

Immunomodulatory Strategies to Treat Periodontal Disease

Clinical Need

Periodontitis is one of the most pressing oral health concerns today, affecting nearly half of adults over the age of 30 in the U.S. When left untreated, patients may require dental implants and bone grafting procedures. Antibiotics are currently used as an adjunct therapy to scaling and root planing, which remain the current gold standard of care for periodontitis. However, recent insights highlight the central role of chronic inflammation in the pathology of periodontal disease and it is this overactive immune response that is responsible for most of the damage and disease progression. Thus, new treatment modalities that target inflammation directly in the oral mucosa are greatly needed.

Solution

A team at the University of Pittsburgh led by Dr. Steven Little and Dr. Charles Sfeir, DDS has identified a non-antibiotic, controlled release microparticle system that repairs the underlying immune-dysfunction responsible for tissue degeneration in periodontitis. This work has led to the founding of Oraxsys Therapeutics, a biotechnology company that is building on Dr. Little and Dr. Sfeir's work to further develop a microparticle-based therapeutic that recruits regulatory T cells to the oral mucosa, controls chronic local inflammation, and induces immune-homeostasis, thereby reducing the destruction caused by periodontitis and promoting tissue regeneration.

Competitive Advantage

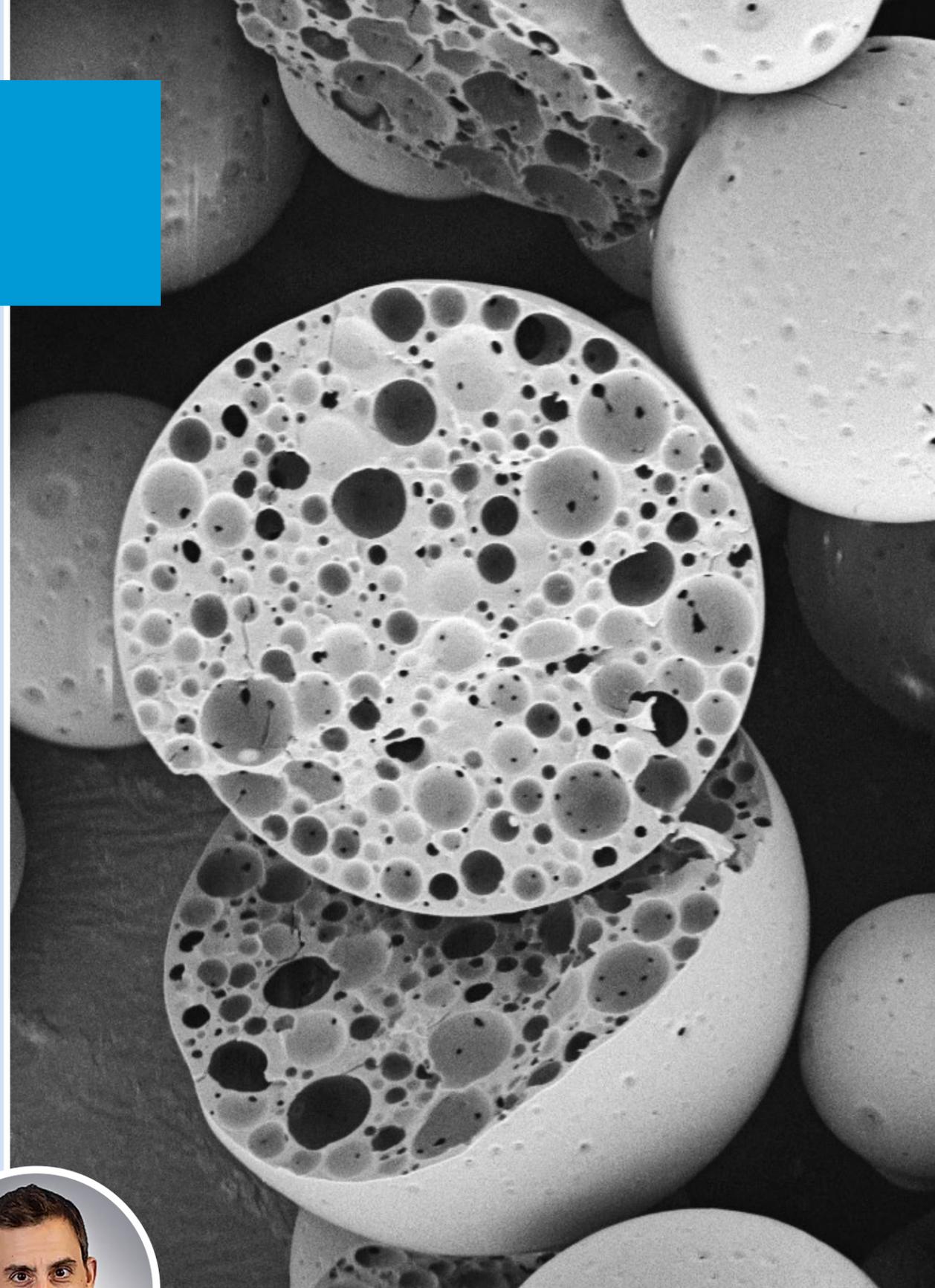
Targeting the underlying chronic inflammatory pillar of periodontitis with an immune-modulatory, controlled release product (a novel treatment strategy that would synergize with SRP) is thought to overcome the current limitations in the treatment of periodontal diseases, peri-implantitis, and other oral inflammatory conditions.

Foundational Publications & Patents

- Glowacki et al. Prevention of inflammation-mediated bone loss in murine and canine periodontal disease via recruitment of regulatory lymphocytes. [Proc Natl Acad Sci USA 2013](#)
- [US8,846,098](#) Artificial Cell Constructs for Cellular Manipulation



Peter Alff, PhD
Oraxsys Therapeutics/
Orange Grove Bio



ITP Support

The project entered the ITP program in 2018 with a robust data package describing the therapeutic mechanism of action and demonstrating preclinical efficacy in multiple disease models. Currently this work is being developed by Oraxsys Therapeutics, a company that has exclusive rights to the technology, and is driving all development efforts. Oraxsys plans to initiate a clinical trial for the treatment of periodontal disease. The ITP program has provided important assistance by enabling early process development and CMC efforts as well as insights into product positioning and market access strategy.

Key Inflection Points/ Regulatory Pathway

- ORX-001 is a biological therapeutic; IND and clinical entry anticipated in 2024 and 2025, respectively
- SBIR Fast Track application submission in Q3 2023
- CMC: Scaled-up production and characterization of API and microparticle at partner CDMO in Q4 2023

Opportunities for Partnerships

- Seeking strategic partners in the dental medicine space to help facilitate product development and commercialization
- Interested in speaking with Seed and Series A investors with an interest in and commitment to supporting companies developing therapeutics for treating inflammatory diseases and improving oral health

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