Company Overview

Toralgen is a preclinical stage biopharmaceutical company focused on oral delivery of biologics. The company is currently in active research collaborations with several global phramaceutical leaders to improve treatments for diabetes and autoimmune disorders. We seek to create a cost-effective oral solution addressing diabetes, autoimmune diseases, and cancer through our proprietary polybile nanopill delivery technology that closely mimics the natural enterohepatic process in the body.

Problem or Market Opportunity

Biologics represent over half of top selling pharmaceuticals, with the global market of biologic drugs estimated to be between $150-200 billion in annual sales. Although protein-based "biologic" drugs represent a major advancement in healthcare, they require administration through injection or infusion due to poor bioavailability or to avoid degradation from digestion through the oral route. Most patients prefer to take drugs orally because it is more convenient, less invasive, and does not require intervention by health professionals in an in-clinic setting. Despite the high level of interest amoung patients and their doctors, there are currently no effective commercial products available for oral bioavailability.

Technical & Competitive Advantage

To date, oral delivery approaches for biologics have been unsuccessful. Toralgen's solution is nanoparticles formulated using polymerized ursodeoxycholic acid, pUDCA. These particles have shown improved GI transport, stomach protection, and enhanced intestinal permeation. Under acidic conditions in the digestive tract pUDCA becomes more hydrophobic, limiting water permeability, a protective mechanism which reverses when distributed into blood and tissues with increased pH conditions. The nanoparticle ferries the API through the stomach and intestine before releasing into the body where it is needed.

Regulatory Strategy & Intellectual Property

Toralgen's business model is that of a biotech platform technology company. The company's goal is partner early with major pharmacuetical companies and develop an oral formulation of their proprietary API and work together to bring oral formulations to patients. The company currently has four ongoing early-stage collaborations with large pharmaceutical companies. Each has the potential to convert into individually crafted IP and significant licensing deals. Toralgen's platform is covered by US patent 10864170B2. Three other provisionals patents have been filed. New developments are leading to IP beyond the scope of Toralgen's core patents.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q3 2018	Company Formation	IP licensed from Yale university
Q4 2020	Research Collaboration	Toralgen enters into an initial research collaboration with a pharmaceutical company for two API
Q3 2022	Research Collaboration	Toralgen enters a fourth major pharamceutical collaboration, seven API total

Capitalization History

Year	Grant or Equity Type	Description	Amount
Q3 2019	Seed Funding 1	Initial phase of funding to transfer technology into company labs and conduct initial POC	$1.9M
Q4 2020	Seed Funding 2	Establishment of development lab, safety testing, scaling path and hiring of team	$6.4M

Current Round, Terms, and Use of Proceeds

If necessary, the company plans to close a $15M Series A round in Q4 of 2023. This will allow the company to complete platform development, expand formulation lab capacity, scale-up production and allow the company to pursue to additional collaborations.

Key Team Members and Advisors

Gerald Rea | CEO

Gerald is co-founder and CEO of Toralgen. He brings over 15 years of experience in early-stage technology development to the team.

Dave Moore | COO

Over 30 years of experience in drug development, business development, commercialization, and operations experience. At Eli Lilly & Co, Dave held a variety of leadership roles that resulted in several in-licensing deals and billion-dollar brand launches in diabetes and neurosciences

Ed Bastyr MD | CMO

Clinical endocrinologist, academic (Indiana University) and industry (Eli Lilly & Co, MB2) researcher 25+ years of experience

Andy Glasebrook, PhD | Vice President, Autoimmune Drug Development

40 years+ of experience in immunology and drug development, Past-President of the Inflammation Research Association, a named inventor on 9 issued US patents and co-author of 100 scientific publications.

John Lee, PhD | Director of Development

Over 15 years of nanomedicine development for treating autoimmune diseases and cancer. Former Yale lab manager. Co-inventor at Yale Labs

Dod Micheal, PhD | Advisor, Metabolic Research

President Thermalin Inc, former head of insulin research at Eli Lilly and Joslin Diabetes Center fellow

Henry Havel, PhD | Advisor, Nanoparticles

Former Inaugural Chair of Nanomedicine Alliance and Senior Research Fellow at Eli Lilly

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