

Solvonis Therapeutics plc

LSE:SVN
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Therapeutics
for mental health
& addiction



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Solvonis

Solvonis is an innovative biotechnology company developing intellectual property related to the treatment of mental health disorders and substance use disorders, and co-developing therapeutics for mental health disorders, with an initial focus on Post-Traumatic Stress Disorder (PTSD).

PTSD affected approximately 13 million adults in the U.S. in 2020, with the Company estimating a current affected population of 20 million across the U.S., UK, and key EU markets.

We are building a UK based Central Nervous System (CNS) biotech.

- **CNS (Neurology) is the second largest therapeutic area of biopharma R&D globally after Oncology**
- **CNS (Neurology) conditions tend to have:**
 - Large address markets
 - Poor current standards of care
 - Significant unmet medical needs
- **Big Pharma is deploying meaningful capital in CNS**
 - Jan 2025: J&J bought Intra-Cellular for US\$14bn
 - Sep 2024: Bristol Myers bought Karuna for US\$14bn

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Recent History

- **2017:** Company incorporated as Graft Polymer
- **Jan 2022:** Admitted to the LSE Standard List
- **2023 – 2024:** Trading difficulties
- **April 2024:** Accounts for financial year ended 31 Dec 2023 published, net loss £3.3m, total negative equity of £1.9m
- **May 2024:** Divestment of loss-making industrial plastics unit
- **May 2024:** Appointment of Anthony Tennyson as CEO
- **June 2024:** Company prioritise opportunities in the healthcare industry
- **July 2024:** Appointment of Prof. David Nutt as Senior Scientific Advisor
- **July 2024:** Company enters partnership Awakn Life Science to develop new generation on medicines to treat PTSD
- **September 2024:** Appointment of Dennis Purcell as Chair
- **December 2024:** Company enters binding Lol to acquire Awakn
- **January 2025:** Company rebrands to Solvonis Therapeutics plc

Solvonis has offered to acquire Awakn

to create leading UK domiciled and UK listed clinical stage neuropsychiatric biotech dedicated to developing therapeutics for mental health disorders and substance use disorders with a focus on alcohol addiction and PTSD conditions with significant unmet medical needs in the UK, US and EU.

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Awakn

Awakn is a clinical-stage biotechnology company developing therapeutics for substance use disorders and mental health disorders. Awakn has a near-term focus on Alcohol Use Disorder (AUD).

AUD affects approximately 29 million adults in the US with Awakn estimating a current affected population of 40 million in the US and US and key European markets for which the current standard of care is inadequate.

