

# Corporate Presentation

July 2023



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Recipients are required to inform themselves of, and comply with, all such restrictions or prohibitions reasons; any other factors or developments which may hinder market growth; the Company's limited operating history and lack of historical profits; reliance on management; the Company's requirements for additional financing, and the effect of capital and the Company does not accept liability to any person in relation thereto. market conditions and other factors on capital availability; competition, including from more established or better financed CAUTIONARY NOTE REGARDING FUTURE-ORIENTED FINANCIAL INFORMATION competitors; and the need to secure and maintain corporate alliances and partnerships, including with customers and suppliers. The foregoing factors are not intended to be exhaustive. Although the Company has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimate or intended.

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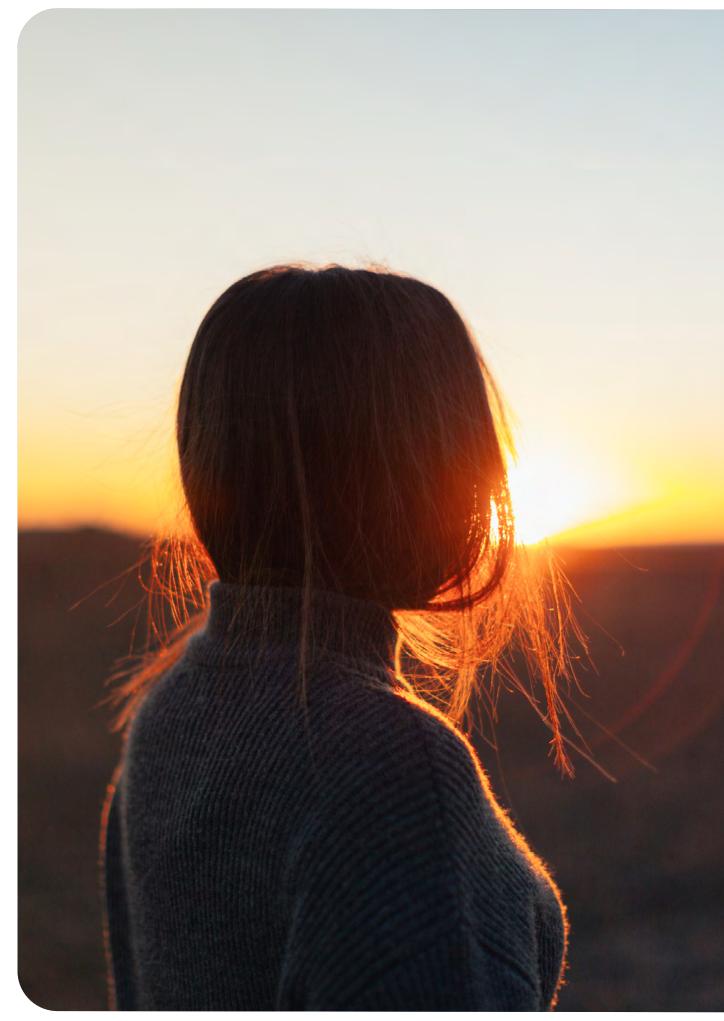
#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

### Our Purpose

### Awakn Life Sciences

is a clinical-stage biotechnology company developing therapeutics to treat addiction, with a near-term focus on Alcohol Use Disorder We are focused on treating addiction because it is a significant unmet medical need driven by high prevalence rates and high relapse rates







# Psychedelic Therapeutics Emerging As Potentially Viable Treatments for Psychiatric and Substance Use Disorders

#### **Key Recent and Near-term Industry Events**

2004 MAPS MDMA Phase II for PTSD initiated

2016 University of Exeter ketamine Phase II a/b for Severe Alcohol Use Disorde trial initiated (program acquired under license by Awakn in 2020)

