

Awakn™  
Life Sciences Corp

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# Corporate Presentation

July 2024

CSE: AWKN | OTCQB: AWKNF

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

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Forward-looking statements contained herein are made as of the date of this presentation and the Company disclaims, other than as required by law, any obligation to update any forward-looking statements whether as a result of new information, results, future events, circumstances, or if management’s estimates or opinions should change, or otherwise. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, the reader is cautioned not to place undue reliance on forward-looking statements.

# 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 filed

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**  
CEO



**Jonathan Held**  
CFO



**Prof. David Nutt**  
CHIEF RESEARCH OFFICER



**Owain Winfield**  
HEAD OF PSYCHOLOGICAL SERVICES



# 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





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

## 1 - UK

**2 million**  
people in the UK suffer  
with AUD

**27,000**  
deaths per annum

## 2 - US

**29 million**  
people in US suffer  
with AUD

**140,000**  
deaths per annum

## 3 - EU4

**9 million**  
people in EU4 suffer  
with AUD

**150,000**  
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 21)

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

OPIOID USE  
DISORDER

Estimated to affect  
**2 million**  
people in the US

DEPRESSION

Estimated to affect  
**21 million**  
people in the US

GENERALISED  
ANXIETY DISORDER

Estimated to affect  
**6.8 million**  
people in the US

POST TRAUMATIC  
STRESS DISORDER

Estimated to affect  
**13 million**  
people in the US

(For references see slide 21)

# AUD Treatment Market

## 1 - UK

**55**

National Health Care Trusts  
treating AUD in UK

Treating

**100,000**

patients for AUD in 2020

Between

**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 21)

# Awakn's Therapeutics Mechanism of Action

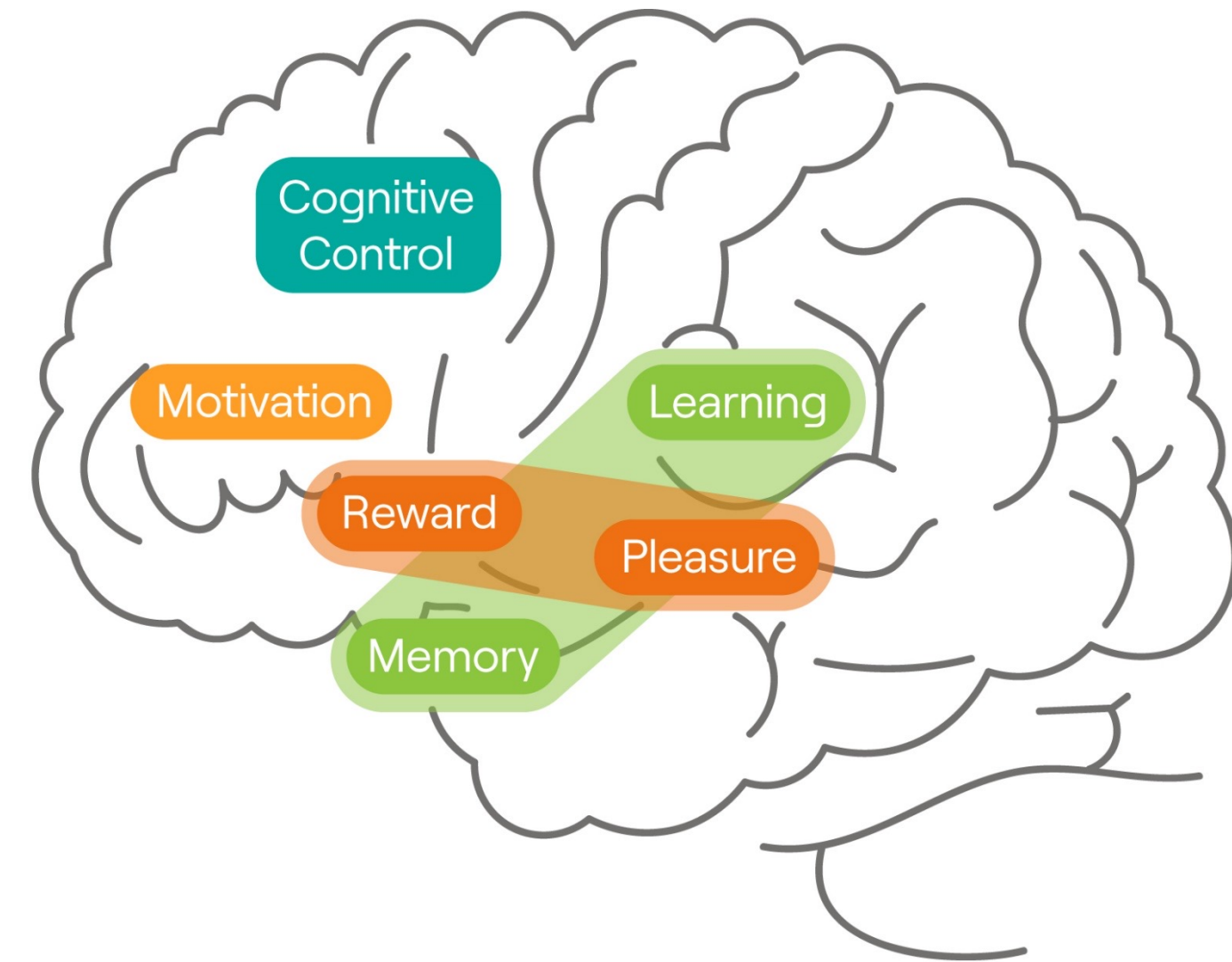
## What are we doing differently?

