

Awakn™
Life Sciences Corp

Corporate Presentation

January 2024

NEO: AWKN | OTCQB: AWKNF

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Psychedelics Emerging as Viable Treatments for CNS Disorders

Key Events

- 2019** Spravato (S-ketamine) for treatment-resistant depression (TRD) launched by J&J
- 2021** Compass Pathways' psilocybin Ph2 for TRD results published
- 2022** Awakn's Ph2 for SAUD results published
- 2023** Spravato H1 FY'23 sales reached US\$300m, full year forecast US\$600m
- 2023** MAPS' MDMA for PTSD Ph3 results published
- 2023** Compass Pathways' Ph3 initiated
- 2023** AMA publish CPT III codes for psychedelic-assisted therapies
- 2023** Awakn's ketamine for SAUD Ph3 trial approved

Company	Awakn	Compass	J&J	MAPS
Indication	SAUD	TRD	TRD	PTSD
UK, US, EU4 Prevalence	17m	9.5m	9.5m	15m
Compound	Ketamine	Psilocybin	S-ketamine	MDMA
Phase	3	3	Approved	3

Awakn is a Clinical Stage Biotechnology Company Developing Psychedelic Medication-Assisted Treatments (MAT) for Alcohol Use Disorder (AUD), with Potential in Other CNS Indications

Significant Addressable Market for AUD

51m 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 for ketamine, MDMA, and NCEs in other addictions and mental health disorders

Intellectual Property

S-ketamine oral thin film (OTF) patents in place

Ketamine for behavioural addictions patents filed

175 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



Prof. Celia Morgan
HEAD OF KETAMINE-ASSISTED THERAPY



Dennis Purcell
SPECIAL ADVISOR TO THE CEO



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



Alcohol Use Disorders Prevalence in Awakn's Target Markets

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

22 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)

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

Treating

550,000

patients for AUD in 2020

US\$22bn

direct medical costs a year

(For references see slide 21)