2018 MAPS MDMA Phase III initiated

**2019** Compass psilocybin Phase IIb for treatment-resistant depression (TRD)

2019 (S)-ketamine nasal spray (Spravato) for TRD launched by Janssen

**2022** Spravato sales reach US375m

Jan 2023 Compass Phase III initiated

May 2023 AMA publish CPT III codes psychedelic-assisted therapies

June 2023 FDA publishes guidance for psychedelic trials

July 2023 Australian TGA permits prescribing of MDMA for PTSD and psilocybir

H2 2023 Awakn ketamine Phase III expected to initiate

**2024** MDMA expected to be approved by FDA to treat PTSD

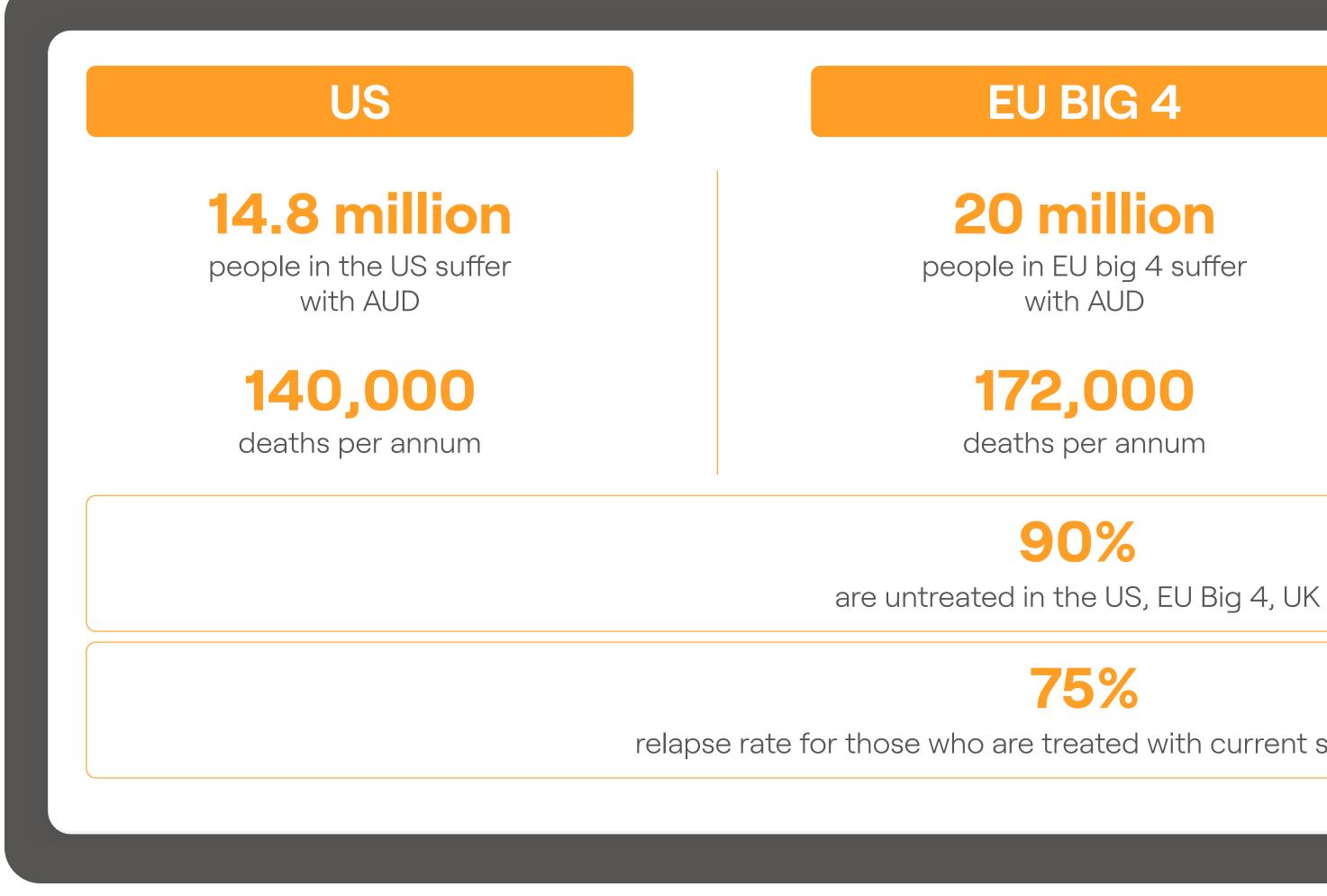


er (SAUD)	Primary psychiatric and substance use disorders	PTSD	TRD	AUD
) initiated	US, EU Big 4*, UK Adult Prevalence	15m	9.5m	37m
	Company with Most Advanced Research	MAPS	Compass	Awakn
	Compound	MDMA	Psilocybin	Ketamine
n for TRD	Phase	III	III	III planning
			* Germany, F	rance, Italy, Spain