Management



CEO
Anthony Tennyson



CHIEF RESEARCH
OFFICER
Prof. David Nutt



FINANCIAL DIRECTOR
Ryan Neates

Board



CEO
Anthony Tennyson



CHAIR
Dennis Purcell

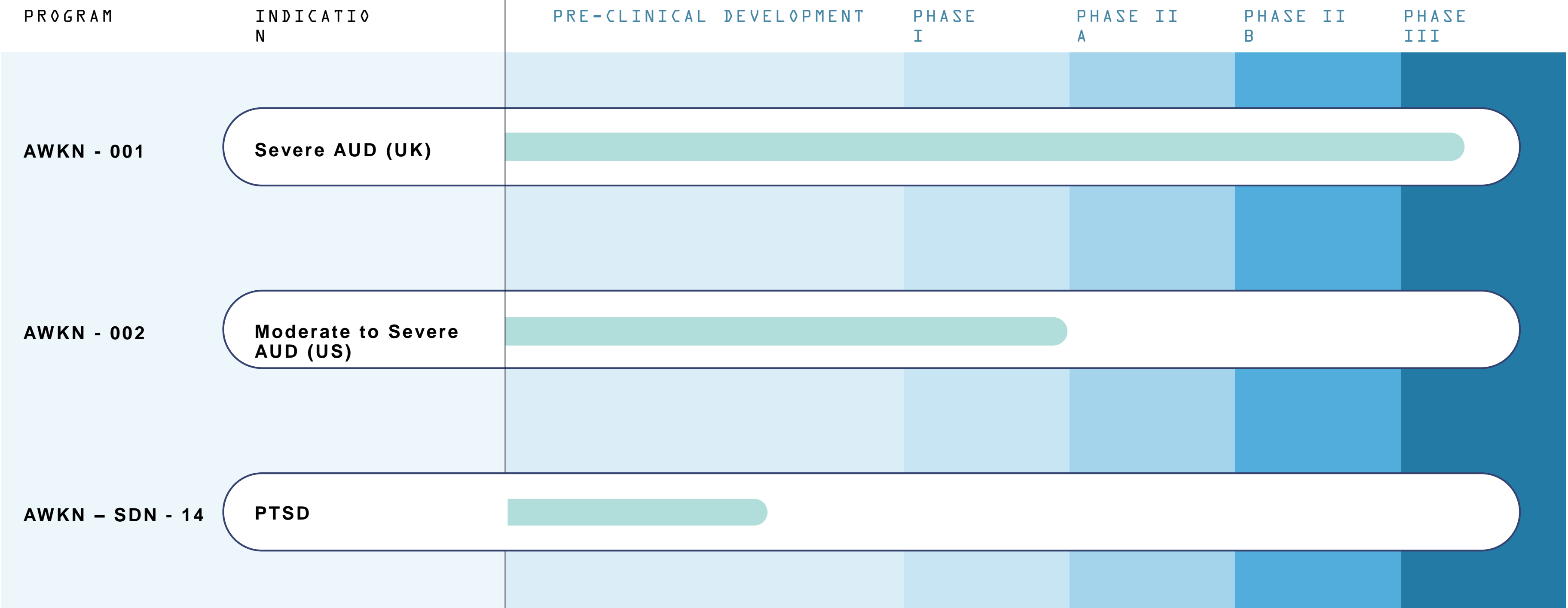


NON-EXECUTIVE DIRECTOR
Nicholas Nelson



Awakn's Pipeline

(being acquired by Solvonis)



Alcohol Use Disorders Prevalence in the UK, US, EU4

(For references see slide 21)

UK

1
million
* people
suffer with
AUD

27,000
deaths per
annum



US

29
million
people suffer
with AUD

140,000
deaths per
annum



EU4 (Germany, France, Italy, Spain)

9
million
* people
suffer with AUD

150,000
deaths per
annum



* Estimated by the Company

Post-Traumatic Stress Disorder Prevalence in the UK, US, EU4

(For references see slide 21)

UK

2.4
million
* people
suffer with
PTSD



US

13
million
people suffer
with PTSD



EU4 (Germany, France, Italy, Spain)

