland Biotherapeutics' U.S. operations are anchored in Tennessee, with a focus on research, product development, regulatory strategy, and commercialization for advanced dental and pharmaceutical solutions. The company combines robust scientific capabilities with seasoned executive management, enabling repeated success in bringing novel therapies to market.

U.S. Operations Overview

- **Headquarters:** Sewanee, Tennessee—central site for R&D, regulatory affairs, and executive leadership.
- **Product Development:** All stages from concept to FDA approval, with flagship innovations (DentoClude F, LigoFlex) advancing dental and musculoskeletal health.
- **Regulatory Expertise:** Proven experience navigating FDA pathways, securing device and drug clearances, and scaling compliant manufacturing and distribution.
- **Commercialization:** Cumberland deploys specialized sales channels targeting dental practices, group networks, and specialty providers throughout North America.

Executive Team Experience

- **Executive Leadership:** The broader management team holds >70 years of experience across pharma commercialization, product licensing, regulatory affairs, field force management, and scaling professional medical products.
- **Track Record:** Cumberland's leaders have repeatedly executed successful launches, regulatory filings, and market expansions—integrating science, compliance, and commercialization for lasting impact in the U.S. healthcare sector.

Cumberland Biotherapeutics blends deep U.S. operational capability and executive experience to efficiently develop, launch, and scale advanced dental therapies, positioning the company for growth and expansion across the North American healthcare landscape.

Bioactive glass is widely applied across multiple dental specialties due to its regenerative, antibacterial, and remineralizing properties. It improves bonding, reduces microleakage, promotes bone and tissue regeneration, and preserves tooth structure in both adult and pediatric dentistry.

Endodontics

- Conventional restorative materials lack bioactivity and are prone to microleakage.
- Bioactive glass enhances dentin remineralization, seals interfaces, and improves bond strength without reducing adhesion.
- Shown effective in preventing microleakage under inlays/onlays and penetrates dentin up to 10 μm.
- Studies confirm it strengthens resin–dentin bonds and outperforms some desensitizing techniques.

Periodontics

- Used in implants, ridge preservation, and particulate grafts.
- Prevents alveolar ridge resorption, fills sockets after extraction, and supports intrabony defect healing.
- Effective in sinus floor augmentation when combined with autogenous bone.

Orthodontics

- Promotes enamel remineralization, especially in white spot lesions, with sustained calcium/phosphate release.
- More effective than topical fluoride or CPP-ACP in some studies.
- New bioactive glass abrasives (e.g., QMAT3) reduce enamel damage compared to traditional removal techniques.

Implantology

- DentoClude™ F(bioactive glass formula with Neem and Dadima) coats implants, offering antibacterial, anti-inflammatory, and osteoinductive properties.
- Bioactive glass bonds with hard/soft tissue, resorbs gradually, and is replaced by natural bone through hydroxyapatite formation.

Pedodontics

- Biocompatible and regenerative in pulp therapy, especially pulpotomy and pulpectomy for primary teeth.
- Supports dentin bridge formation, reduces bacterial load, and shows superior antimicrobial efficacy compared to chlorhexidine or $Ca(OH)_2$-based treatments.
- Useful as cavity liners, desensitizers, sealant additives, and in trauma repair.

Oral & Maxillofacial Surgery

- Bioactive glass is osteoconductive, resorbable, and mechanically strong, making it suitable for ridge preservation, sinus augmentation, and craniofacial reconstruction.
- Clinical trials confirm effectiveness in orbital floor repair, alveolar ridge maintenance, and extraction socket grafting when combined with calcium sulphate.

Overall, bioactive glass serves as a versatile biomaterial in dentistry, offering antibacterial protection, remineralization, tissue regeneration, and long-term stability across restorative, surgical, and preventive applications.

DentoClude™ F gel, a desensitizing and restorative aid containing **submicron bioactive glass particles**, was evaluated in multiple clinical studies for its effects on dentin hypersensitivity and microleakage. The studies demonstrated that DentoClude™ F occludes dentinal tubules, reduces sensitivity, promotes hydroxyapatite formation, and provides a protective seal superior to other marketed treatments, with consistent safety and tolerability.

Key Points from the Report

Introduction

- Current restorative materials restore tooth form and function but lack **bioactivity** and may fail due to **shrinkage-related microleakage**, leading to secondary caries.
- Bioactive glass can stimulate **dentin remineralization** and block exposed dentin tubules, reducing sensitivity and microleakage.
- DentoClude™ F is designed to penetrate dentin tubules and form **hydroxycarbonate apatite**, improving sealing and sensitivity outcomes.

Indication for Use

- Intended as a **desensitizing agent** under direct/indirect restorations after dentin etch and prior to dentin adhesive.
- Useful in **Class V restorations** and for treatment of dentinal hypersensitivity and cervical erosion.

Clinical Studies

1. **Comparative Study vs Stannous Fluoride & Gluma** (30 patients, double-blind):
    - DentoClude™ F significantly decreased sensitivity and inflammation compared with competitors.
2. **Head-to-Head with Four Bioactive Glass Products** (10 patients):
    - All four products reduced dentinal hypersensitivity, but **DentoClude™ F showed statistically superior reduction** at baseline and 4-week follow-up.
3. **Randomized Split-Mouth Study vs Placebo** (20 subjects):

- DentoClude™ F produced a **highly significant reduction in VAS scores** by 45 days (p=0.0003).

4. **Viscosity Comparison Study** (24 patients):
    - Two formulations tested; both effective, but **Sample 3 viscosity gave superior clinical performance** in reducing sensitivity.
    - No adverse events reported.

Discussion

- Bioactive glass in DentoClude™ F promotes **apatite formation and self-sealing at restoration margins**, reducing micro/nanoleakage.
- Submicron particle size leads to **better surface area and faster remineralization**.
- Mechanism mimics natural tissue processes, enhancing long-term durability and biocompatibility.

Conclusion

- **Dentin hypersensitivity** arises from fluid shifts in dentin tubules due to enamel/dentin defects.
- DentoClude™ F is **safe, tolerable, and effective** in reducing microleakage and dentinal pain within 4 weeks.
- Demonstrated **superior improvement in dentine sensitivity and cervical restoration outcomes** compared with other tested desensitizers.

Contact Information

Clifford Price, CMO and Investor Relations Executive

clifford@cumberlandtx.com

+1-858-373-9885

USA HQ
1565 Jackson Point Road, Sewanee, Tennessee 37375

INDIA HQ
70 to 73, Ground Floor, EVK Complex, Krishna Nagar Cross Road Junction, Jubilee Hills, Hyderabad-500045, India

+1-858-373-9885 or 1-800-845-0279

The current raise amount $20,000,000.00

WHAT IS THE PRE-MONEY VALUATION* (USD) $260,000,000 valuation by Deloitte.

Notable investors* $22,000,000