

Eric Schlumpf, President & CEO of Stuart Therapeutics, has extensive experience leading early-stage companies in various industries. This experience informs how he thinks strategically about the opportunity Stuart Therapeutics represents. A bias for action, sense of urgency, and creative differentiation are critical factors for success that have propelled Stuart to the forefront of precision tissue reparative therapeutics. He knows that moving quickly, establishing a strong scientific case, and always acting with the end in mind gives the company the best chance for success.

Stuart, which has operated virtually since its founding, is a small team of full time colleagues whose day-to-day work activities are largely conducted online, with team members residing and working in Florida, Tennessee, Virginia and South Carolina. "Careful planning in a coordinated way with our business partners has kept our development programs moving forward. We will be conducting our first clinical trial June thru September 2021, consistent with plans developed in early 2019," says Schlumpf.

The company is developing PolyColTM, a unique therapeutic platform that has shown promise as a direct tissue reparative for collagen membranes and structures in the eye. The PolyCol platform represents the first technology that targets damaged collagen in diseases of the eye. "The eye has numerous extracellular matrix structures which are composed primarily of collagen, and are implicated in chronic eye diseases," says Schlumpf. "Our technology is specifically designed as a precision reparative of the portions of the collagen molecule that are damaged during diseases such as dry eye, glaucoma, and dry age-related macular degeneration. The approach being taken is new, and as such, we knew we needed to show compelling pre-clinical results and combine that with a strong scientific foundation to explain the mechanism of action." This approach has led to Stuart Therapeutics' alignment with leading ophthalmology-focused investors from the venture community and the leading clinical research organization in ophthalmic drug development. "These key partnerships are critical in our industry, as you are 'known by the company you keep'. Our success in developing the PolyCol platform is underpinned by our promise to meet our commitments through strong execution of our program goals," adds Schlumpf. "Our track record is our best asset. Meeting our schedule commitments and research and development goals puts us in a strong position going into the clinic for human trials."

Based on preclinical results, Stuart's first drug candidate, ST-100, appears to be an extremely fast-acting therapeutic that may directly address the corneal tissue damage associated with dry eye disease. Dry eye is an indication typically caused by tear film deficiency, which exposes the delicate epithelial cells on the surface of the eye to the elements, and of course, damage. As it progresses, cells die, inflammation begins, and if allowed to progress, it will dramatically affect the patient's quality of life. ST-100 appears to act by repairing the collagen damage in the cornea, which heals quite slowly under normal conditions. "Our repair happens quite quickly, which in turn allows the epithelium to recover quickly, while reducing inflammation."

These drugs act quite slowly and do nothing for the tissue damage (both epithelium and collagen) that caused the inflammation in the first place. "Based on our pre-clinical results, the mechanism of action of ST-100 appears to deal first with the causal tissue damage, which can thereby accelerate the repair and recovery process in the cornea. ST-100 appears to do in hours what takes weeks with a typical anti-inflammatory approach," says Schlumpf. "Our strategy is to focus on the broad and fast acting nature of ST-100, as these are clear differentiators against the established competition, and most other drugs in development."

Stuart Therapeutics is adding two new drug candidate assets to its portfolio based on the same PolyCol platform technology. "ST-113 for glaucoma and ST-109 for dry age-related macular degeneration are in preclinical testing right now, and we expect to be in a position to begin discussions with FDA later this year about clinical trial timing and requirements," says Schlumpf. IE