4.6
million
* people
suffer with AUD



* Estimated by the Company

Awakn's Therapeutics Mechanism of Action



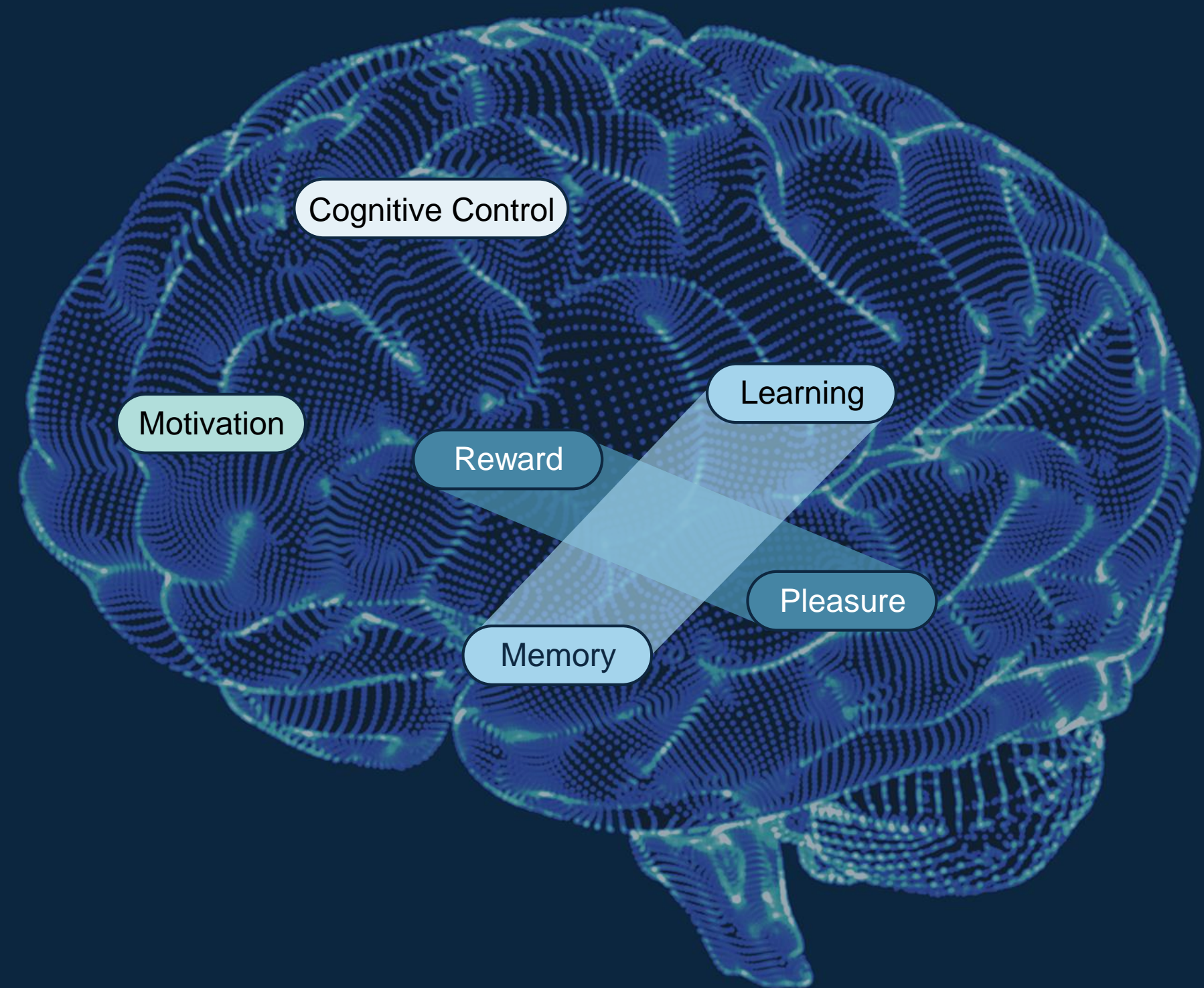
Brain Circuits

