

Skye Bioscience is a biopharmaceutical company developing proprietary, synthetic cannabinoid-derived molecules to treat glaucoma and other diseases with significant unmet needs.

Market Information

OTCQB : SKYE

Market Cap: \$27.9M¹

OS Shares: 309.8M

Options + Warrants: 157.7M

21/01/15¹

Recent Advances

20/12/16: Launches rebrand including name change to Skye Bioscience

20/12/16: Reports superior reduction of intraocular pressure of its unique nanoemulsion formulation of THCVHS is published in peer-reviewed journal

20/08/10: Appoints biotech executive Punit Dhillon as CEO.

20/08/10: Appoints biotech veteran Dr. Margaret Dalesandro to board of directors.

20/08/04: Raises approximately \$7.0 million in upsized registered offering.

20/06/02: CBDVHS composition of matter patent issued in Japan.

Unlocking the pharmaceutical potential of cannabinoids

Merging Cannabis and Science

Science and cannabis have barely crossed paths beyond characterizing cannabinoids like THC and CBD, and the body's endocannabinoid system. Clinical studies proved CBD's ability to control epileptic seizures, and this effort encourages life science practices to 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 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 75 million people worldwide and is a \$10 billion market. Yet current drugs that reduce eye pressure cannot necessarily prevent the progression of glaucoma to vision loss; and they do not address the other key cause of blindness, neurodegeneration of optical nerve cells. Notably, human studies have previously shown THC's ability to help protect the eye. Skye got an early start to address this untapped opportunity.

Distinctive Technology, Novel Drugs

Designed to provide advantages over current approved drugs and natural cannabinoids to treat glaucoma, Skye's THCVHS prodrug 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, THCVHS was superior in a key outcome of lowering intraocular pressure. THCVHS may also be unique in potentially providing neuroprotection to prevent another key cause of vision loss: optical nerve cell death. Skye is working toward its first Phase 1 study planned for H2 2021, which will assess not only safety, but intraocular pressure and other efficacy indicators. The nature of glaucoma allows this study to be relatively short, low cost, yet also provide an initial assessment of THCVHS' ability to lower intraocular pressure in addition to its safety and tolerability. This first human study may therefore have the potential to be a game-changer in exposing the company's potential.

Standing Alone in a Positive Investment Sector

With growing popular support of cannabis and progressive US state legalization, future legalized banking, investment, public listings, interstate trading, and federal legalization are conceivable and would support growing sales, profit, and investor interest in the sector. Skye's lead drug is unique, with promising prior evidence of the utility of the active ingredient; its stock price and valuation are low; and the company and its potential are not widely unrecognized.

Product Pipeline

Research Preclinical Phase 1 Phase 2 Phase 3

THCVHS

Glaucoma

CBDVHS

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Completed Studies

- Optimized ocular formulation of THCVHS demonstrated the potential to be dosed once daily, enhancing the drug's possible competitive profile in the marketplace
- THCVHS demonstrated greater ability to lower intra-ocular pressure (IOP) in head-to-head study versus latanoprost and timolol, medications that comprise more than 90% of the current glaucoma market
- Ex-vivo studies with THC, the API of THCVHS, demonstrated IOP-lowering effects as well as significant antifibrotic, anti-inflammatory, and anti-neovascularization effects, supporting multiple potential mechanisms of action in lowering IOP

Planned Studies

- Head-to-head study in rabbits of THCVHS' effect on IOP versus netarsudil and latanoprost alone and in combination to evaluate potential additive and/or synergistic effects of THCVHS
- Optic nerve crush model to further study the neuroprotective effects of THCVHS
- Toxicity studies to assess the potential for induction of genetic mutations or chromosomal damage
- Repeated dose toxicology study in multiple species to satisfy FDA's IND requirement
- In-vitro epi-ocular local irritation study (DRAIZE test)

First In-Human Studies

- Assess safety, tolerability, and pharmacokinetics of single and multiple ascending doses in healthy volunteers and patients with glaucoma and in patients without glaucoma but with elevated IOP
- Study readouts will measure any changes in IOP, visual acuity, conjunctival redness, ocular comfort as well as slit lamp and retinal exam.
- Skye plans to initiate its first Phase 1 study of THCVHS for the treatment of glaucoma in H2 2021

Additional Highlights

University of Mississippi Partnership

Drawing on 50 years of intellectual capital in cannabinoid chemistry and physiology from the first entity with a federal license to directly study cannabinoids.

"All Fields" Licensing

Skye secured from U.Miss. "all fields" licenses for THCVHS and CBDVHS permitting development for any therapeutic indication by any route of administration for any human and veterinary indication.

Our Team

Leadership

Punit Dhillon

Chief Executive Officer

Mr. Dhillon was the co-founder, CEO, and director of ONCS, a leading biopharmaceutical company developing cancer immunotherapies where he oversaw and completed a partnership with Merck to launch a Phase 2/3 global multi-center clinical study and raised over \$200 million.

Scientific Advisory Board

Jeffery Goldberg

MD, PhD. Department of Ophthalmology, Stanford

Professor and Chair of Ophthalmology and Director of the Spencer Center for Vision Research at the Byers Eye Institute at Stanford University.

Louis Pasquale

MD. Professor of Ophthalmology, Mt. Sinai

Professor of Ophthalmology at the Icahn School of Medicine at Mt. Sinai in New York City and Site Chair of the Department of Ophthalmology at Mt. Sinai Hospital and Vice Chair of Translational Ophthalmology Research for the Mount Sinai Healthcare System.

Robert Ritch

MD. Professor of Ophthalmology, Mt. Sinai College of Medicine

Dr. Robert Ritch holds the Shelley and Steven Einhorn Distinguished Chair and is Surgeon Director Emeritus; Chief of Glaucoma Services; Director of International Ophthalmic Education and Director of Glaucoma Research at the New York Eye & Ear Infirmary of Mount Sinai, New York City.