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.



Brain Circuits

**REWARD PREDICTION AND PLEASURE**  
(NUCLEUS ACCUMBENS & VENTRAL PALLIDUM)

**COGNITIVE CONTROL**  
(PREFRONTAL CORTEX)

**MOTIVATION DRIVE AND SALIENCE ATTRIBUTION**  
(ORBITOFRONTAL CORTEX)

**LEARNING AND MEMORY**  
(HIPPOCAMPUS & AMYGDALA)

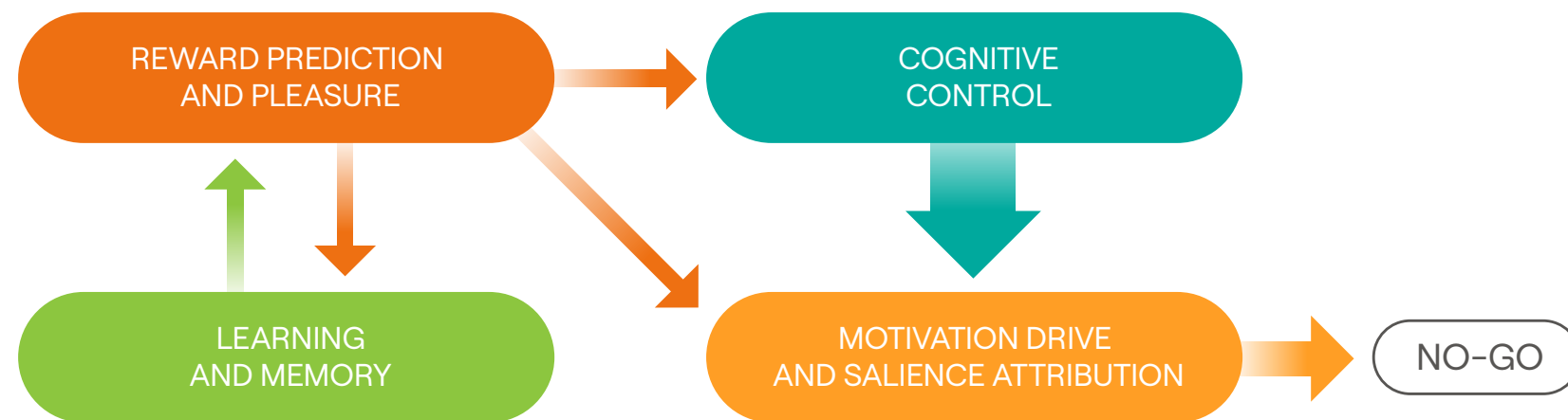
(For references see slide 21)