Reward prediction and pleasure
(NUCLEUS ACCUMBENS & VENTRAL PALLIDUM)

Cognitive control

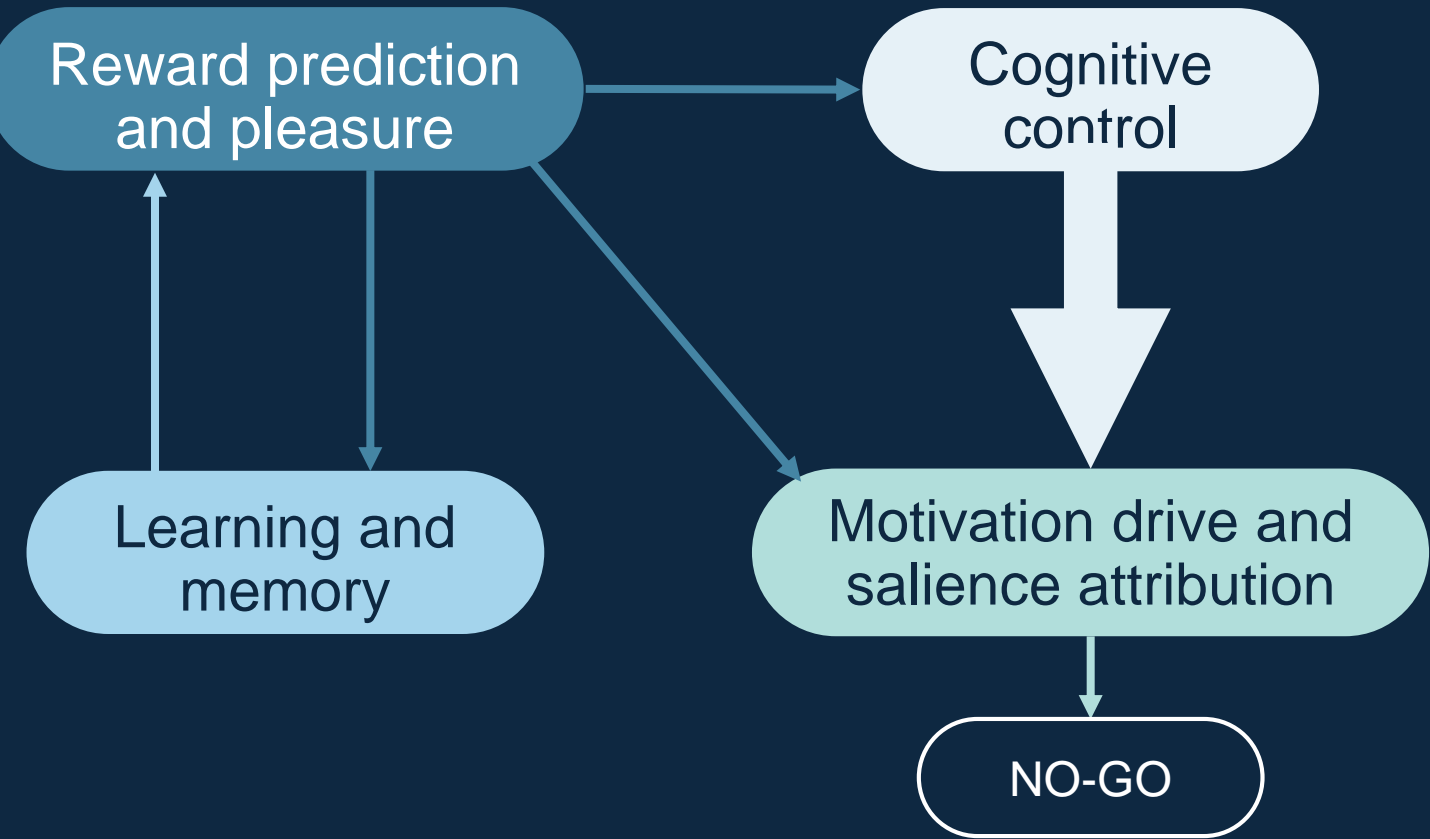
Motivation drive and salience attribution

