

# Corporate Presentation

February 2025

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CSE: AWKN | OTCPink: AWKNF AwaknLifeSciences.com Corporate Presentation | February 2025

# Awakn is a Clinical Stage Biotechnology Company Developing Therapeutics for Substance Use and Mental Health Disorders, with a Near-Term Focus on Alcohol Use Disorder

#### Significant Addressable Market for AUD

40m with AUD in UK, US, and EU4

90% untreated

75% of treated relapse within 12 months

# Efficacy Proven for Severe AUD (SAUD) in Ph2

Lead program, AWKN-001, achieved:

- 86% abstinence over six month period vs 2%pre-trial
- 50% reduction in heavy drinking days vs placebo

# De-risked Pipeline with Expansion Potential

Lead program, AWKN-001, for Severe AUD in UK market

Secondary program, AWKN-002, for AUD in US market

Pipeline expansion potential in other addictions and mental health disorders

# Intellectual Property

Esketamine oral thin film (OTF) formulation and method of use patents field

175 new chemical entity (NCE) series developed with some patents filed

Ketamine-assisted therapy manual for addiction copywritten

MDMA for AUD patent filed

#### Low Cost and Low Risk R&D Strategy

AWKN-001 n=280 Ph3 trial to cost Awakn only US\$1m, balance funded by UK Gov.

AWKN-002 to focus on low cost, low risk, rapid speed to market 505(b) (2) pathway

(For references see slide 21)

### Management



Anthony Tennyson



Jonatha n Held CFO



Prof. Davi d Nutt CHIEF RESEARCH



Owain Winfield HEAD OF PSYCHOLOGICAL





new / spark



**Imperial College** 

London









**Merrill Lynch** 



#### Board



George Scorsis CO-FOUNDER & CHAIRMAN CORPORATE BOARD



Anthony Tennyson CO-FOUNDER & CHIEF EXECUTIVE OFFICER



Paul Carter INDEPENDENT NON-EXECUTIVE DIRECTOR CORPORATE BOARD



Prof. John Papastergiou INDEPENDENT NON-EXECUTIVE DIRECTOR CORPORATE BOARD



Stephen Page INDEPENDENT NON-EXECUTIVE DIRECTOR CORPORATE BOARD







**GILEAD** 











### Alcohol Use Disorders Prevalence in the UK, US, EU4

1 - UK 2 - US 3 - EU4 1 million 29 million 9 million people in US suffer people in the UK people in EU4 suffer suffer with AUD with AUD with AUD 27,000 140,000 150,000 deaths per annum deaths per annum deaths per annum 90% are untreated in the UK, US, EU4 **75%** relapse rate for those who are treated with current standard of care



(For references see slide 22)

#### Other Substance Use and Certain Mental Health Disorder Prevalence in the US

**OPIOID USE** DISORDER

**DEPRESSION** 

**GENERALISED ANXIETY DISORDER** 

**POST TRAUMATIC STRESS DISORDER** 

Estimated to affect

2 million people in the US

Estimated to affect

21 million people in the US

Estimated to affect

6.8 million people in the US

Estimated to affect

13 million people in the US



(For references see slide 22)

#### **AUD Treatment Market**

#### 1 - UK

**55** 

National Health Care Trusts treating AUD in UK

Treating

100,000

patients for AUD in 2020

US\$4bn

direct medical costs a year

2 - US

14,500

Clinics treating AUD in UK

Treating

500,000

patients for AUD in 2020

Between

US\$27bn & US\$38bn

direct medical costs a year to public (65%) and private (35%) payers

3 - EU4

550,000

patients treated for AUD in 2020

US\$22bn

direct medical costs a year



(For references see slide 22)