# Awakn's Therapeutics Mechanism of Action

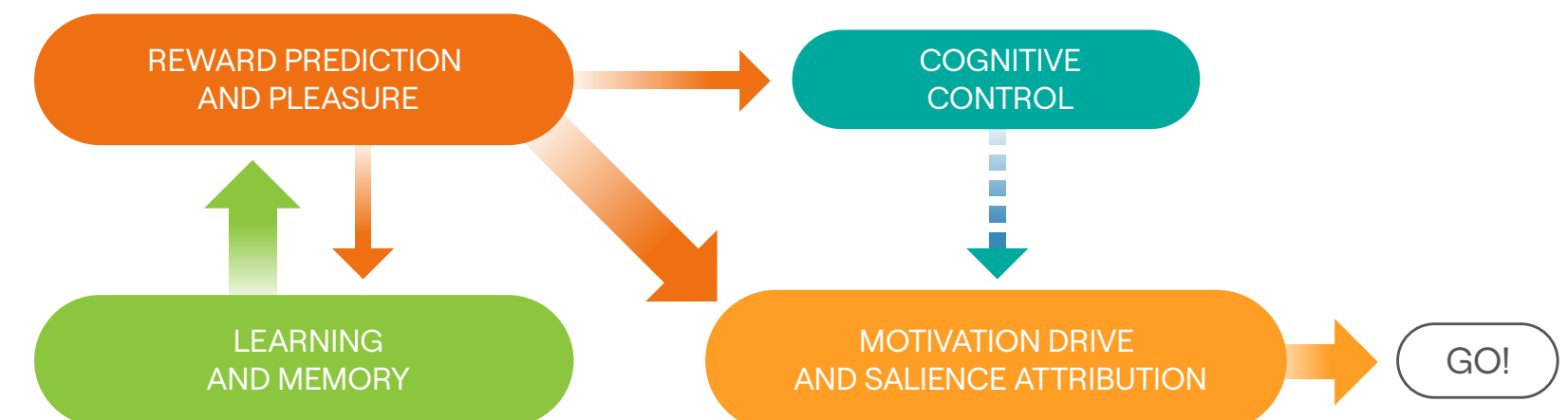
## Balanced brain state – no addiction

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

## Ketamine (Racemic & Esketamine)

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

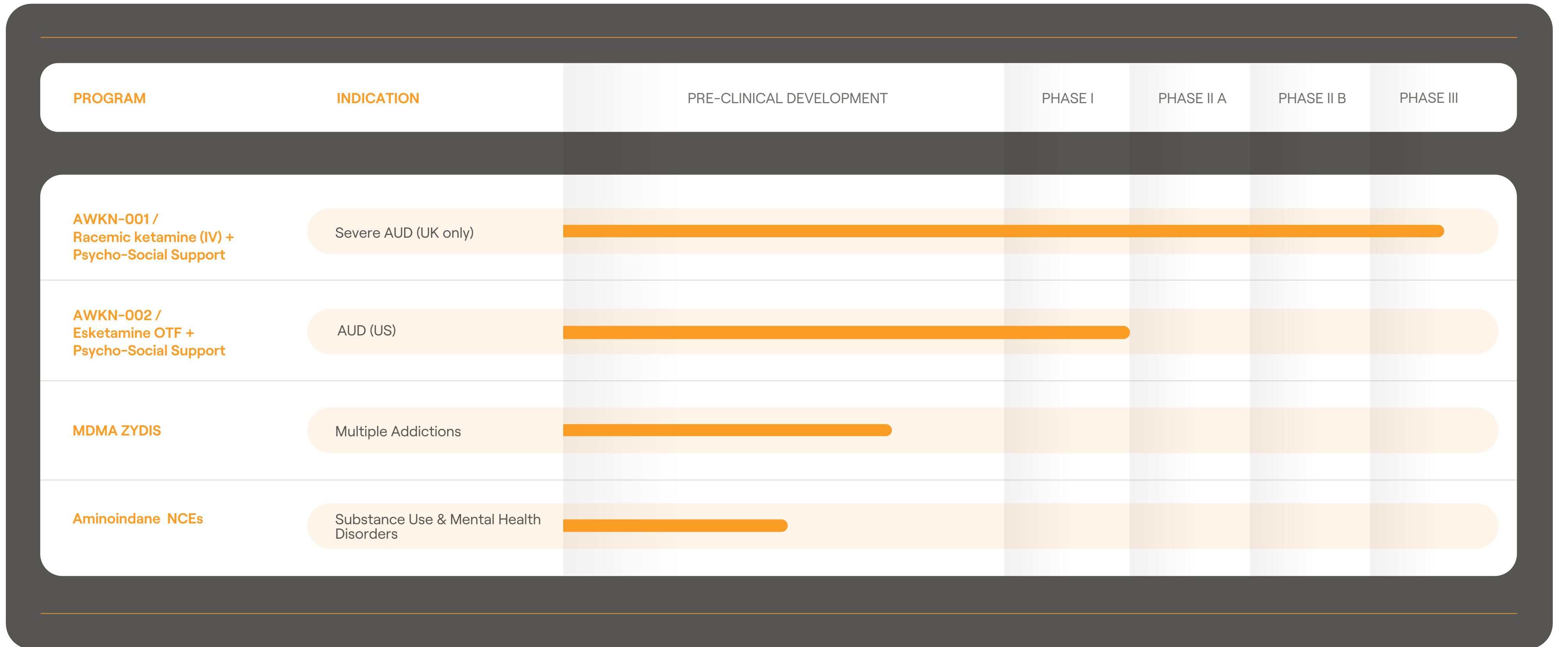
## MDMA

- Serotonin release
- Oxytocin release
- Suppress amygdala activity
- Allows re-engagement with traumatic memories
- Extinction of PTSD symptoms

## Awakn's Entactogenic NCE's

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

