Skye Bioscience is a clinical-stage pharmaceutical company developing proprietary, synthetic cannabinoid derivatives to treat glaucoma and other diseases with significant unmet needs

Market Information

OTCQB : SKYE

Market Cap: $14.1M[1]

Shares o/s: 972.5M[2]

Common shares f/d: 1.2B[2]

[1]23/05/10
[2]23/03/29

Recent Advances

23/04/27: Begins dosing fourth cohort in clinical trial of SBI-100 Ophthalmic Emulsion ("OE")

23/04/04: Receives positive safety review of third cohort in Phase 1 study

23/04/03: SBI-200 reduces pain in animal model; results published in scientific journal

23/03/15: Receives human research ethics committee approval to start multiple ascending dose arm of Phase 1

23/03/07: Doses third cohort of Phase 1 clinical trial of SBI-100 OE

23/02/23: Receives positive safety review of SBI-100 OE after second cohort of Phase 1 study

Unlocking the pharmaceutical potential of cannabinoids

Investment Highlights

Exploiting the Endocannabinoid System

The endocannabinoid system's (ECS) role in modulating body functions makes it a promising target for cannabinoids and small molecules able to provide therapeutic benefit while meeting modern medical standards. Recent clinical studies proved a particular cannabinoid's ability to control epileptic seizures. This was just one result further justifying discovery efforts to enhance and validate mechanisms to affect the ECS; improve the delivery and bioavailability of promising molecules; establish intellectual property; and advance novel compounds through development. This is Skye's focus and forte.

Large Market, Unmet Needs

The eye is rich with cannabinoid receptors that can be targeted to affect multiple conditions in that organ. A key eye disease, glaucoma, afflicts ~60M (Glaucoma Foundation) people worldwide and is a $7B pharmaceutical drug market. Current drugs that reduce eye pressure cannot consistently prevent glaucoma progression to vision loss. Notably, independent human research has shown THC's ability to reduce intraocular pressure but that enhanced delivery directly into the eye was necessary to realize its potential as a clinically viable therapeutic. Skye's proprietary and patented cannabinoid derivative drug candidate has resulted in a promising new approach to potentially address this untapped opportunity.

Novel Drugs

Designed to provide distinct capabilities compared to currently approved glaucoma drugs, Skye's SBI-100 Ophthalmic Emulsion ("OE") is engineered to enhance its local delivery (avoiding/minimizing systemic side effects) and bioavailability in the eye. In an animal study comparing latanoprost, the glaucoma standard of care, SBI-100 OE, which targets the CB1 receptor, compared very favorably in its ability to lower intraocular pressure. Skye has completed dosing of its first four cohorts for its Phase 1 study and aims to start Phase 2 mid-2023 to assess the utility and safety of SBI-100 OE.

Creating a New Class of Therapeutics

The recent success of a pharmaceutical development company in realizing the therapeutic and commercial value of a cannabinoid for a notable disease, epilepsy, led to its $7.2B acquisition. Skye is similarly pursuing the relatively untraveled path of applying modern science and rigorous clinical and regulatory review to a cannabinoid. In its pursuit of a new class of ocular medicine, Skye's aspiration is to create benefits for both patients and shareholders.

Product Pipeline

Preclinical | Phase 1 | Phase 2

SBI-100 Ophthalmic Emulsion

SBI-100 OE: Phase 1

- Objectives: Evaluate safety, tolerability, and effect on intraocular pressure (IOP) in healthy volunteers
- Design: randomized, double-masked, placebo-controlled study; ~48 participants topically administered SBI-100 OE or placebo in a total of three single ascending dose (SAD) cohorts and three multiple ascending dose (MAD) cohorts
- Dosing of SAD cohorts complete; first MAD cohort dosed in April; dosing of final cohorts planned for May and June

Positioned for Value Creation

Completed Steps

- Head-to-head study in rabbits of SBI-100 OE effect on IOP versus netarsudil and latanoprost alone and in combination showed superior and beneficial effects
- Began dosing participants in Phase 1 study of SBI-100 OE in December 2022 in Australia
- FDA authorized Investigational New Drug application to start clinical studies of SBI-100 OE in U.S.
- Received institutional review board approval for Phase 2 clinical trial sites

Upcoming Milestones

- Completion of MAD arm of SBI 100 OE mid-2023
- Phase 1 data for SBI-100 OE in Q3 2023
- Initiate Phase 2 study for SBI-100 OE mid-2023
- Phase 2 data for SBI-100 OE in Q1 2024
- Finalize assessment of development potential of SBI-200
- Identify new molecules with clinical development potential through proprietary screening platform

Cannabinoid Pharmaceutical Innovation Program

Vivacell Biotechnology España

Vivacell is a global pioneer in the discovery and development of novel cannabinoid derivatives for the treatment of serious disease.

Under an exclusive sponsored research agreement, Vivacell has developed a proprietary screening platform used to screen over 90 molecules to analyze key molecular targets in a range of disease pathways initially focused on ophthalmology.

University of Mississippi

Drawing on 50 years of intellectual capital in cannabinoid chemistry and physiology from the first entity with a federal license to cultivate cannabis for research purposes.

Skye secured from Ole Miss “all fields” licenses for SBI-100 molecule and SBI-200, permitting development for any therapeutic indication by any route of administration for any human and veterinary indication.

Our Team

Management

Punit Dhillon
Chief Executive Officer and Chair

Kaitlyn Arsenault, CPA
Chief Financial Officer

Tu Diep, MSc
Chief Development Officer

Chris Twitty, PhD
Chief Scientific Officer

Board of Directors

Punit Dhillon
Chief Executive Officer and Chair

Margaret Dalesandro, PhD
Board Director, OncSec Medical

Praveen Tyle, PhD
President & CEO, Invectys, Inc

Keith W. Ward, PhD
President & CEO, InterveXion Therapeutics

Deborah Charych, PhD
Co-founder and former CTO, RayzeBio

Scientific Advisory Board

Eduardo Munoz, MD, PhD
Professor of Immunology, University of Córdoba

Giovanni Appendino, PhD
Professor of Chemistry, University of Eastern Piedmont

Clinical Advisory Board

Jeffery Goldberg, MD, PhD
Professor & Chair of Ophthalmology, Stanford University

Louis Pasquale, MD
Professor of Ophthalmology, Mt. Sinai School of Medicine

Robert Ritch, MD
Professor of Ophthalmology, Mt. Sinai School of Medicine