## Awakn's Therapeutics Mechanism of Action

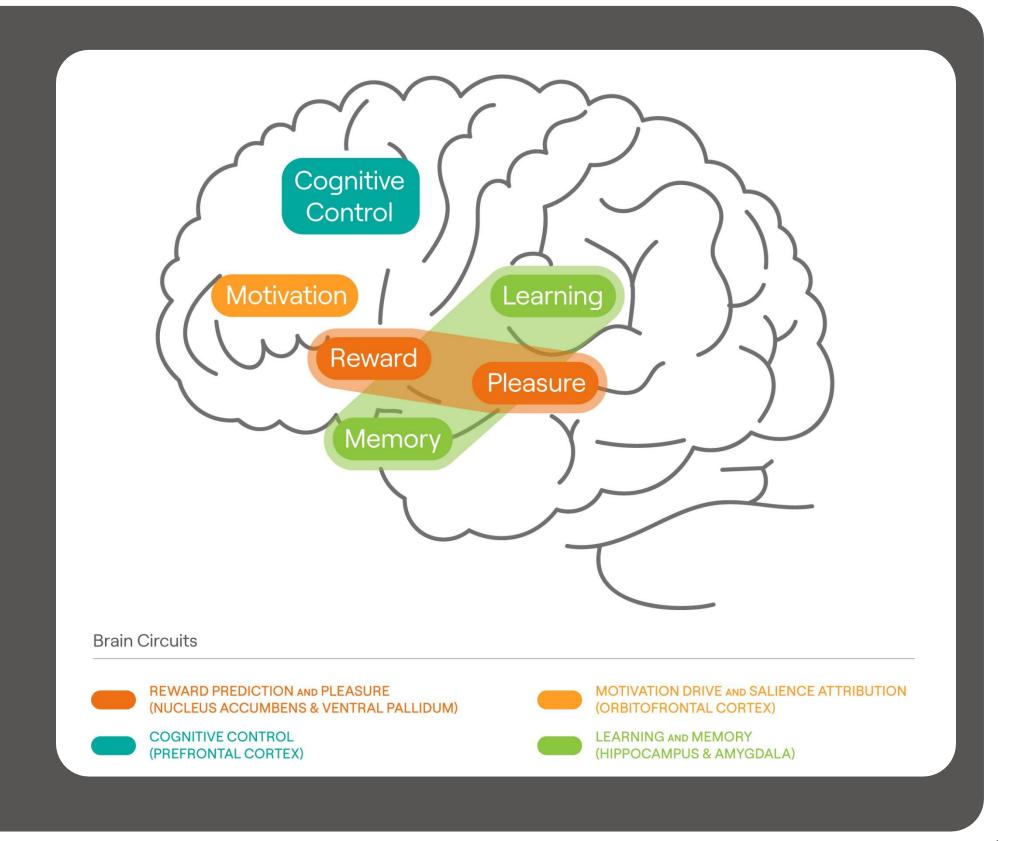
#### What are we doing differently?

Awakn's therapeutics target the brain circuits that drive addiction. These circuits control the behavioural drivers of addiction.

This disruption allows the individual to escape from the repetitive addictive behaviours and thoughts, and in doing so engage with a psychotherapeutic process to enable lasting positive change.

Our therapies work in conjunction with our medicines enabling the patients to regain control over their lives and helping them to learn new more adaptive ways to respond to addictive urges, cravings and the underlying processes that drive them.

Our therapies are manualized and our protocols are condensed, ensuring efficient use of healthcare resources, including people, time, and real estate.



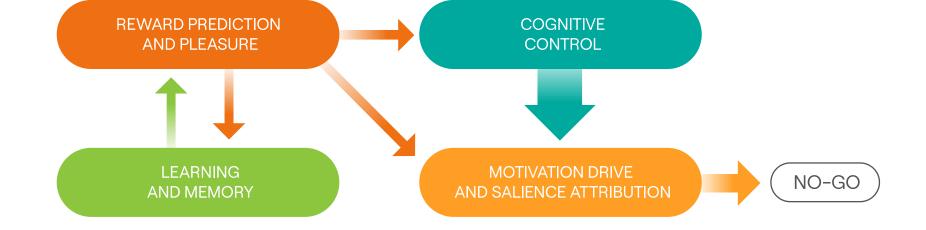
(For references see slide 21)



## Awakn's Therapeutics Mechanism of Action

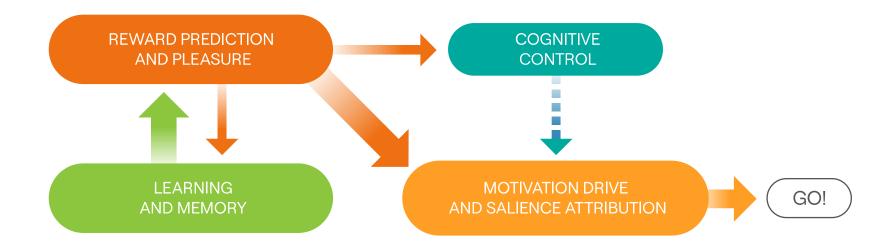
#### Balanced brain state - no addiction

Cognitive control controls the final decision making.



#### Addicted brain

Excessive drives from memory and reward/pleasure circuits depress cognitive control and enhance the drive and salience functioning so the cognitive control no longer controls the behaviour.