Learning and memory



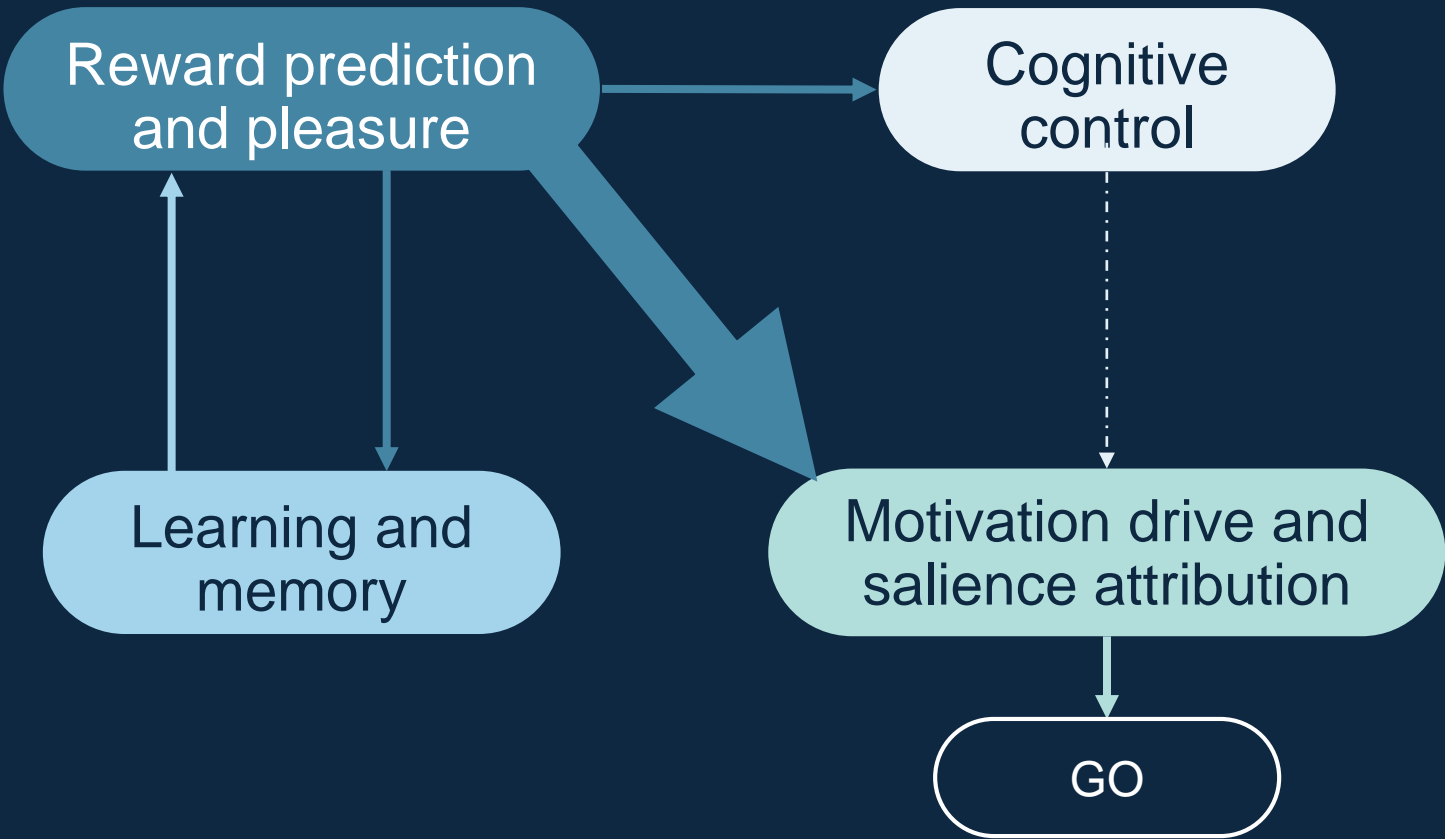
Balanced brain state

Cognitive control controls the final decision making.



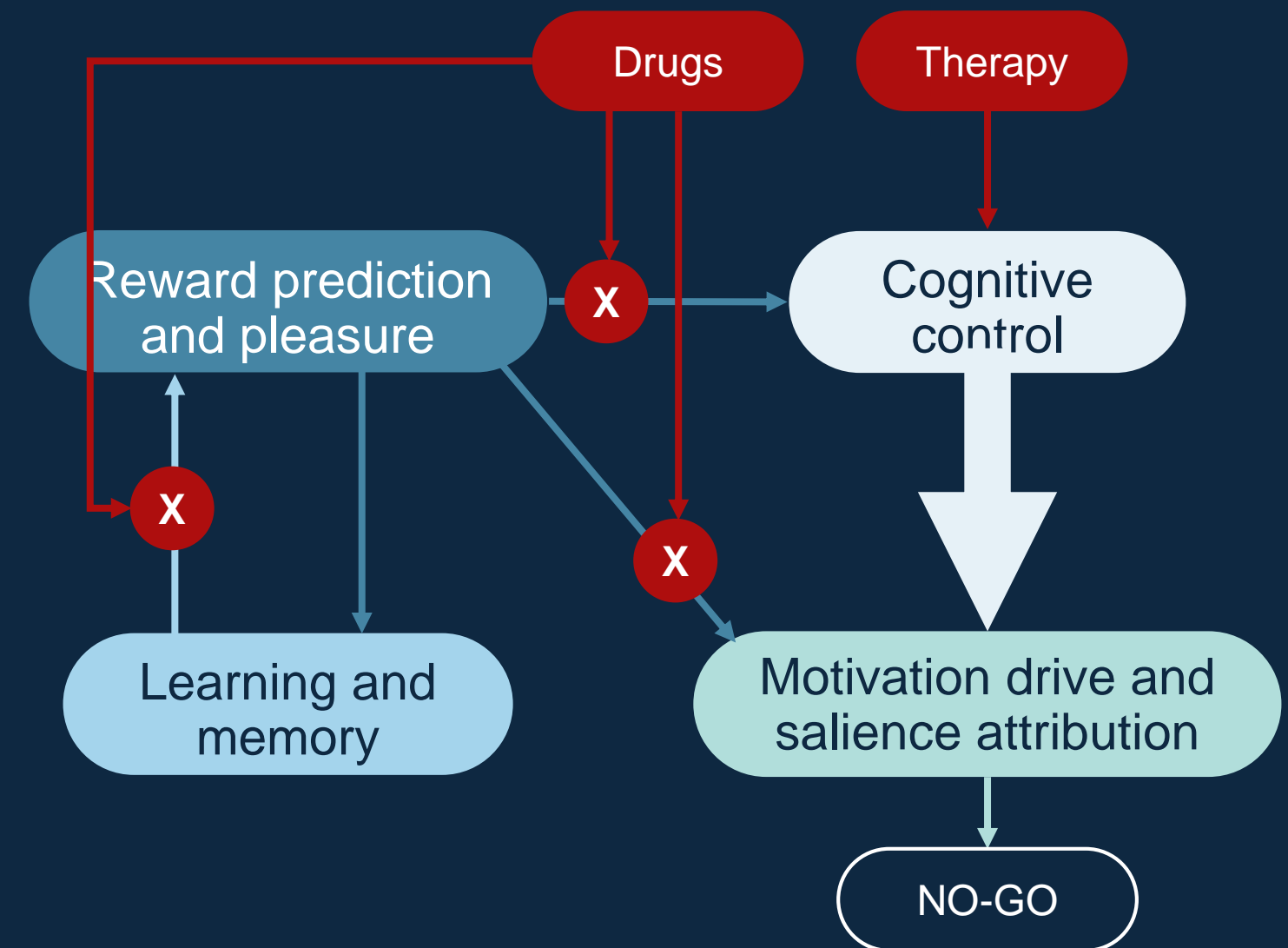
Addicted brain

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.