# Alcohol Use Disorders (Severe, Moderate, Mild), the Size of the Problem in US and Key International Markets





AwaknLifeSciences.com

### EU BIG 4

# **20** million

people in EU big 4 suffer with AUD

# 172,000

deaths per annum

### UK

### 2 million

people in the UK suffer with AUD

27,000 deaths per annum

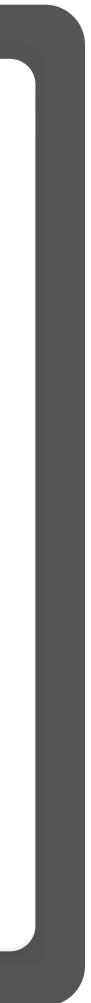
90%

### 75%

relapse rate for those who are treated with current standard of care

(For references see slide 20)





# Awakn's Approach

Awakn is developing therapeutics, consisting of drugs and psycho-social support used in combination, to treat AUDs:

- The drug element of Awakn's therapeutics utilizes a polypharmacological approach to disrupt the brain circuits that house the behaviours that drive AUDs
- The psycho-social support element of Awakn's therapeutics utilizes manualized Cognitive Behavioral Therapy (CBT) to efficiently develop and implement lasting relapse prevention behaviours

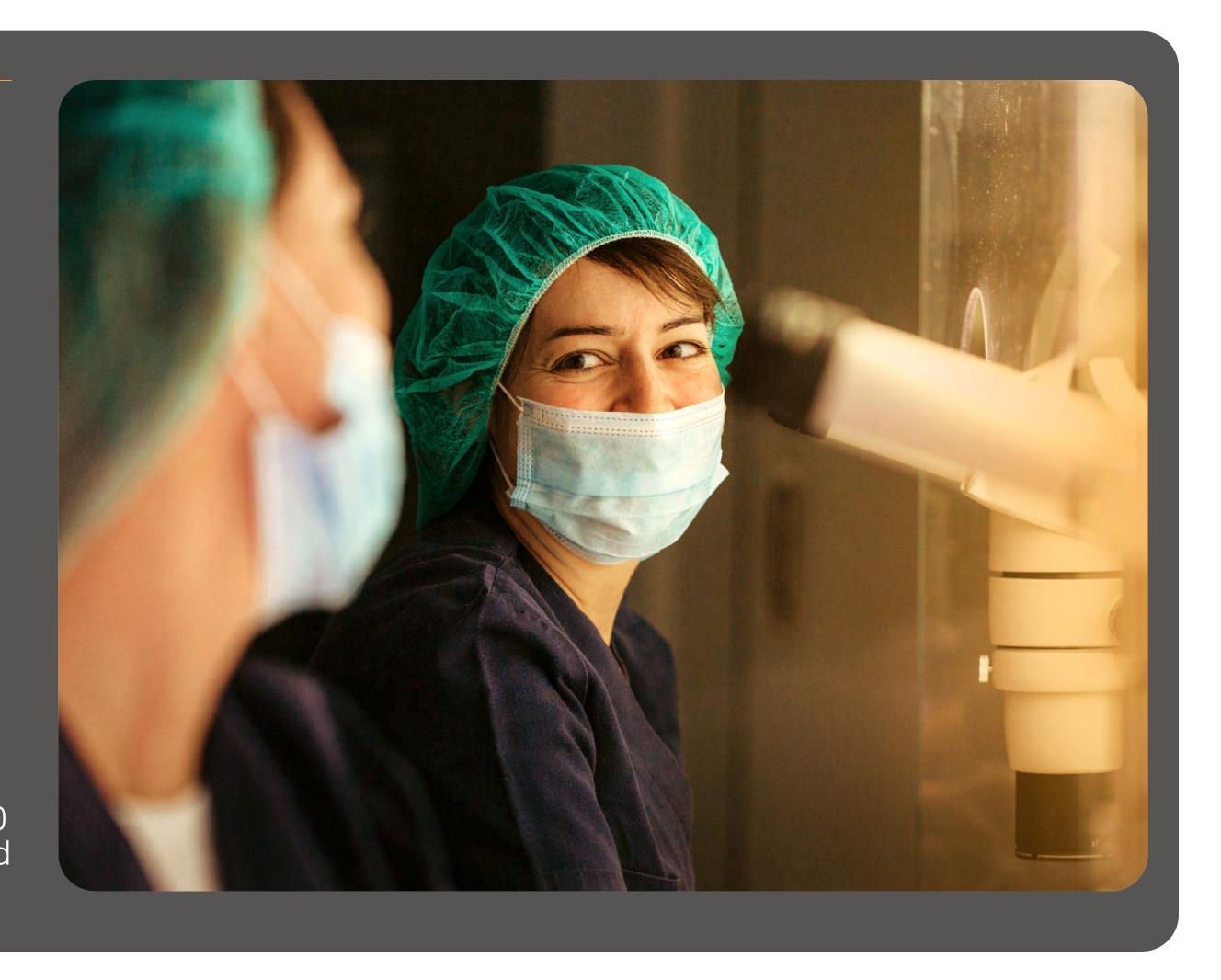
#### R&D

Awakn's R&D is focused on re-purposing approved drugs and developing soon to be approved drugs to treat AUDs

Awakn partners with established pharma industry companies and state bodies on research and development

Awakn's lead program, AWKN-P001, repurposing racemic ketamine in combination with CBT to treat SAUD, which affects 10 million people in US and key international markets, has completed Phase IIb





# Awakn's Approach

### Reduces Risk and Time



Reduces risk and time to market by focusing on repurposing already approved and soon to be approved drugs