## Awakn's AUD Therapeutics Mechanism of Action

#### Racemic & Esketamine (AWKN-001 & AWKN-002)

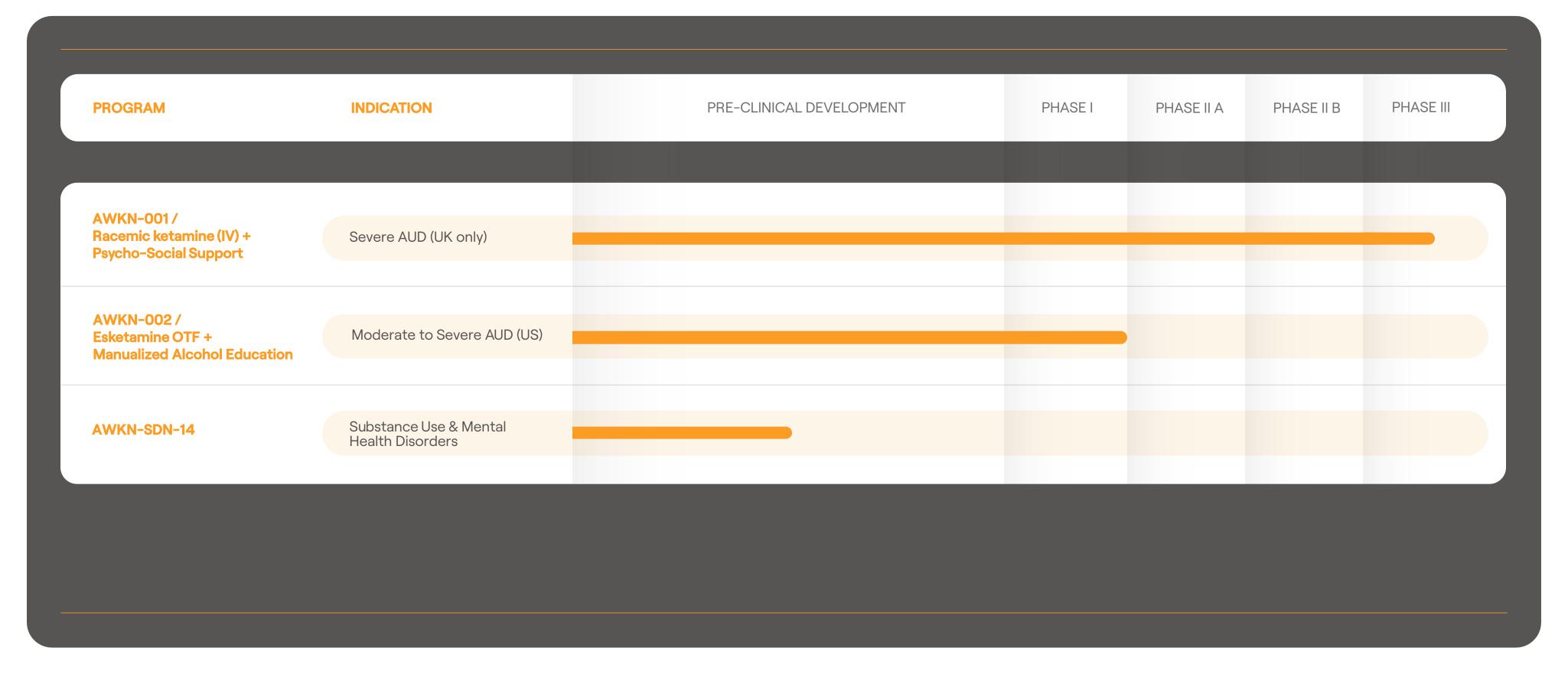
- Glutamate receptor antagonism
- Disruption of brain circuits
- Rupture of addiction networks
- Resetting addiction memories
- Increased neuroplasticity