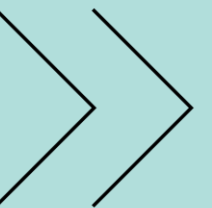


Awakn treatment disrupt the addiction circuits to restore balance in the brain

Awakn's approach using proprietary therapeutics, disrupts the circuits and the deep-rooted addictive behaviours with drugs and allows the therapy to penetrate deeper and to restore the necessary control back in the cognitive control centre.



Awards Key Programs



AWKN-001

for Severe AUD for UK
Market

Overview:

AWKN-001 is a first-of-its-kind combination therapy combining IV ketamine (an NMDA receptor antagonist) with copyrighted manualized 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 Mixed New application in the UK for approval as a new indication – provide 8 years data exclusivity and 2 additional years market protection

AWKN-001 FORECAST TIMELINE

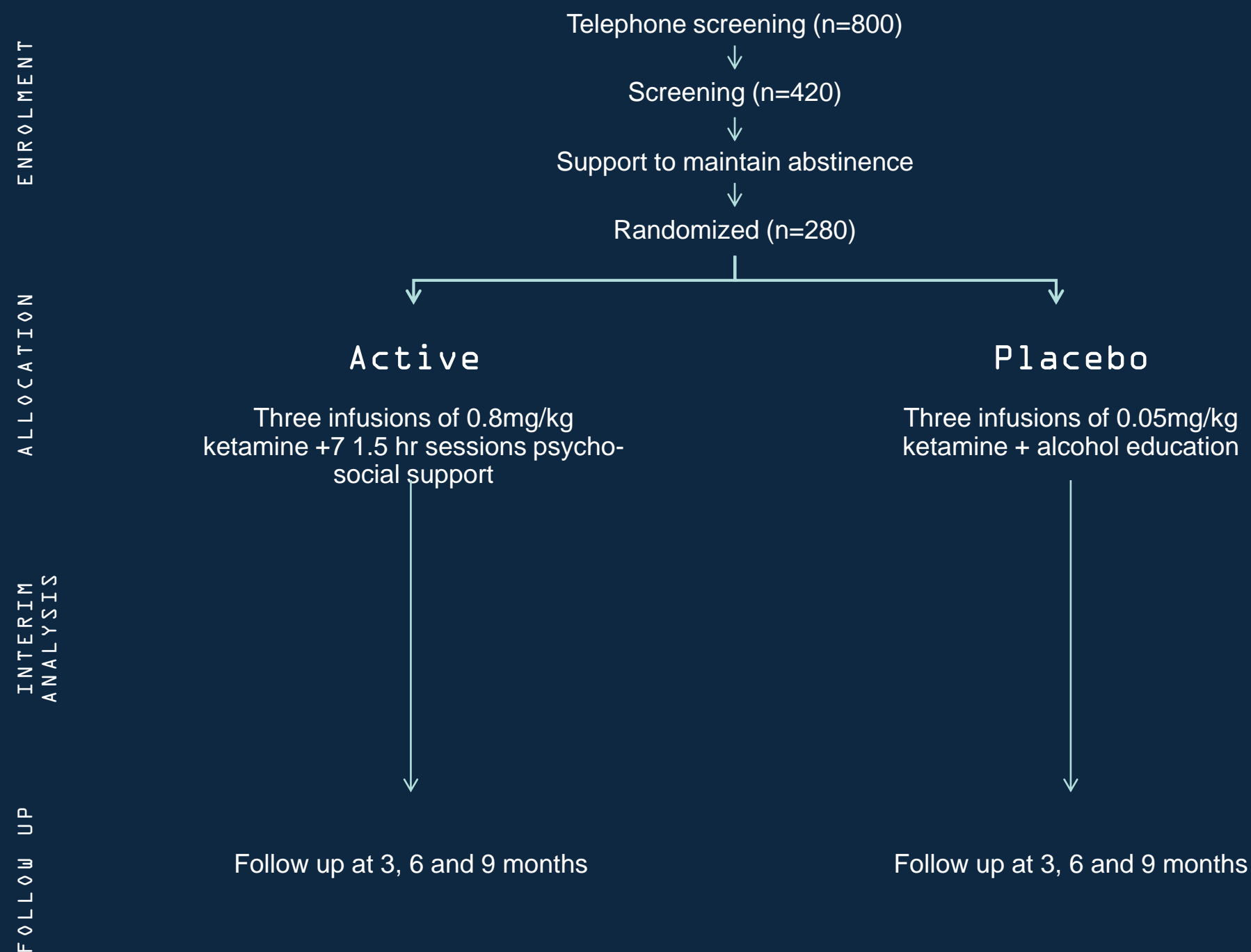
| | H2 2023 | Q3 2024 | 2026 If) | 2027 (f) | 2028 (f) |
|--|------------------------------------|-----------------------|---------------------------|-------------------|---|
| | Reg. and ethical approval | Enrolmen t started | Enrolmen t complete | Trial complete | UK marketing authorization submission |