### Reduced Cost



AWKN-P001 Phase II fully funded and Phase III to be majority funded by UK Dept. of Health, Awakn costs for Phase III capped at approx. US\$1m



### Safety and Efficacy is Proven

Phase II a/b trial of AWKN-P001 targeting SAUD complete. 86% abstinence was achieved at 6 months post treatment vs 2% pre-trial, and 25% abstinence in the current standard of care

### Designed to Aid Adoption & Enable Scale

AWKN-P001 protocol is condensed and psychosocial support is manualized to aid efficient adoption in existing addiction treatment healthcare infrastructure



# US AUD Treatment Services Market



Treating **475,000** 

patients for AUD in 2020

Between

# **US\$27bn & US\$38bn**

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



average relapse rates within 1 year of completing Approx.



of direct medical cost for medication for AUD in the US

### **75%**

Vs.

Average of

28%

of direct costs for medication for other top 10 chronic diseases in the US

(For references see slide 20)



# Pipeline INDICATION COMPOUND PRECLINICAL DEVELOPMEN AWAKN-POO1 (SEVERE AUD) Racemic ketamine (IV) (S)-ketamine (SL) MILD AND MODERATE AUD MDMA/Zydis (SL) MULTIPLE

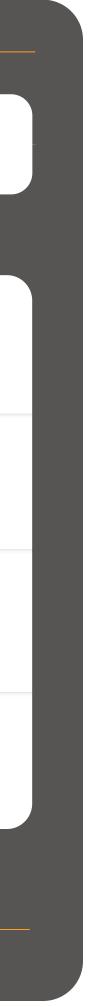
**BEHAVIORAL ADDICTIONS** 

(S)-ketamine (SL)



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ENT	CLINICAL DEVELOPMENT PHASE	PHASE I	PHASE II a	PHASE II b	PHASE III	
		_			_	
		_				
		_	_	_	_	
				Acquired	Live Researcl	1







# AWKN-P001

AWKN-P001 – is a novel combined therapeutic consisting of racemic ketamine, delivered IV, and specifically designed psycho-social support to treat Severe AUD (SAUD).