#### AWKN-SDN-14

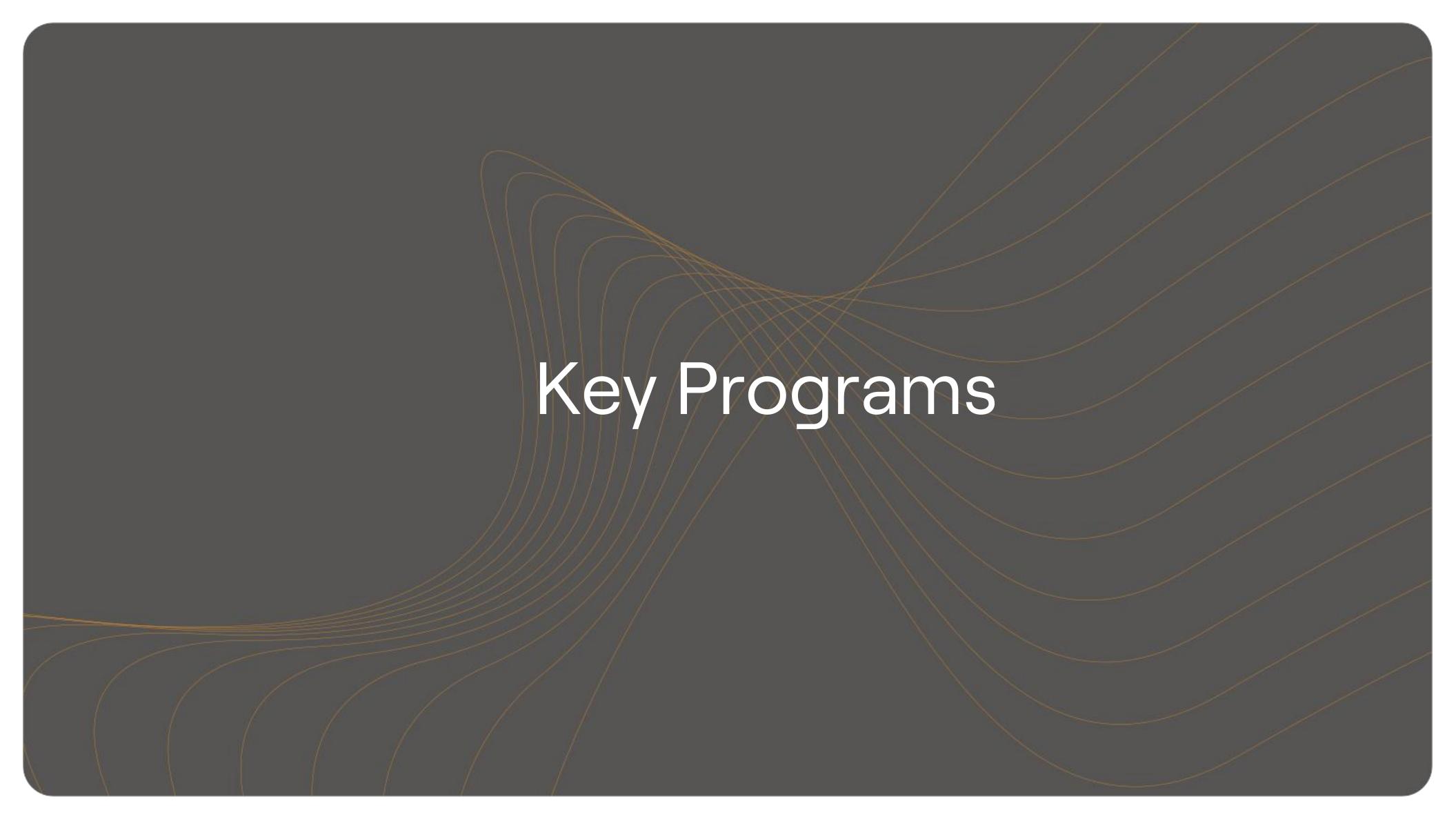
- Similar ratio of 5-HT and dopamine release to MDMA
- Improved kinetics of MDMA particularly faster clearance
- Novel IP with freedom to operate



# Pipeline







#### **AWKN-001**

#### Overview:

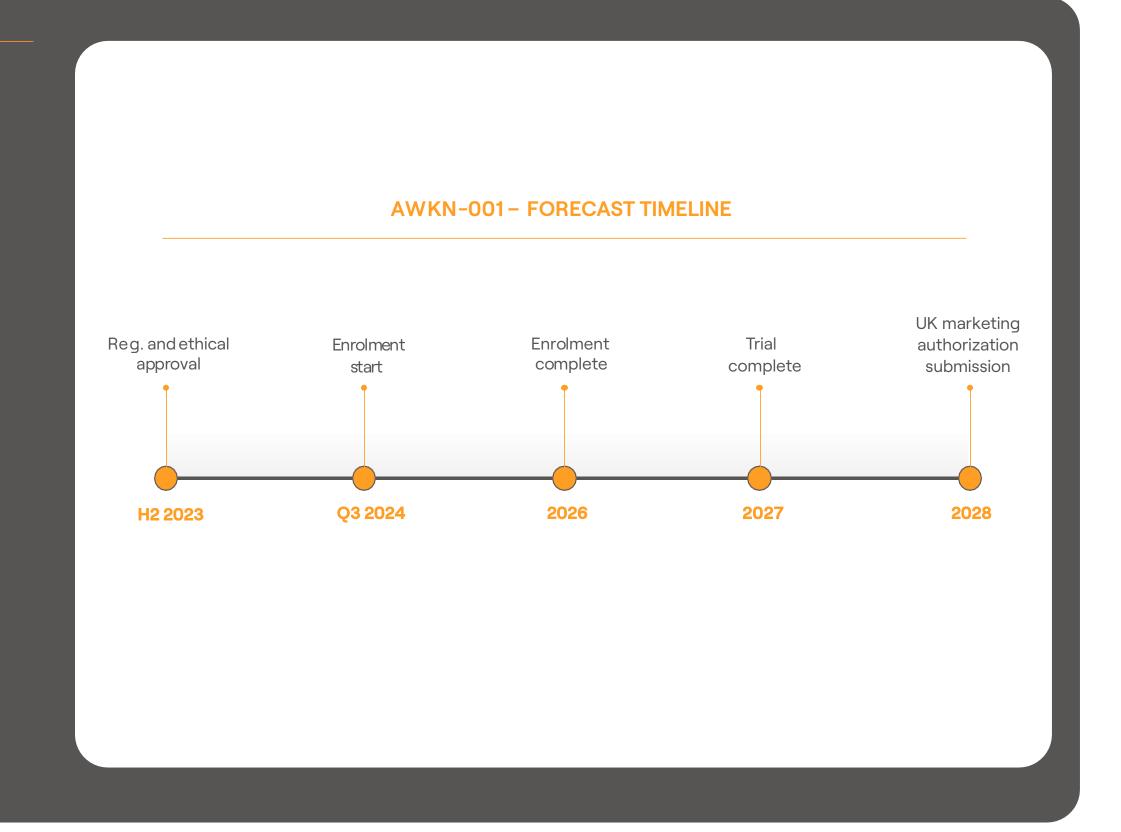
AWKN-001 is a first-of-its-kind combination therapy combining IV ketamine (an NMDA receptor antagonist) with copyrighted manualised relapse prevention cognitive behavioral therapy (CBT) targeting both the biological and psychosocial aspects of AUD.