# Pipeline





# Key Programs

# AWKN-001

AWKN-001 - is a novel medication-assisted treatment for SAUD, consisting of an N-methyl-D-aspartate receptor-modulating drug (ketamine) delivered intravenously (IV) in combination with manualized psycho-social support. AWKN-001 is currently in phase 3 planning. The phase 3 trial ("MORE-KARE") will be run by the University of Exeter and is co-funded by the Efficacy and Mechanism Evaluation (EME) Programme (a partnership between the UK National Institute for Health and Care Research (NIHR) and the UK Medical Research Council (MRC)) and Awakn Life Sciences.

## Treatment Cycle:

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

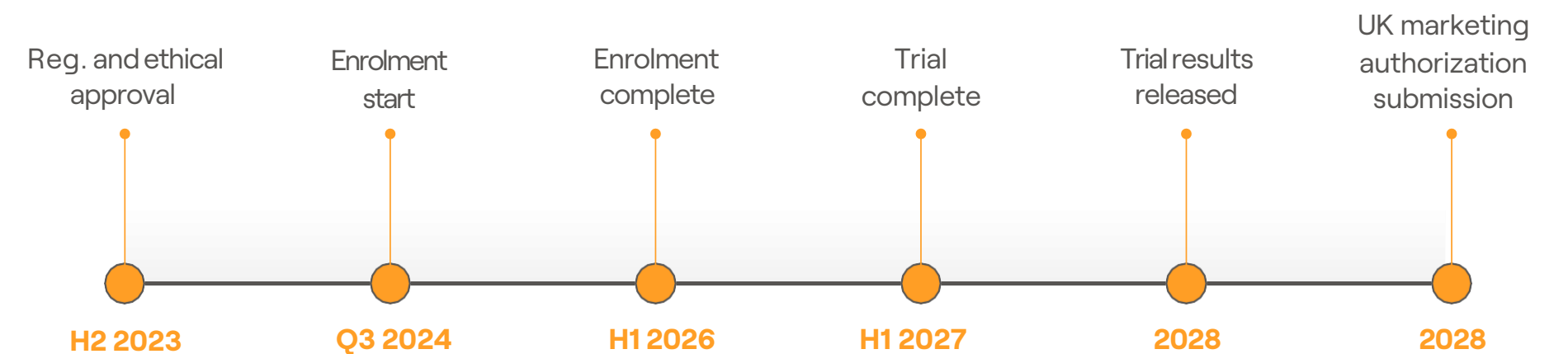
## Status & Data:

- Ph3 regulatory and ethical approval secured
- Ph3 majority funded via grants by UK Gov. Awakn's cost capped at approx. US\$1m
- ILAP innovation passport secured from UK MHRA
- Efficacy proven in successful Ph2

## Near-term Catalysts:

- Ph3 enrolment due to start Q3 2024
- UK Pricing, market access, and reimbursement discussions to start in Q1 2024

## AWKN-001 – FORECAST TIMELINE





# AWKN-001 – Ph2

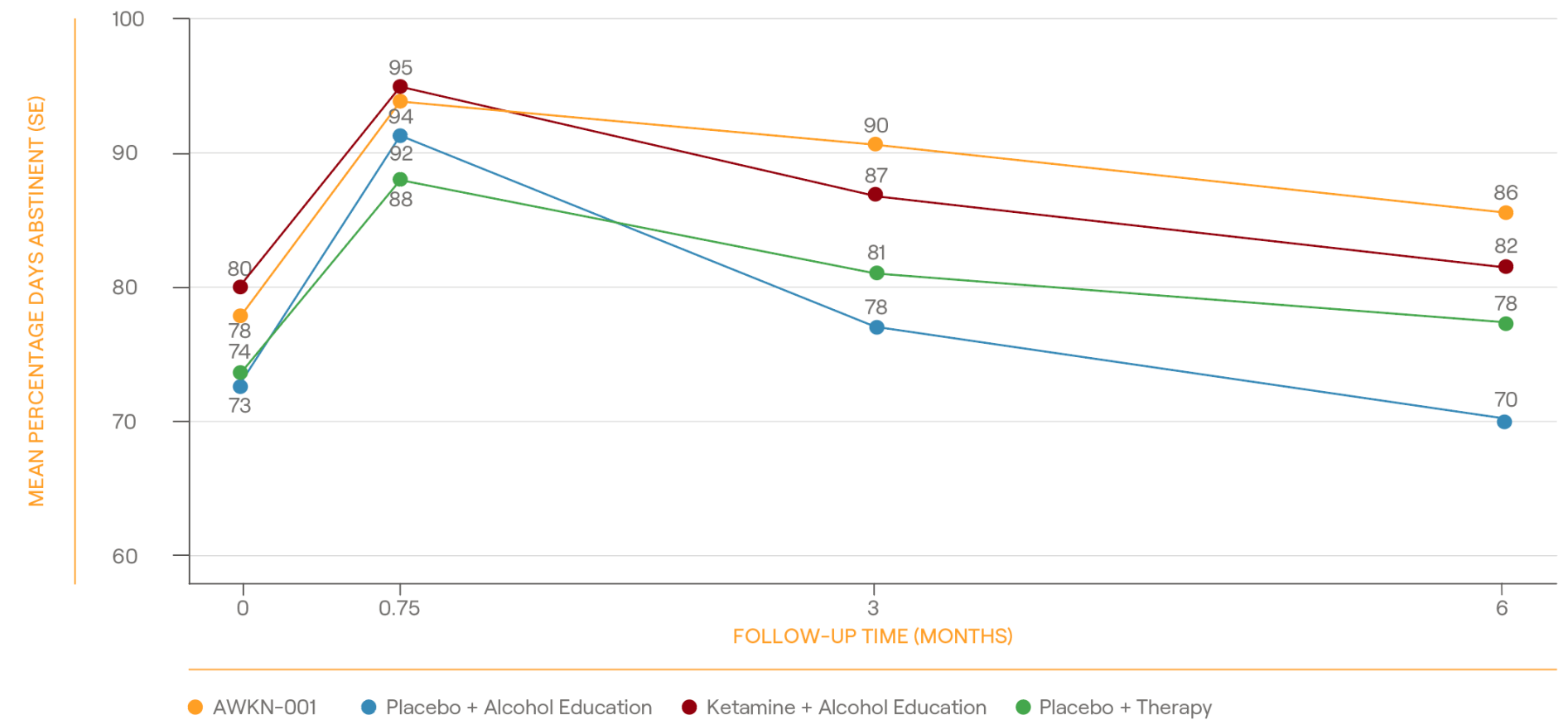
## Results, AWKN-001:

- 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:

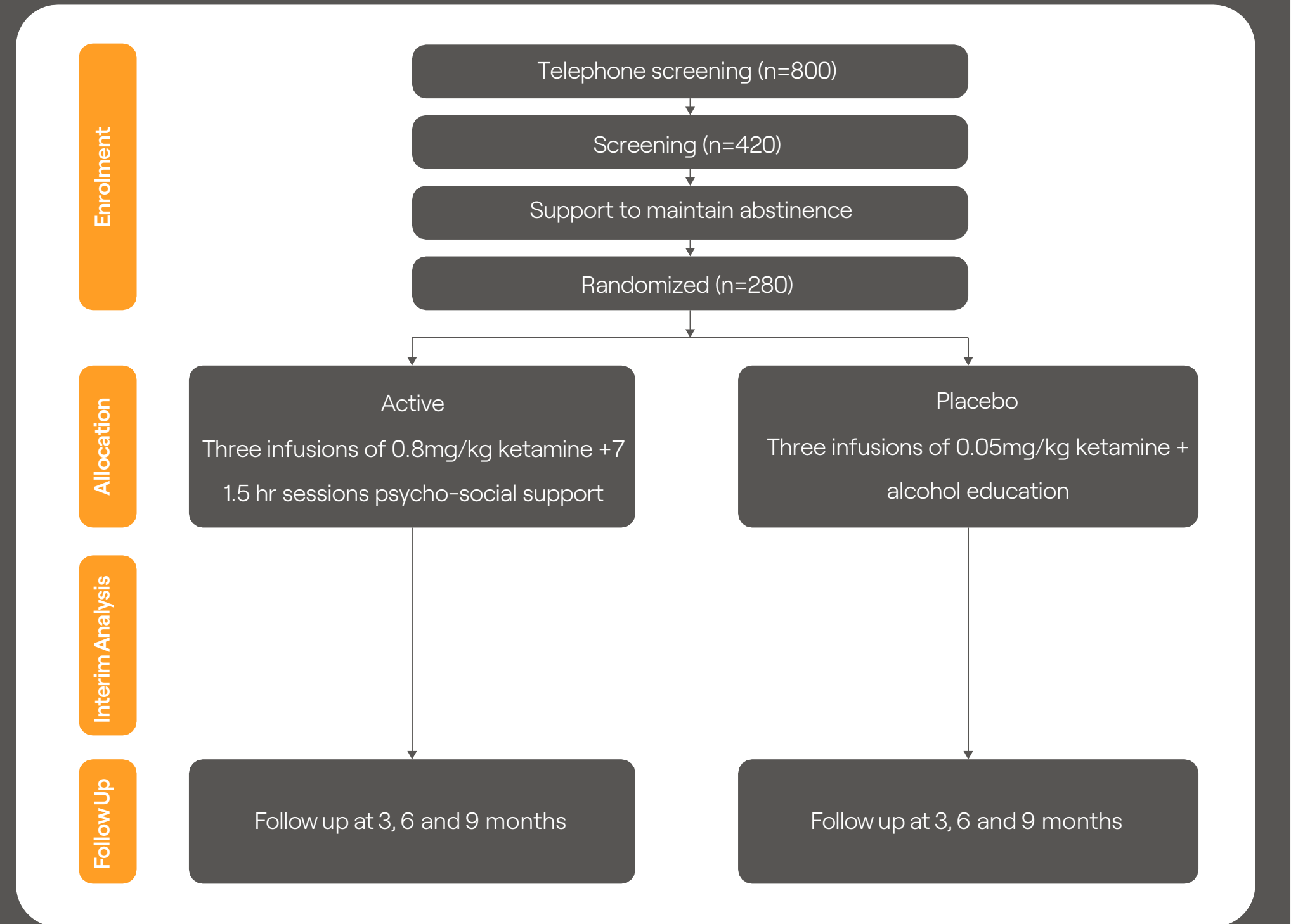
- Four-armed, double-blind placebo clinical trial, N=96:
  - Arm 1 (AWKN-001): Ketamine + manualized relapse prevention CBT. N=24
  - Arm 2: Ketamine + Alcohol Education. N=24
  - Arm 3: Placebo + + manualized relapse prevention CBT. N=24
  - Arm 4: Placebo + Alcohol Education. N=24
- Primary endpoint: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