#### Goal:

 Develop AWKN-P001 into a licensed therapeutic to treat SAUD and establish regulatory precedent for drug plus psycho-social support to treat addiction

#### Status:

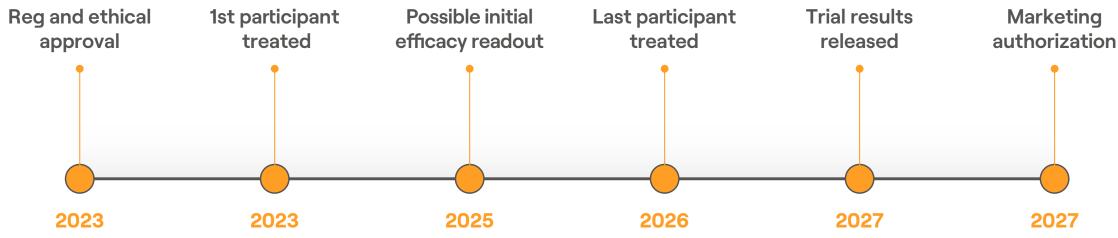
- Phase II complete. Phase III trial in planning.
- Awakn awarded an ILAP innovation passport from the MHRA.
- Grant awarded by UK Dept. for majority of the trial's costs. Awakn's cost capped at approx. US\$1m

#### Near-term Catalysts:

- Regulatory and ethical approval H2 2023.
- Phase III first participant forecast for Q4 2023/Q1 2024.



#### **AWKN-P001 – TIMELINE**

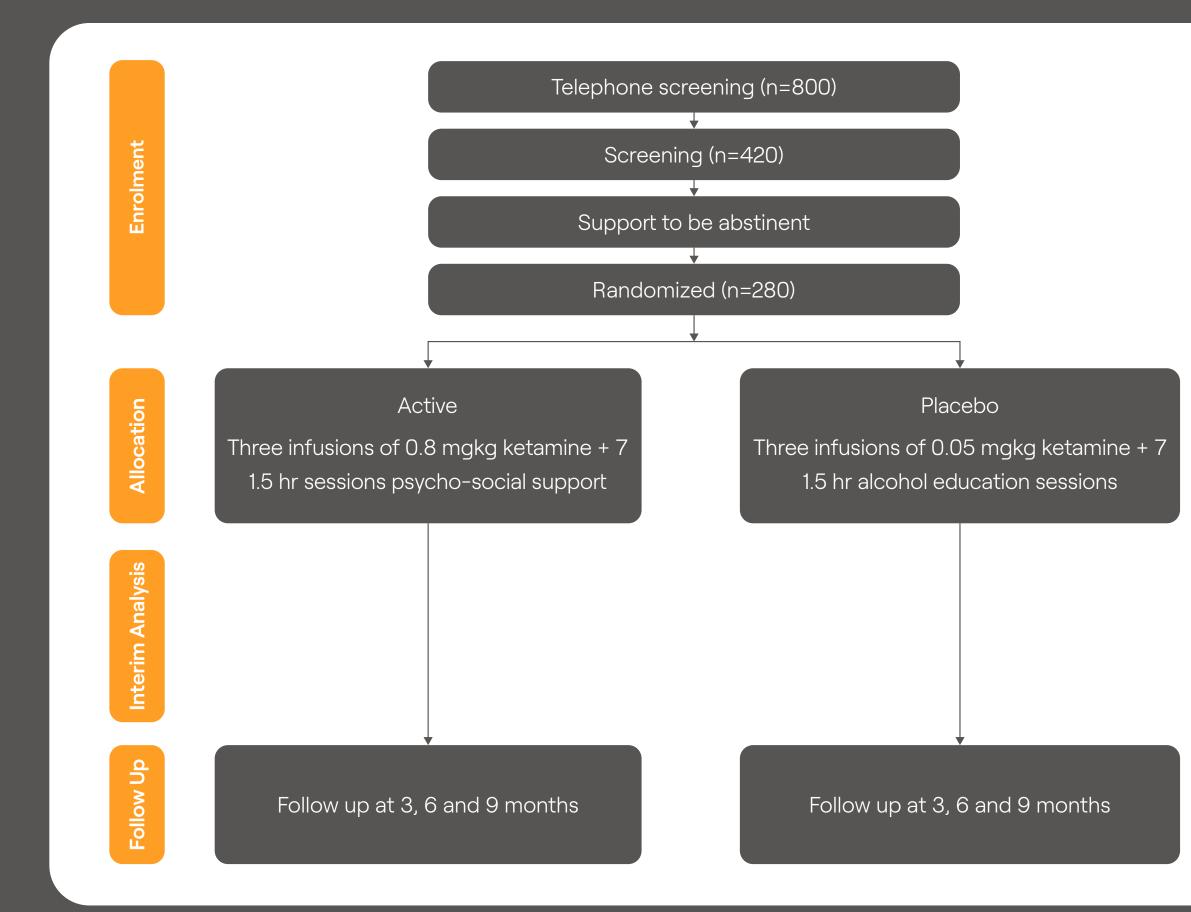




# AWKN-P001 Phase III Trial Design

- Tripartite partnership: Awakn, University of Exeter, UK Dept. of Health (NIHR & NHS)
- n=280 two-armed placebo-controlled trial
- Nine NHS Trust Sites
- Program initiation March 2023
- First participant forecast Dec 2023