#### Strong Clinical Evidence:

- Phase 2 results demonstrated a 50% reduction in Heavy Drinking Days (HDD) vs to placebo
- Long-Term Impact: 86% abstinence on average sustained for 6 months post-treatment, compared to just 2% pre-trial

#### Clinical Development & Regulatory Pathway:

- Phase 3 trial ongoing with strong Phase 2 data backing its potential
- Targeting a Regulation 52b hybrid application in the UK for approval as a new indication – provide 8 years data exclusivity and 2 additional years market protection





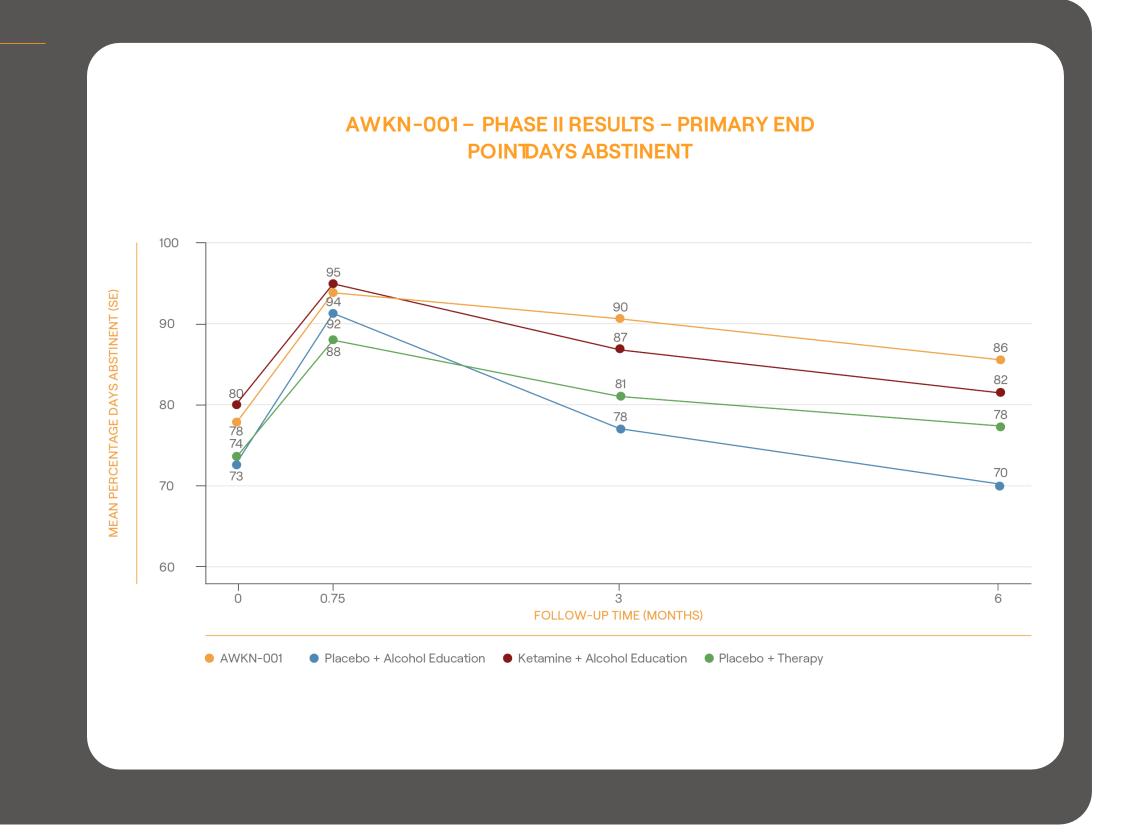
#### AWKN-001 - Ph2

#### Results, AWKN-001:

- 86% abstinence on average in the 6 months post treatment vs 70% in Arm 4
  - (Placebo + Alcohol Education), and 2% abstinence pre-trial.
- 2.7 times more likely than Arm 4 to have no HDD in the 6 months post treatment
- 50% reduction in HDD in the 6 months post treatment vs Arm 4