AWKN-001 – PHASE II RESULTS – PRIMARY END POINT  
DAYS ABSTINENT



# AWKN-001 – Ph3

- n=280 two-armed placebo-controlled trial
- Nine NHS Trust Sites
- Regulatory and ethical approval Q4 2023
- Enrolment forecast to start Q3 2024
- Market access discussions with UK Dept. of Health forecast to start in 2024



# AWKN-002

AWKN-002 is a novel MAT consisting of a patent pending proprietary esketamine oral thin film (OTF), administered sub-lingually and buccally in combination with manualized psycho-social support to treat AUD in the US.

## Status:

- Awakn has in-licensed a successfully completed Ph1 program with patents filed internationally and with global exclusivity for addiction, anxiety, and eating disorders
- n=30 mechanistic study in harmful drinkers initiated in Q1' 2023

## Goals:

- Target 505(b) (2) pathway
- Progress this program to late clinical stage and seek commercial opportunities

## IP:

- Esketamine OTF formulation patents filed in US, China, Canada, Europe, and Japan
- Esketamine OTF AUD method of use patents filed

## Near-term Catalysts:

- Complete mechanistic study
- Pre-IND FDA meeting

## AWKN-002 AUD – TIMELINE



# MDMA/Zydis® Program

## Goals:

- Develop MDMA into an Oral Disintegrating Tablet (ODT) for pre-gastric absorption to address known pharmacokinetic (PK) challenges with MDMA
- Target 505(b)(2) pathway
- Progress to clinical stage and seek commercial opportunities

## Status:

- Development agreement in place with Catalent with exclusivity for CNS indications

## Near-term Catalysts:

- Pre-clinical PK study
- Execute exclusive global licensing agreement with Catalent for MDMA on their Zydis® platform ODT technology for all CNS indications

## Zydis® Technology

- Zydis® ODT fast-dissolve formulation is a unique, patent protected freeze-dried oral solid dosage form that disperses almost instantly, typically less than 3 seconds in the mouth – no water required
- Enhances pharmacokinetics through pre-gastric absorption, to improve PK and patient compliance
- Faster onset of effects
- Possibility to shorten therapy sessions, reducing cost, improving experience and outcomes

## PROPOSED TIMELINE AND MILESTONES – MDMA/ZYDIS



# Aminoindane NCE Program

## Asset Acquired:

- Awakn acquired six years of proprietary research data from Prof. David Nutt
- This data described potentially fast acting aminoindane compounds

## Status:

- Hit to Lead program completed with Evotec
- In vitro and in vivo data shows efficacy for drug-like hits, defining chemical series for lead optimization
- Patents filed
- Two chemical series identified for lead optimization

## Near-term activity:

Commence initial pharmacology testing of selected series to assess biological activity, potency, and selectivity in cell-based assays.