Awakn's Psychedelic Medication-Assisted Treatments Mechanism of Action

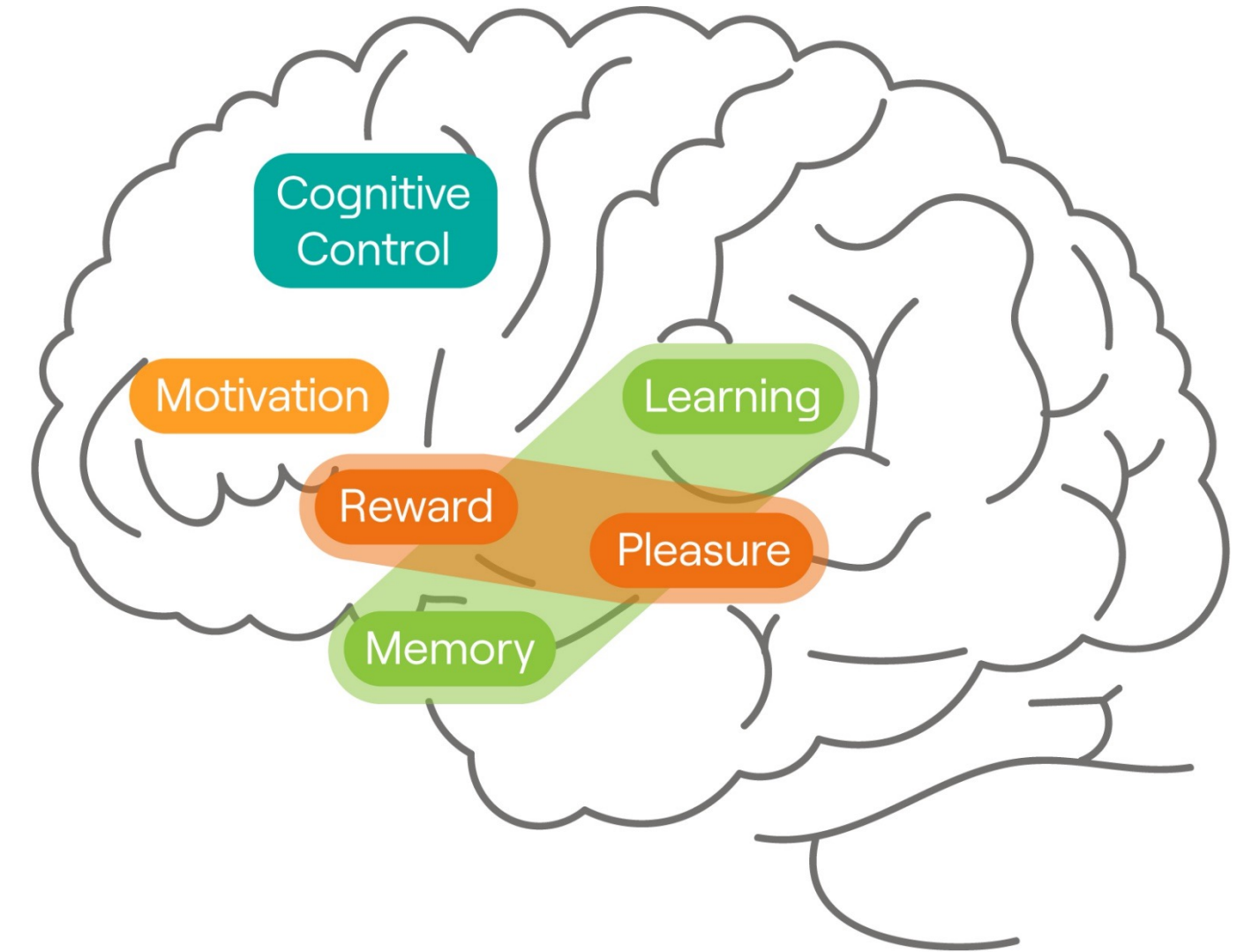
What are we doing differently?

Awakn's MATs 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

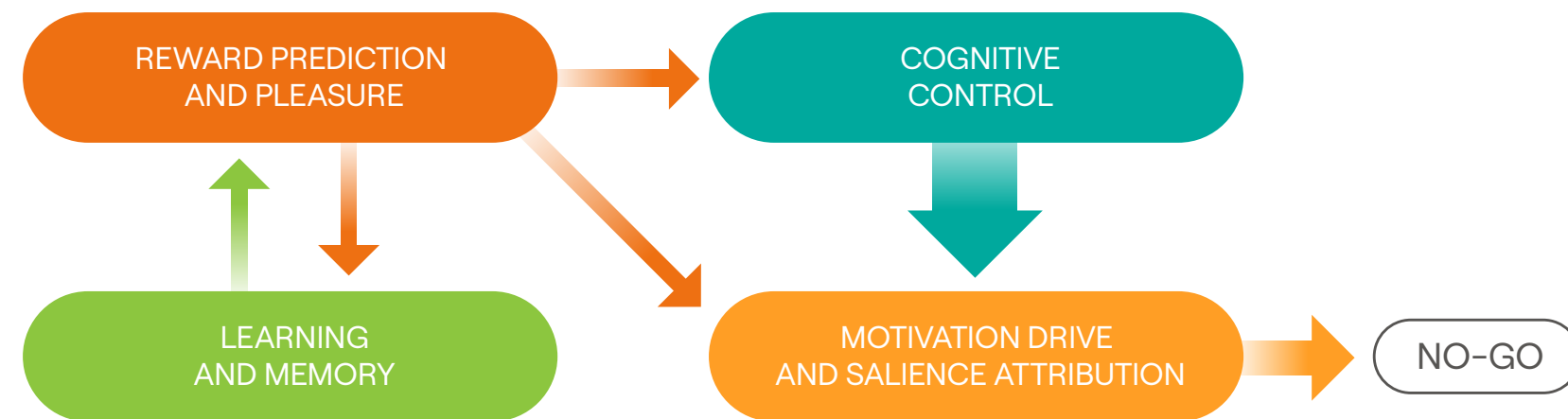
- | | |
|---|--|
|  REWARD PREDICTION AND PLEASURE (NUCLEUS ACCUMBENS & VENTRAL PALLIDUM) |  MOTIVATION DRIVE AND SALIENCE ATTRIBUTION (ORBITOFRONTAL CORTEX) |
|  COGNITIVE CONTROL (PREFRONTAL CORTEX) |  LEARNING AND MEMORY (HIPPOCAMPUS & AMYGDALA) |