#### Ph2 – Trial design:

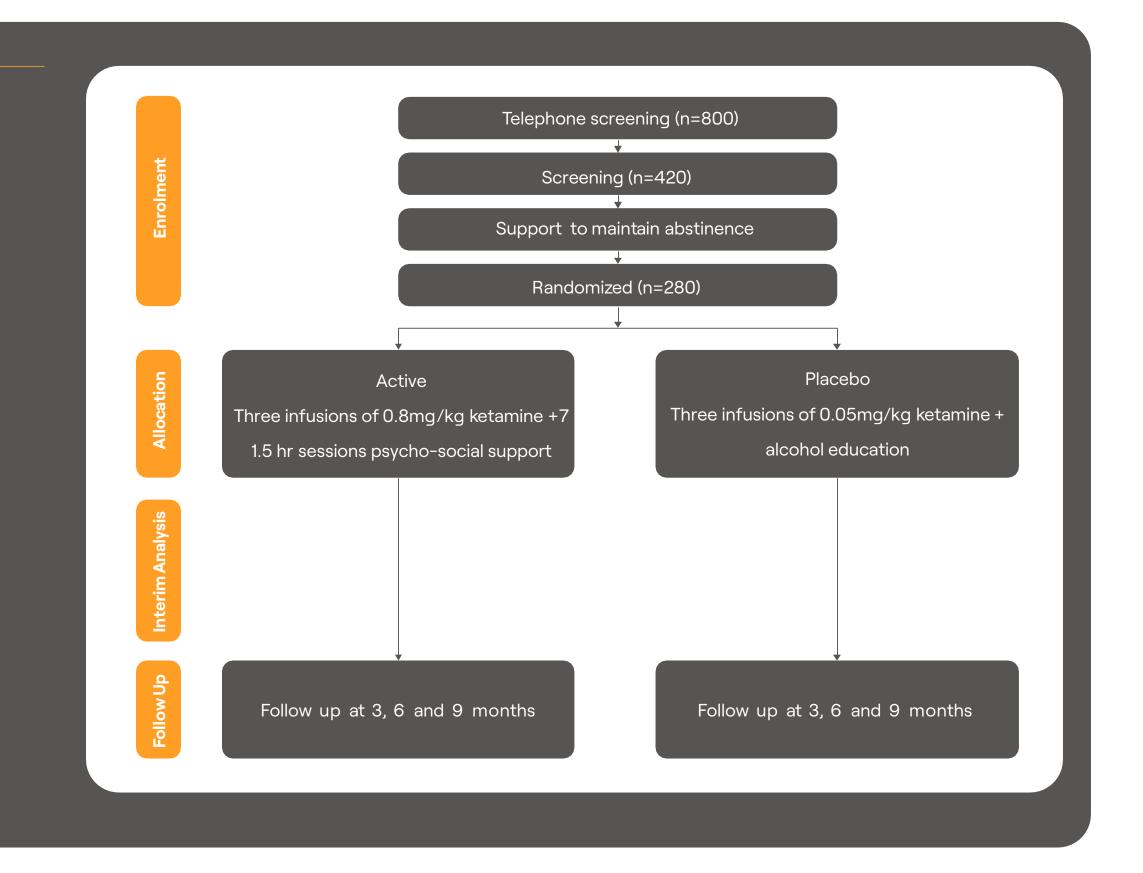
- Four-armed, double-blind placebo clinical trial, N=96:
  - Arm 1 (AWKN-001): Ketamine + manualized relapse prevention CBT. N=24
  - Arm 2: Ketamine + Alcohol Education. N=24
  - Arm 3: Placebo + + manualized relapse prevention CBT. N=24
  - Arm 4: Placebo + Alcohol Education. N=24
- Primary endpoint: Days Abstinent
- Co-Primary endpoint: Relapse
- Exploratory analysis: Number of Heavy Drinking Days (HDD)





#### AWKN-001 - Ph3

- n=280 two-armed placebo-controlled trial
- Trial co-funded by UK Dept of Health and Social Care
- Cost to Awakn of Phase 3 capped at only £800,000
- Nine NHS Trust Sites
- Trial started Q3 2024
- MHRA innovative passport (ILAP) awarded





