Company Overview

Akeila Bio is a biotech start-up company developing breakthrough medicines that target the retinoid X receptor (RXR) to treat a broad range of diseases driven by dysregulation of the immune system and metabolism. During the 1990s, many companies pursued RXR drug programs, but only a single drug, bexarotene, ever reached FDA approval (in 1999). Other RXR drugs had too much toxicity relative to their patient benefits. Bexarotene is used to treat cutaneous T-cell lymphoma (CTCL). Even though bexarotene was approved and remains a standard of care today, doctors do not like it because it still has significant side effects, such as dose-limiting lipid elevation. Now, 20 years later, with the aid of new biological understanding and a team with decades of RXR research experience, Akeila Bio is primed to unleash this potential with the industry's broadest portfolio of next-generation RXR therapeutics that combine efficacy without the side effects of previous RXR drugs.

Problem or Market Opportunity

Akeila Bio's initial market focus is on three diverse indications, with three distinct compounds, with major needs for novel effective and safe therapeutics. NF1 neurofibromatosis (NF1) is a genetic disease that is usually diagnosed by the age of 10 and has only one approved drug, selumetinib. CTCL, the disease for which an RXR drug has been approved, lacks any treatments that are both safe and effective. Finally, advanced diabetic retinopathy has a critical need for drugs that target the inflammatory and metabolic aspects of the disease that drive cell death and vision loss. Each represents large global markets with further potential for expansion into adjacent indications. In order to commercialize the technology, Akeila will seek biopharmaceutical partners with expertise in the specific disease areas of each compound. There is already interest in these programs and we expect to enter our first partnership licensing agreement in 2025.

Technical & Competitive Advantage

RXR agonists are drugs designed to activate RXR binding. However, the biological impact of this binding is complex and varies greatly between different RXR agonists. This complexity and variability have been central to the challenge of developing safe and effective RXR drugs, but also highlights the opportunity for Akeila Bio. For example, our collaborators at UAB identified the key chemical interaction that has caused lipid toxicity of many RXR drugs. Our collaborators at ASU demonstrated that given the "flexibility" of the RXR drug binding site, very subtle changes in the chemical structure of the drugs can have very different downstream signaling properties. And, our scientific founders from MSU demonstrated that the primary mode of efficacy of RXR drugs are through modulation of the immune system. With this new understanding, we can thoughtfully design novel and distinct RXR drugs for different drivers of specific diseases, while minimizing the side effect profile for each.

Regulatory Strategy & Intellectual Property

Akeila Bio has exclusive option agreements to license distinct, broad, and diverse RXR agonist portfolios from three universities (Michigan State, Arizona State, and Alabama-Birmingham), which represent almost all the commercializable IP in the field. The agreements include business terms within typical guidelines for spin-out companies and major milestone payments deferred until late-stage clinical development and regulatory milestones. Given the clinical nature of our target indications and the history of side-effects for RXR drugs, each program will enter the clinic treating patients rather than healthy volunteers. As small molecules with a novel drug substance, each will follow a standard 505(b)(1) regulatory pathway through the CDER division of the FDA. The NF1 and CTCL programs can also qualify for orphan drug status in the US and other jurisdictions, which will be pursued following pre-IND meetings with the FDA.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q1 2024	Safety Profiling	Complete in vitro and in vivo experiments to generate early safety package of MSU42011
Q3 2024	NF1 Efficacy Study	Complete efficacy of MSU42011 in NF1 model.
Q3 2024	DR Lead Selection	Screen multiple RXR candidates for diabetic retinopathy
Q1 2025	Pre-IND Meeting	Prepare comprehensive pre-IND briefing package and meet with FDA.

Capitalization History

Year	Grant or Equity Type	Description	Amount
2024	Pre-Seed	Ongoing Pre-Seed Round (~$120,000 complete)	$500K

Current Round, Terms, and Use of Proceeds

Complete MSU42011 early preclinical development; Prepare for MSU42011 Pre-IND meeting with FDA; Select lead candidate for CTCL; Select lead candidate for diabetic retinopathy.

Key Team Members and Advisors

John Prista Freshley | Co-Founder and Executive Chairman

John has more than 20 years experience as an entrepreneur, company builder, and leader who has founded, launched, and/or led more than 10 early-stage life science companies, including Compendia Bioscience and ONL Therapeutics.

Karen Liby | Co-Founder and CSO

Karen has 20 years of experience in academic drug discovery and in vivo models, with a focus on therapeutics that modulate the immune system. Her work on Nrf2 agonists led to the approval of Skyclarus for Friedrich's Ataxia in 2023 and the subsequent acquisition of Reata by Biogen.

Edmund Ellsworth, PhD | Co-Founder and VP

A medicinal chemist by training, Edmund has more 25 years experience in the pharmaceutical industry holding leadership positions at Parke-Davis, Pfizer, and Zoetis with a multidisciplinary understanding of drug discovery process .