(For references see slide 21)

Awakn's Psychedelic Medication-Assisted Treatments Mechanism of Action

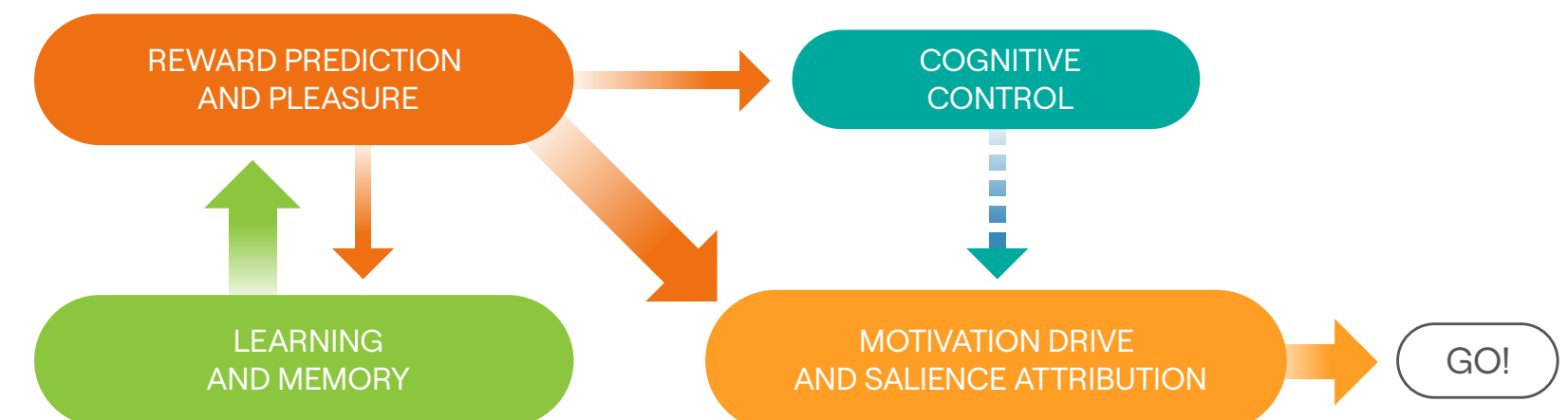
Balanced brain state – no addiction

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 Psychedelic Medication-Assisted Treatments Mechanism of Action

Ketamine (Racemic & S-ketamine)