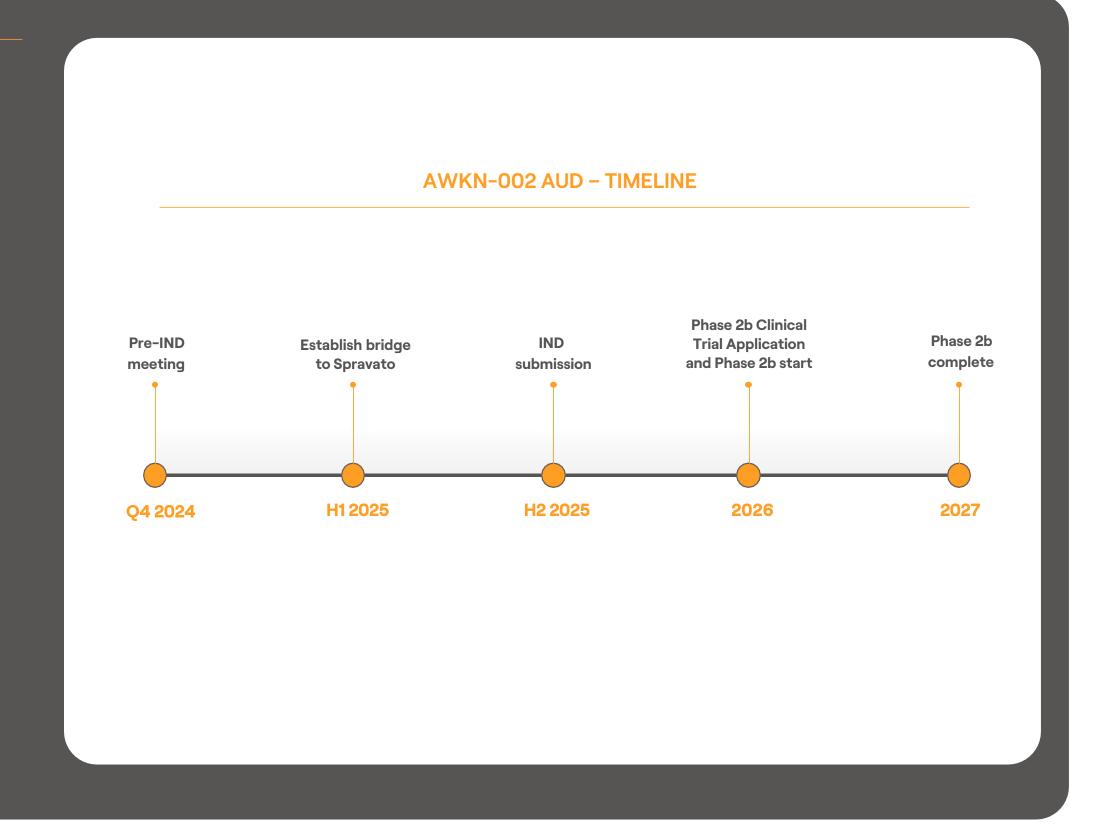
#### AWKN-002

#### Overview:

AWKN-002 is a novel combination therapy consisting of a patent pending proprietary esketamine oral thin film (OTF) with manualised psycho-social support to treat moderate to severe AUD in the US.

#### Clinical Development & Regulatory Pathway:

- In Phase 2b planning
- Positive Pre-Investigational New Drug Application (IND) meeting with FDA
- Agency supportive of 505(b)(2) pathway refencing to J&J's Spravato
- Agency supportive of Phase 2b once bridge established to Spravato
- Spravato forecast to achieve US\$1bn in annual sales in 2024





#### AWKN-SDN-14

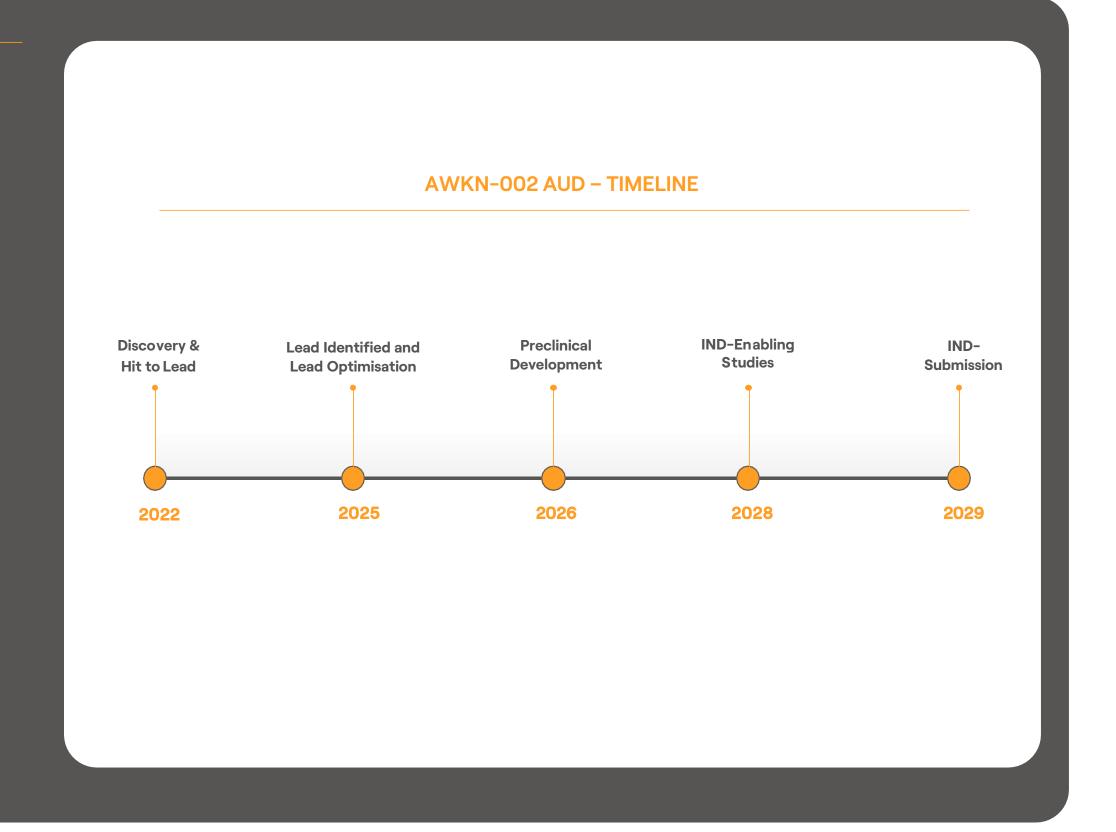
#### Overview:

AWKN-SDN-14 are a series of serotonin, dopamine, and noradrenaline modulators under pre-clinical investigation by Awakn.