Treatment Cycle

20 hours delivered outpatient. 2 hours with physician, 18 hours with low intensity therapist, 3 ketamine sessions with manualized relapse prevention CBT

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 potentially definitive trial capped at only £800,000
- Nine NHS Trust Sites
- Trial started Q3 2024
- MHRA innovative passport (ILAP) designated
- Market access discussions with UK Dept. of Health started to start in 2024



AWKN-002

for Moderate to Severe AUD for US Market

Overview:

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

Clinical Development & Regulatory Pathway

- In Phase 2b planning
- Positive Pre-IND meeting with FDA
 - Agency supportive of 505(b)(2) pathway refencing to J&J’s Spravato
 - Agency supportive of ph2b once bridge established to Spravato
- Spravato forecast to reach US\$1bn in annual sales in 20242

AWKN-002 AUD - TIMELINE

| | | | | |
|-----------------|------------------------------|----------------|--|-------------------|
| Q4 2024 | 2025 (f) | H2 2025 (f) | 2026 | 2027 (f) |
| Pre IND meeting | Establish bridge to Spravato | IND submission | Phase 2b Clinical Trial Application and Phase 2b start | Phase 2b complete |

Intellectual Property

- Esketamine OTF formulation patents filed
- Esketamine OTF AUD method of use patents filed
- Patents could increase US market data exclusivity to 5 years

AWKN-SND-14

for PTSD

Overview:

AWKN-SDN-01 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 for PTSD.

Pro-social behavior is increasingly recognized 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.

AWKN-SND-14 - ESTIMATED TIMELINE

| | | | | |
|-------------------------|---------------------------------------|-------------------------|----------------------|----------------|
| | | | | |
| 2022 | 2025 (f) | 2026 (f) | 2028 (f) | 2029 (f) |
| Discovery & Hit to Lead | Lead Identified and Lead Optimisation | Preclinical Development | IND-Enabling Studies | IND-Submission |

Status

- Patents filed
- Hit to Lead series program completed
- In vitro and in vivo data shows efficacy for drug-like hits

