Skye Bioscience is targeting the CB1 receptor to affect inflammatory, fibrotic and metabolic processes encompassing diseases such as glaucoma, obesity and chronic kidney disease. Skye is preparing two first-in-class molecules for Phase 2 clinical trials.

Market Information

OTCQB : SKYE

Shares o/s: 12.3M[1]

Common shares f/d: 17.1M[1]

Institutional holding: 66%

[1]Based on unaudited pro forma numbers from filing of 23/08/18 and 23/08/24

Recent Advances

- Phase 1 data shows SBI-100 OE is safe and well-tolerated, with very low levels of hyperaemia compared to approved drugs, and early indications of lowering of intraocular pressure
- Received clinical site authorizations for glaucoma Phase 2a study
- Effected 1:250 reverse split
- Raised $17M in new capital
- Acquired Phase 2-ready peripheral CB1-inhibiting therapeutic, nimacimab

Unlocking the pharmaceutical potential of the endocannabinoid system

Investment Highlights

Broad Potential to Activate or Inhibit CB1 and other ECS Receptors
The endocannabinoid system ("ECS") and its receptors, such as CB1, help regulate body functions and are promising drug targets for various diseases. Recent acquisitions highlight interest in the ECS: Jazz Pharmaceuticals/GW Pharmaceuticals/epilepsy – $7.2B (2021); Horizon/Zynerba/Fragile X drug – up to $200M (2023); in 2023, the largest seller of drugs used for weight loss, Novo Nordisk, acquired Inversago Pharma and its peripheral CB1-inhibiting drug (with only Phase 1 data) for up to $1.075 billion.

Skye's Novel Drugs
Recently-acquired **nimacimab** is a peripherally-acting negative allosteric modulating CB1 inhibitor, with potential for cardiometabolic indications such as obesity and chronic kidney disease. Early CB1 inhibitors acting on the CNS to realize weight loss showed efficacy but sometimes caused anxiety, depression, and suicidal thoughts. Novo's acquisition of Inversago highlights the appeal of CB1 inhibition peripheral to the CNS. As a monoclonal antibody, nimacimab acts outside the CNS. Skye plans to start a Phase 2 for nimacimab in early 2024.

SBI-100 Ophthalmic Emulsion ("OE") is a CB1 agonist (activator) focused on lowering intraocular pressure ("IOP") related to glaucoma and ocular hypertension. Ophthalmology opinion leaders have described the unmet need for a new class of medicine. In October, Skye announced Phase 1 data indicating this novel eyedrop was safe and well tolerated, with lower hyperaemia (red eyes) than approved drugs, and providing a first indication in humans of lowering intraocular pressure. SBI-100 OE is starting a P2a clinical study in Q4 2023, with interim data expected in Q1 2024.

Large Markets for Cardiometabolic and Ocular Diseases
In 2016, 39% of adults worldwide aged 18 years and over were overweight (WHO). Medical issues relating to obesity, kidney diseases, and other associated cardiometabolic diseases represent one of the largest opportunities for new therapeutics, with projected sales potential estimated at tens of billions of dollars. Among various receptors and pathways being evaluated for development, peripheral CB1 inhibition is one avenue showing potential as a standalone or combination mechanism of action.

Glaucoma afflicts ~60M (Glaucoma Foundation) people worldwide and is a $7B drug market. Current drugs that reduce eye pressure associated with glaucoma have side effects for many and may not halt the progression to vision loss: 40% of patients fail 1st line therapy and 50% require two therapies. Ocular specialists have indicated the need for a new class of drug and expressed a positive view of SBI-100 OE's distinct mechanism of action.

Experienced Team and Specialized Life Science Investors
Skye's management team has extensive experience in drug development. Its board directors have been individually involved in the commercialization of over 47 drug/device products, as well as strategic transactions. Skye is backed by 5AM Ventures, Versant Ventures, and other successful specialist life science investors, who own 66% of the company.

Product Pipeline

Nimacimab: Phase 2a

- Profile: 26-week animal toxicity studies showed no drug accumulation in the brain, a key variable to avoid detrimental CNS effects, with positive toxicity and pharmacokinetic results. A Phase 1b study showed excellent safety and encouraging trends in exploratory biomarkers after three-week dosing.
- Objectives: Skye has an extensive preclinical package and data for nimacimab, open Investigational New Drug files with the FDA for NASH, gastroporesis, and chronic kidney disease, data from a completed Phase 1 study showing a positive safety profile, and sufficient manufactured drug for P2
- Clinical study: Skye plans to start a Phase 2a study for broad cardiometabolic endpoints in H1 2024. Establishing proof- of-concept could pave the way to address multiple diseases with significant prevalence and unmet needs.

SBI-100 OE: Phase 2a

- Profile: Independent research shows THC reduces IOP, but psychoactivity and other side effects prevented its therapeutic use via systemic administration. The lipophilic environment of the eye prevented topically delivery. Skye's novel THC prodrug formulated with a proprietary nanoemulsion was designed to result in an eyedrop to overcome this delivery challenge. Animal data show that SBI- 100 OE IOP-lowering extent and duration compare favorably to commercialized drugs as a monotherapy and combination. Skye achieved positive Phase 1 data (described on p.1) in healthy subjects and will launch a Phase 2a in Q4 2023..
- Objectives: primary endpoint: assess changes in intraocular pressure from baseline versus placebo; secondary endpoints: assess psychotropic effects, biomarkers of neuroprotection, safety and tolerability
- Clincal study: randomized, double-masked, placebo-controlled study of 54 patients with glaucoma and ocular hypertension treated twice a day for 14 days; assessing two concentrations of SBI-100 OE

Positioned for Value Creation

SBI-100 OE

- Head-to-head study in rabbits of SBI-100 OE effect on intraocular pressure versus netarsudil and latanoprost alone and in combination showed favorable effects
- Phase 1 study of 48 healthy volunteers showed SBI-100 OE was safe, well-tolerated, with very low hyperaemia, and indication of IOP-lowering
- Phase 2a dosing to start in Q4 2023
- Interim P2a data expected in Q1 2024

Nimacimab

- CB1 inhibition has extensive proof as MOA to positively impact significant diseases
- Peripheral CB1 inhibition has potential to avoid CNS liabilities of early-generation molecules
- Strong nimacimab animal data with positive 26-week toxicity and pharmacokinetic results
- Phase 2a planned to start 2024 for cardiometabolic-related indication

Our Team

Management

Punit Dhillon
Chief Executive Officer and Chair

Kaitlyn Arsenault, CPA
Chief Financial Officer

Tu Diep, MSc
Chief Development Officer

Chris Twitty, PhD
Chief Scientific Officer

Board of Directors

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Chief Executive Officer and Chair

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Pharma. Dev. Consultant, Brecon Pharma Consulting

Praveen Tyle, PhD
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Keith W. Ward, PhD
President & CEO, Kuria Therapeutics

Deborah Charych, PhD
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Andy Schwab,
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Paul Grayson, Venture Partner, Versant Ventures; President and CEO Tentarix Biotherapeutics

Scientific Advisory Board

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Professor of Chemistry, University of Eastern Piedmont