Being assessed for potential to promote pro-social behavior and offer an improved safety profile compared to existing treatments being developed PTSD.

Pro-social behavior is increasingly recognised as a key factor in addressing PTSD.

Enhancing these behaviors may help individuals with PTSD overcome feelings of isolation, rebuild interpersonal relationships, and engage more effectively in therapeutic interventions.





# Near-term Catalysts

#### 2025

- Acquisition of Awakn completed
- AWKN-001 Phase 3 recruitment increases
- AWKN-002 Phase 2b IND submission
- AWKN-SND-14 Lead identified, and lead optimisation initiated

#### 2026

- AWKN-001 recruitment completed
- AWKN-002 Phase 2b clinical trial application and Phase 2b start
- AWKN-SND-14 pre-clinical development initiated



# Cap Table

Capital Structure		
	Common Shares	41,662,623
	Warrants	15,073,178
	Stock Options	1,784,828
	DSU's and RSU's	1,525,172
	Full Diluted	60,045,801
	Management Ownership	16.48%
	Locked Up Shares	24.75%



# Awakn Analyst Coverage

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2 111001	 <b>.</b>	

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#### Awakn Coverage

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Jason Mc Carthy, Maxim Group jmccarthy@maximgrp.com



# References

In relation to references on slides 4,6 & 7

STATISTIC	SCOPE	SOURCE
Number of people with AUD	US	US Substance Abuse and Mental Health Services (SAMHSA), 2022 National Survey on Drug Use and Health
Number of people with AUD	UK	UK The National Institute for Health and Care Excellence (NICE) - Alcohol-use disorders diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence
Number of people with AUD	GER	Jahrbuch Sucht 2020 der Deutschen Hauptstelle für Suchtfragen
Number of people with AUD	FRA	Inserm. Reducing the harm associated with alcohol consumption. Summary and recommendations. Collection Expertise collective. Montrouge: EDP Sciences, 2022.
Number of people with AUD	ITA	Istituto Superiore di Sanità EpiCentro
Number of people with AUD	ESP	Monografía. Alcohol 2021: Consumo y Consecuencias
Number of people with OUD	US	Opioid Use Disorder, Alexander M.Dydyk; Nitesh K. Jain; Mohit Gupta.
Number of people with Depression	US	US National Institute of Mental Health, Depression. https://www.nimh.nih.gov/health/statistics/major-depression
Number of people with GAD	US	Anxiety & Depression Association of America, Anxiety Disorders-Facts & Statistics. https://adaa.org/understanding-anxiety/facts-statistics
Number of people with PTSD	US	VA National Center for PTSD. US Department of Veterans Affairs
AUD relapse rates		Mekonen, T., Chan, G. C. K., Connor, J., Hall, W., Hides, L. and Leung, J. (2021) 'Treatment rates for alcohol use disorders: a systematic review and meta-analysis'
AUD treatment rates	US, UK, EU	NCBI. ww.ncbi.nlm.nih.gov/pmc/articles/PMC4534056/
Annual AUD deaths	US, UK, EU	OECD. www.oecd-ilibrary.org/sites/82129230-en/1/3/2/2/4/index.html?itemId=%2Fcontent%2Fpublication% 2F82129230-en&csp_=e7f5d56a7f4dd03271a59acda6e2be1b&itemIGO=oecd&itemContentType=book



# References

In relation to references on slides 5,6 & 7

STATISTIC	SCOPE	SOURCE
AUD economic burden	US	Sacks JJ, Gonzales KR, Bouchery EE, Tomedi LE, Brewer RD. 2010 National and State Costs of Excessive Alcohol Consumption.
AUD economic burden	UK	Lister, G. et al (2006), Comparing the Societal Impacts of Common Health Risks. National Social Marketing Centre.
AUD economic burden	GER	DHS Jahrbuch Sucht 2020 der Deutschen Hauptstelle für Suchtfragen (DHS)
AUD economic burden	FRA	Le Cout Social des Drogues: Estimation en France. Le Cout Social des Drogues: Estimation en France
AUD economic burden	ITA	OECD: Preventing Harmful Alcohol Use: Italy
AUD economic burden	ESP	Alcohol consumption in Spain and its economic cost: A mathematical modeling approach. Francisco-José Santonja, Emilio Sánchez, María Rubio, José-Luis Morera