Near-Term Catalysts

2025

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

2026

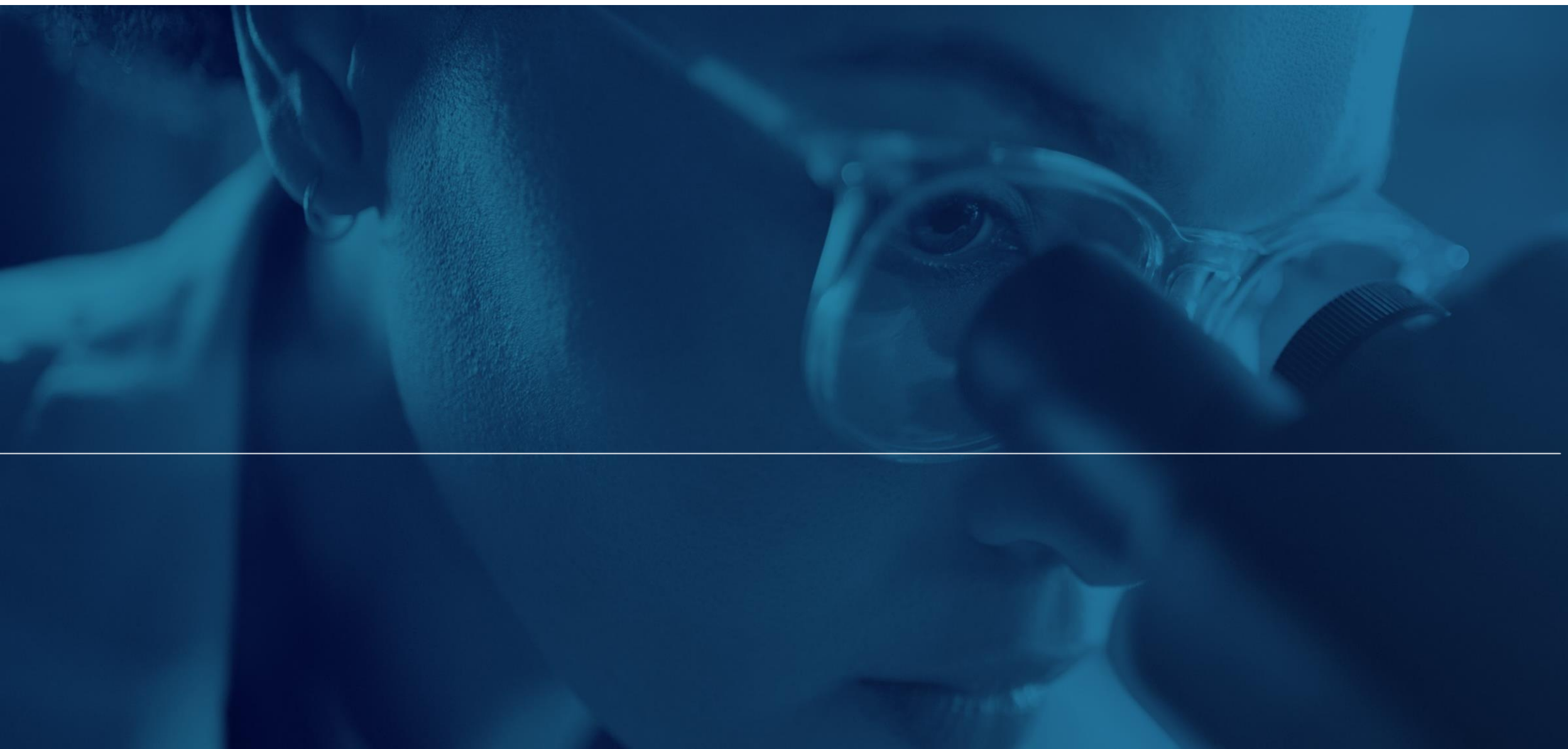
- AWKN-001 recruitment forecast to complete
- AWKN-002 Phase 2b clinical trial application in the US and Phase 2b start
- AWKN-SND-14 pre-clinical development initiated

References

In relation to references on slides 6-8

| 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 | ITS | Istituto Superiore di Sanità EpiCentro |
| Number of people with AUD | ESP | Monografía. Alcohol 2021: Consumoy Consecuencias |
| Number of people with PTSD | US | VA National Center for PTSD. US Department of Veterans Affairs. |
| Number of people with PTSD | UK | NHS, Adult Psychiatric Morbidity Survey: Survey of Mental Health and Wellbeing, England, 2014. |
| Number of people with PTSD | GER | Maercker, A., Forstmeier, S., Wagner, B. et al. Posttraumatische Belastungsstörungen in Deutschland. Nervenarzt 79, 577–586 (2008). |
| Number of people with PTSD | FRA | Nemeroff, Charles B., and others, 'Trauma and PTSD in Europe', in Charles B. Nemeroff, and Charles Marmar (eds), Post-Traumatic Stress Disorder (New York, 2018; online edn, Oxford Academic, 1 Sept. 2018). |
| Number of people with PTSD | ITS | Nemeroff, Charles B., and others, 'Trauma and PTSD in Europe', in Charles B. Nemeroff, and Charles Marmar (eds), Post-Traumatic Stress Disorder (New York, 2018; online edn, Oxford Academic, 1 Sept. 2018) |
| Number of people with PTSD | ESP | Nemeroff, Charles B., and others, 'Trauma and PTSD in Europe', in Charles B. Nemeroff, and Charles Marmar (eds), Post-Traumatic Stress Disorder (New York, 2018; online edn, Oxford Academic, 1 Sept. 2018) |

Thank you



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THERAPEUTICS