

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: \$24.63M¹

Shares OS: 912.2M²

Common shares f/d: 1.2B²

¹23/03/09

²22/09/30 pro forma

Recent Advances

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

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

23/02/16: Appoints Deborah Charych, PhD to board of directors

23/02/15: Closes sale of subsidiary, Verdélie Sciences, to C3 Souvenir Holding, with USD \$5.60M closing payment

23/02/13: Doses second cohort of Phase 1 clinical trial of SBI-100 Ophthalmic Emulsion

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 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 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 three cohorts for its Phase 1 study and expects to start Phase 2 in the first half of 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; dosing of MAD cohorts planned for Q2 2023

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
- Closed acquisition of Emerald Health Therapeutics in Q4 2022 to extend operating runway
- 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.

Upcoming Milestones

- Finalize assessment of development potential of SBI-200
- Identify new molecules with clinical development potential through proprietary screening platform
- Phase 1 data for SBI-100 OE in 2023
- Initiate Phase 2 study for SBI-100 OE in H1 2023
- Phase 2 data for SBI-100 OE in Q1 2024

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 Executive Chairman
- 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 Executive Chairman
- 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
- Bob Rai, BPharm RPh**
Chairman & CEO, Canadian Pacific Global Pharmaceuticals

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