## What are Aminoindanes

Aminoindanes are a class of molecules that offer an alternative source of medical empathogens to MDMA for use alongside psycho-social support in the treatment of trauma related mental health disorders.

Aminoindanes have similar pharmacological properties to MDMA, they promote serotonin dopamine and noradrenaline release and block their reuptake. This combination of effects is believed to underpin the empathogenic activity. They offer a novel patentable approach to the treatment of trauma-related disorders.



# Awakn's History & Near-term Catalysts

## Completed

### 2021

- **Q1:** Acquired Ph2 (AWKN-001) program for ketamine to treat SAUD
- **Q2:** Listed on NEO

### 2022

- **Q1:** AWKN-001 Ph2 trial data published, achieved 86% abstinence in the 6 months post treatment
- **Q2:** Signed exclusive agreement with Catalent for feasibility study of MDMA on their Zydis<sup>®</sup> platform
- **Q3:** Signed exclusive agreement with an established pharma co. for a Phase I S-ketamine program to enable testing of drug product for suitability in treating addiction

### 2023

- **Q1:** Secured grant funding for AWKN-001 Ph3 from UK state, Awakn contribution capped at approx. US\$1m
- **Q1:** AWKN-001 granted ILAP (FDA FastTrack equivalent) by UK regulator
- **Q4:** Regulatory and ethical approval for AWKN-001 Ph3 secured
- **Q4:** Exclusive global licensing agreement signed for S-ketamine OTF for use in addiction (AWKN-002)

## Near-term Catalysts

### 2024+

- Begin enrolment in AWKN-001 Ph3 trial
- AWKN-002 FDA pre-IND meeting
- Complete MDMA/Zydis<sup>®</sup> pre-clinical pharmacokinetic study
- Complete MDMA/Zydis<sup>®</sup> feasibility study and potentially sign global license agreement
- Complete initial pharmacology testing of selected Aminoindane NCE series to assess biological activity, potency, and selectivity in cell-based assays.

# Cap Table

## Capital Structure

Common Shares	39,091,197
Warrants	14,760,232
Stock Options	2,306,746
DSU's	1,525,172
<b>Full Diluted</b>	<b>57,683,347</b>
Management Ownership	16.48%
Locked Up Shares	24.75%

# Awakn Analyst Coverage

## Awakn Contact

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# 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. <a href="https://www.nimh.nih.gov/health/statistics/major-depression">https://www.nimh.nih.gov/health/statistics/major-depression</a>
Number of people with GAD	US	Anxiety & Depression Association of America, Anxiety Disorders-Facts & Statistics. <a href="https://adaa.org/understanding-anxiety/facts-statistics">https://adaa.org/understanding-anxiety/facts-statistics</a>
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. <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4534056/">www.ncbi.nlm.nih.gov/pmc/articles/PMC4534056/</a>
Annual AUD deaths	US, UK, EU	OECD. <a href="http://www.oecd-ilibrary.org/sites/82129230-en/1/3/2/2/4/index.html?itemId=%2Fcontent%2Fpublication%2F82129230-en&amp;csp_=e7f5d56a7f4dd03271a59acda6e2be1b&amp;itemIGO=oecd&amp;itemContentType=book">www.oecd-ilibrary.org/sites/82129230-en/1/3/2/2/4/index.html?itemId=%2Fcontent%2Fpublication%2F82129230-en&amp;csp_=e7f5d56a7f4dd03271a59acda6e2be1b&amp;itemIGO=oecd&amp;itemContentType=book</a>

# References

In relation to references on slides 4, 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



The image features the word "Awakn" in a white, sans-serif font, centered horizontally. A small "TM" trademark symbol is positioned to the upper right of the letter "n". The background is a dark gray with a pattern of thin, flowing, golden-brown lines that create a sense of movement and depth, resembling a stylized landscape or abstract data visualization. The lines are most concentrated around the text and fade out towards the edges of the frame.

Awakn<sup>TM</sup>