

**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:** \$11.6M<sup>1</sup>

**Shares OS:** 912.2M<sup>2</sup>

**Common shares f/d:** 1.2B<sup>2</sup>

<sup>1</sup>22/12/22

<sup>2</sup>22/09/30 pro forma

## Recent Advances

**22/12/20:** Receives FDA authorization of Investigational New Drug application for SBI-100 OE

**22/12/16:** Doses first cohort of participants in Phase 1 clinical trial of SBI-100 Ophthalmic Emulsion

**22/12/13:** Appoints Chris Twitty, PhD, as Chief Scientific Officer

**22/11/17:** Submits Investigational New Drug application for SBI-100 Ophthalmic Emulsion to FDA

**22/11/16:** Starts recruiting for first-in-human phase 1 clinical trial for SBI-100

# 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 ~80M (American Academy of Ophthalmology) people worldwide and is a \$7B pharmaceutical drug market. Current drugs that reduce eye pressure cannot consistently prevent glaucoma progression to vision loss. Notably, human studies have shown THC's ability to positively affect a key risk factor of glaucoma - but THC in its natural form is not a clinically viable therapeutic. Skye got an early start on creating an enhanced cannabinoid derivative to address this untapped opportunity and establishing patent protection.

## 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, was superior in lowering intraocular pressure and demonstrated superior duration of response. Skye has begun dosing participants 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 Pharmaceutical 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. Applying modern science and rigorous clinical and regulatory review, Skye is developing proprietary synthetic cannabinoid derivatives and small molecules able to potentially facilitate therapeutic benefit to 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 cohorts and three multiple ascending dose cohorts
- First cohort dosed in December 2022; second cohort dosing planned in February 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
- Begin dosing of 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 Q2 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, MSoc**  
Chief Development Officer
- Chris Twitty, PhD**  
Chief Development 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
- 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
- Miguel González-Andrades, MD, PhD**  
Clinician Scientist of Ophthalmology, Reina Sofia University Hospital