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

Market Information

OTCQB : SKYE

Market Cap: $16.9M[1]

Shares OS: 495.9M[2]

Options + Warrants: 168.9M[2]

[1]22/08/01
[2]22/03/24

Recent Advances

22/07/21: Selects NextPharma as Phase 2 Contract Drug Manufacturer

22/06/30: Receives Australian Ethics Committee approval to start first-in-human Phase 1 study of SBI-100 Ophthalmic Emulsion

22/06/07: Expands Cannabinoid Pharmaceutical Innovation Program with Leading Cannabinoid Medicinal Chemistry Groups

22/05/12: Signs agreement to acquire Emerald Health Therapeutics; expected to fund SBI-100 Ophthalmic Emulsion Phase 2 study

Unlocking the pharmaceutical potential of cannabinoids

Investment Highlights

Merging Cannabinoids and Science

Science and cannabinoids have barely crossed paths beyond characterizing cannabinoids like THC and CBD as well as the body's endocannabinoid system and its role in controlling various functions in the body. Clinical studies proved CBD's ability to control epileptic seizures. This effort added to the premise and inspiration to further define cannabinoids' therapeutic mechanisms; enhance their delivery and bioavailability; create protectable intellectual property; and advance novel compounds through development to potential commercialization. This is Skye's focus and forte.

Large Market, Unmet Needs

The eye is rich with receptors that can be beneficially affected by cannabinoids to address many diseases. Glaucoma, for example, afflicts approximately 80M people worldwide and is a $7B pharmaceutical drug market. Yet current drugs that reduce eye pressure cannot reliably prevent the progression of glaucoma to vision loss. Notably, human studies have previously shown THC's ability to address the key risk factor of glaucoma – but native THC by itself 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.

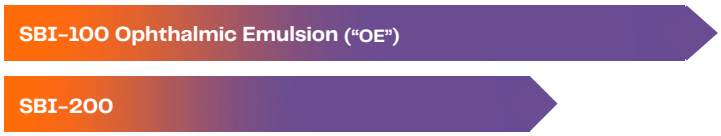
Distinctive Technology, Novel Drugs

Designed to provide advantages over currently approved drugs and natural cannabinoids to treat glaucoma, Skye's SBI-100 cannabinoid derivative 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 Ophthalmic Emulsion was superior in a key outcome of lowering intraocular pressure, in addition to demonstrating a superior duration of response. Skye expects to start enrolling patients in a first-in-human study starting in Q4 2022 and plans to start Phase 2 activities in the same quarter- a fast timeline! – to assess the potential utility and safety profile of SBI-100 Ophthalmic Emulsion.

Creating a New Class of Pharmaceutical Therapeutics

Skye's efforts are inspired by GW Pharmaceuticals' success in creating value by proving the pharmaceutical and commercial value of a cannabinoid for a notable disease, epilepsy, which lead to its $7.2B acquisition. By applying modern science and rigorous clinical and regulatory review, Skye's aspiration is to realize the development of proprietary cannabinoid derivatives that represent a new class of medicine to benefit both patients and shareholders.

Product Pipeline



Positioned for Value Creation

Completed Steps

- GLP toxicology study for SBI-100 OE
- Head-to-head study in rabbits of SBI-100 OE effect on IOP versus netarsudil and latanoprost alone and in combination to evaluate potential additive and/or synergistic effects of SBI-100 OE
- CMC & GLP manufacturing of SBI-100 OE
- Genotoxicity studies to assess potential for induction of genetic mutations or chromosomal damage
- Repeated dose toxicology study in multiple species to satisfy FDA's IND requirement
- Phase 1 approval from Australian Human Ethics Research Committee (HREC)

Upcoming Milestones

- Begin subject enrollment for Phase 1 study of SBI-100 OE for the treatment of glaucoma in Q4 2022
- Establish development plan of SBI-200
- Acquisition of Emerald Health Therapeutics in Q3 to extend operating runway
- Preliminary Phase 1 data for SBI-100 OE in Q1 2023
- Submit Investigational New Drug Application for Phase 2 study of SBI 100 OE in Q4 2022
- Final Phase 1 data for SBI-100 in Q2 2023

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 is developing a proprietary screening platform able 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

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Chief Executive Officer and Executive Chairman

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Tu Diep, MSc
Chief Development Officer

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