skye BIOSCIENCE

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

Market Information

OTCQB : SKYE

Market Cap: $27.9M[1]

OS Shares: 350M

Options + Warrants: 117.6M

21/03/01

Recent Advances

21/03/08: Appoints cannabinoid science experts Giovanni Appendino, PhD, and Eduardo Muñoz, MD, PhD to scientific advisory board

21/01/19: 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

20/08/13: Appoints biotech veteran Dr. Margaret Dalesandro to board of directors

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

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

Unlocking the pharmaceutical potential of cannabinoids

Merging Cannabinoids and Science

Science and cannabinoids 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 approximately 80 million people worldwide and is a $7 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.

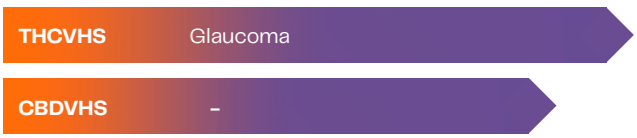
Distinctive Technology, Novel Drugs

Designed to provide advantages over currently approved drugs and natural cannabinoids to treat glaucoma, Skye's THCVHS prodrug is engineered to enhance its local delivery (avoiding systemic side effects) 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, in addition to demonstrating a superior duration of response. 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. 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 tolerabilty. Therefore, this first human study may 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



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 80% of the current glaucoma market
- Ex-vivo studies with THC, the API of THCVHS, demonstrated IOP-lowering effects as well as significant antifibrotic, and anti-inflammatory 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
- Geneotoxicity 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 or 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

Richard Janney
Principal Accounting Officer

Tu Diep, MSc
SVP, Development

Tom Kim, Esq
General Counsel & Director of IP

Karam Takhar
VP, Corporate Development & Investor Relations

Scientific Advisory Board

Eduardo Munoz, MD, PhD.
Department of Ophthalmology, Stanford

Giovanni Appendino, PhD
Professor of Ophthalmology, Mt. Sinai

Clinical Advisory Board

Jeffery Goldberg, MD, PhD.
Department of Ophthalmology, Stanford

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

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