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

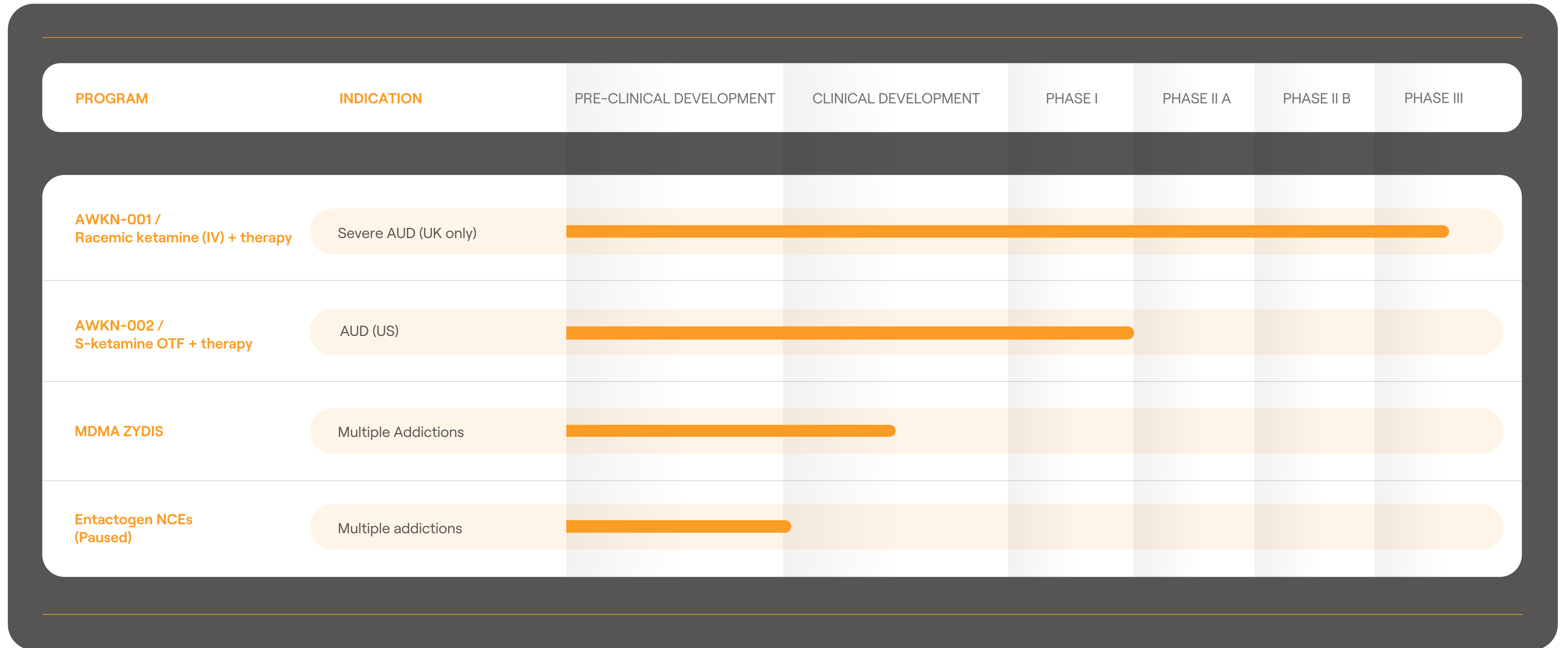
MDMA

- 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 – a novel psychedelic MAT of an N-methyl-D-aspartate receptor-modulating drug (ketamine) used in combination with manualized relapse prevention cognitive behavioral therapy (CBT) for SAUD in the UK.

Treatment Cycle:

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

Goal:

- Complete Ph3 AWKN-001
- Seek commercial partnering opportunities
- Data to support AWKN-002 US R&D program

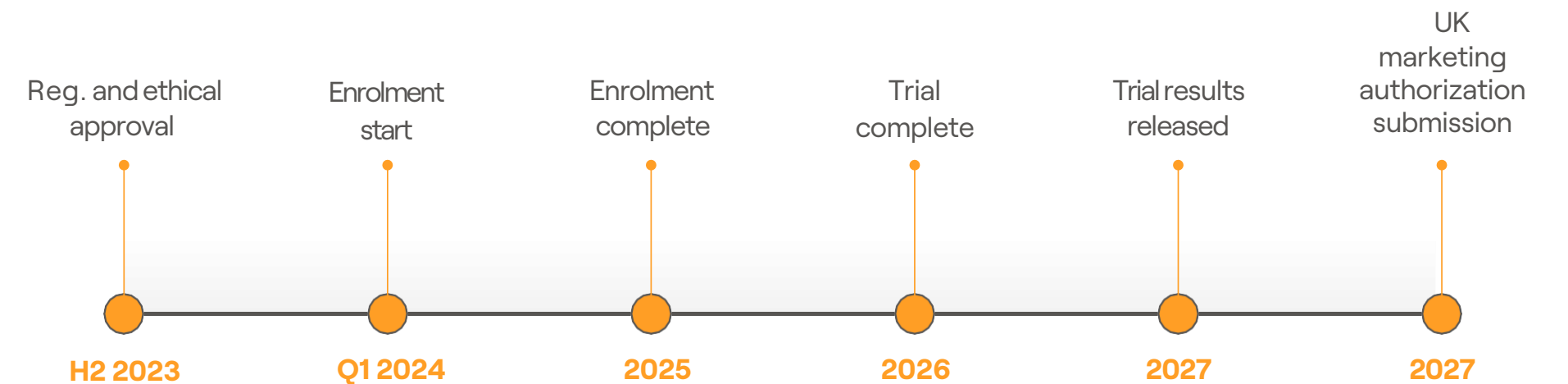
Status & Data:

- 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 Q1 2024
- UK Pricing, market access, and reimbursement discussions to start in Q1 2024

AWKN-001 – FORECAST TIMELINE



AWKN-001 – Ph2

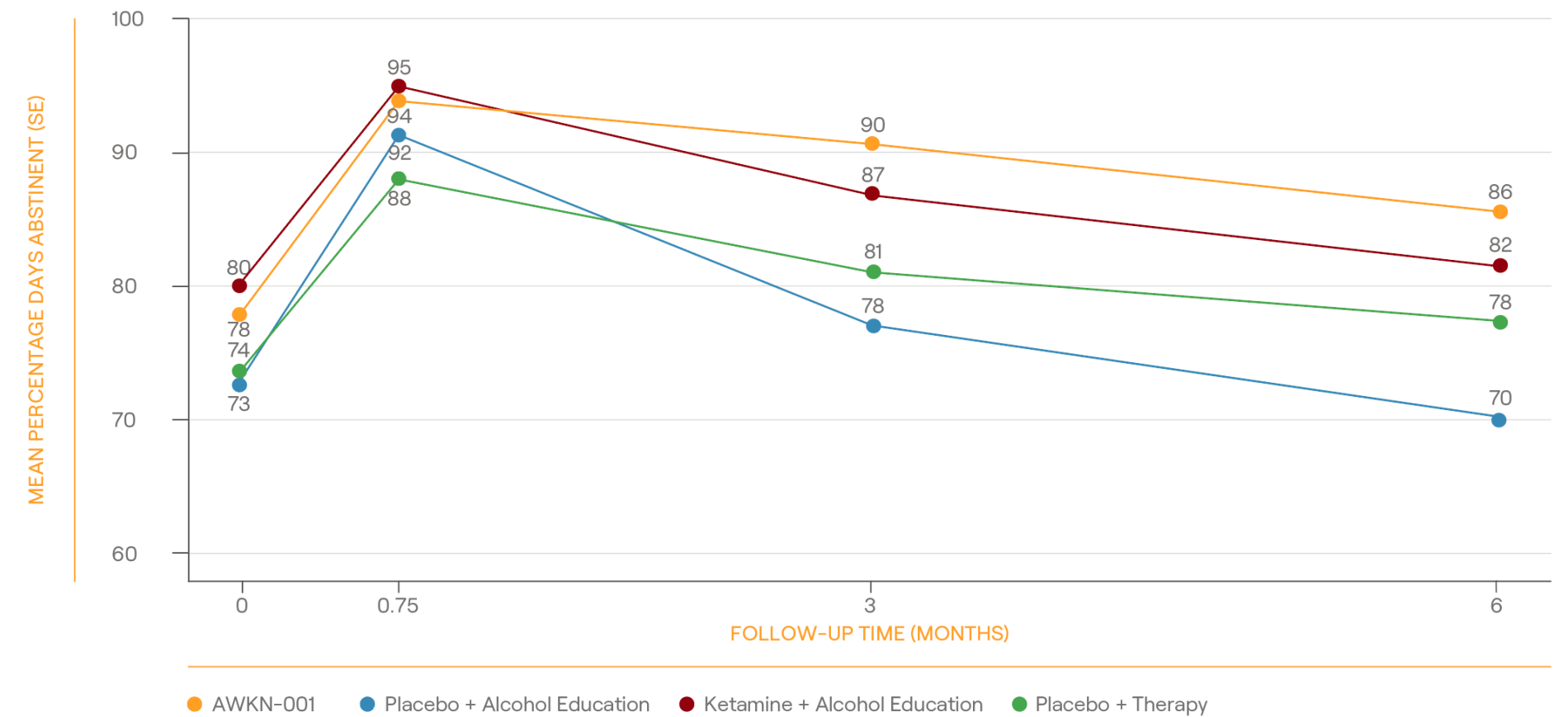
Results, AWKN-001:

- 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

- Tripartite partnership: Awakn, University of Exeter, UK Dept. of Health (NIHR & NHS)
- Jointly funded by Awakn and the NIHR Efficacy and Mechanism Evaluation (EME) Programme (NIHR150193), an MRC and NIHR. Awakn's costs capped at approx. US1m
- n=280 two-armed placebo-controlled trial
- Nine NHS Trust Sites
- Regulatory and ethical approval Q4 2023
- Enrolment forecast to start Q1 2024
- Market access discussions with UK Dept. of Health forecast to start in 2024



AWKN-002

AWKN-002 is a novel psychedelic MAT consisting of a patent pending proprietary S-ketamine OTF used in combination with manualized relapse prevention CBT 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:

- S-ketamine OTF patents filed in US, China, Canada, Europe, and Japan

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



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[®] 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[®] pre-clinical pharmacokinetic study
- Complete MDMA/Zydis[®] feasibility study and potentially sign global license agreement

Cap Table

Capital Structure

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

Awakn Analyst Coverage

Awakn Contact

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Awakn Coverage

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Jason Mc Carthy, Maxim Group

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References

In relation to references on slides 4, 6 & 7

INDICATIONS	SCOPE	SOURCE
NUMBER OF PEOPLE WITH AUD	US	https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/understanding-alcohol-use-disorder
TREATMENT	US	https://www.niaaa.nih.gov/alcohols-effects-health/alcohol-topics/alcohol-facts-and-statistics
ANNUAL DEATHS NUMBER	US	https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm
ANNUAL ECONOMIC BURDEN	US	https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/understanding-alcohol-adverse-impact-health#:~:text=Alcohol%20misuse%20costs%20the%20United%20States%20about%20%24249%20billion%20per%20year.&text=In%20the%20United%20States%2C%20approximately,disorder%20(AUD)%20in%202021.
NUMBER OF PEOPLE WITH AUD	UK & EU	https://pubmed.ncbi.nlm.nih.gov/25342593/
TREATMENT	UK & EU	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4534056/
ANNUAL DEATHS NUMBER	UK & EU	https://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
ANNUAL ECONOMIC BURDEN	UK & EU	https://www.uems.eu/_data/assets/pdf_file/0011/1550/Summary_Report_Interventions_for_Alcohol_Dependence_in_Europe.pdf
GLOBAL STATUS REPORT	GLOBAL	https://www.who.int/publications/i/item/9789241565639
GLOBAL ECONOMIC BURDEN	GLOBAL	https://pubmed.ncbi.nlm.nih.gov/17132572/

In relation to references on slide 8

SAMSHA - National Survey of Substance Abuse Treatment Services - 2020 Data on Substance Abuse Treatment Facilities

National Institute on Drug Abuse - Costs of Substance Abuse

SAMSHA - Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010-2020

The background features a dark grey, almost black, color with a series of thin, flowing, wavy lines in a light orange or gold hue. These lines originate from the left side and curve towards the right, creating a sense of movement and depth. The lines vary in density and curvature, some being more vertical and others more horizontal, all contributing to a dynamic and organic feel.

Thank You

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, particularly concentrated around the text.

AwaknTM