#### NEO: AWKN | OTCQB: AWKNF



# (S)-ketamine for Mild and Moderate AUD

(S)-ketamine in combination with psycho-social support to treat Mild and Moderate AUD

#### Goal:

Re-purpose and develop (S)-ketamine, in a proprietary formulation, as a marketed combined therapeutic to treat Mild and Moderate AUD.

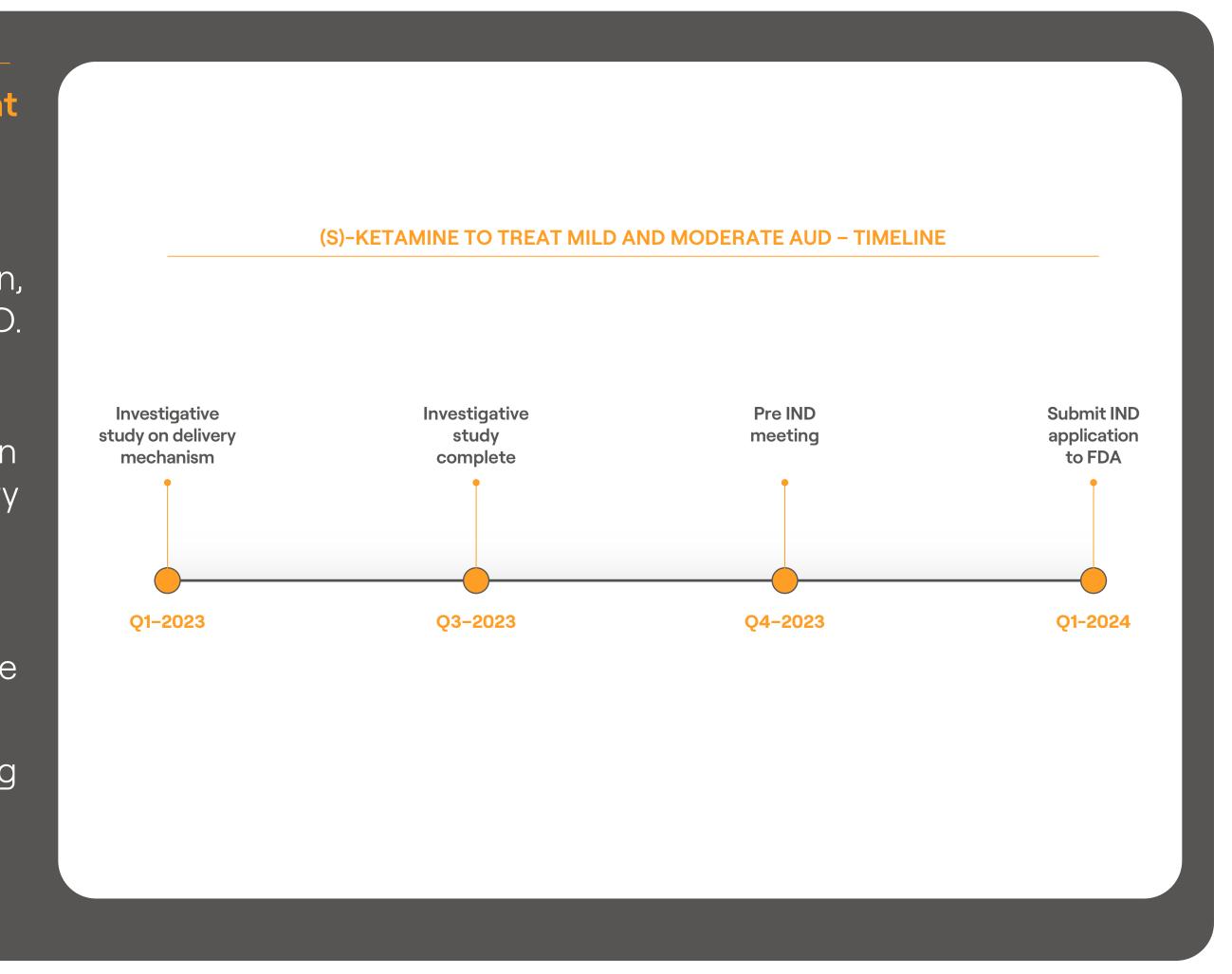
#### Status:

Awakn has signed 18-month exclusive agreement with a European pharmaceutical company to test the suitability of a proprietary formulation of (S)-ketamine with Phase I completed.

#### Near-term Catalysts:

- Complete and announce results of investigative study into dissociative effects of proprietary formulation of (S)-ketamine
- Execute global licensing agreement for Phase I data of patent pending proprietary formulation of (S)-ketamine
- Submit IND application to FDA





# MDMA/Zydis® Program

#### Goal:

Develop MDMA into an Oral Disintegrating Tablet (ODT) for pre-gastric absorption to address known pharmacokinetic challenges with MDMA in oral tablet format.

#### Status:

- Awakn has executed an exclusive development agreement with Catalent, a global leader in drug formulation.
- Agreement focuses on developing and testing a market-ready proprietary formulation and optimized delivery route for MDMA using Catalent's proprietary Zydis<sup>®</sup> platform orally disintegrating tablet (ODT) technology.

#### Near-term Catalysts:

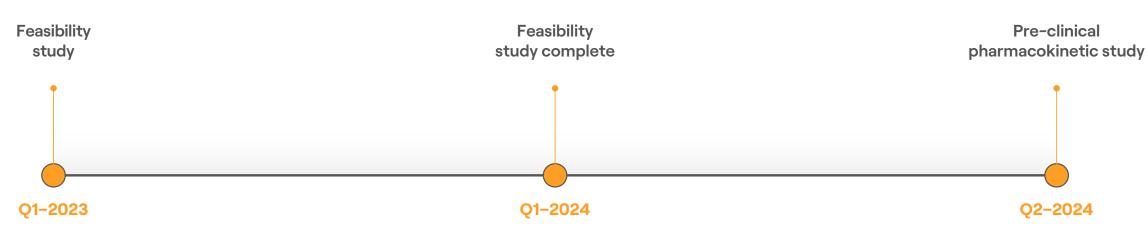
- Complete feasibility study
- Execute excusive global licensing agreement with Catalent for MDMA on their Zydis<sup>®</sup> platform ODT technology
- Pre-clinical pharmacokinetic study



### Zydis<sup>®</sup> Technology

- Zydis<sup>®</sup> 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







# Management

Anthony co-founded Awakn in 2020 and has

built Awakn into a leading biotechnology com-

pany focused on developing therapeutics to

Prior to Awakn Anthony worked in financial

services for 15 years with Aon, Merrill Lynch and

Anthony holds an MBA in Strategy and Finance

Anthony leads Awakn's strategy development



treat addiction.

Bank of Ireland.

and execution.

#### Anthony Tennyson

CO-FOUNDER & CHIEF EXECUTIVE OFFICER



Jonathan Held

CO-FOUNDER & CHIEF FINANCIAL OFFICER

Jonathan co-founded Awakn in 2020, and is a chartered professional accountant, with CFO level experience for private /public companies.

Jonathan has worked in a number of sectors including technology, biotech and natural resources, both domestic and international, and has been involved in numerous successful public market transactions including Initial Public Offerings, Reverse Takeovers and financings.

Jon leads Awakn's capital markets, investor relations and finance activity.



### Prof. David Nutt

CHIEF RESEARCH OFFICER

David is a psychiatrist and the Edmund J. Safra Professor of Neuropsychopharmacology in the Division of Brain Science, Dept of Medicine, Imperial College London, UK.

David is acknowledged as a world authority in addiction research. He has published over 400 original research papers and 28 books.

David sets Awakn research and development strategy.

### Board

and an MSc in Technology.



#### George Scorsis

CO-FOUNDER & CHAIRMAN CORPORATE BOARD

George has 15 years experience leading companies in highly regulated industries to rapid growth, including alcohol, energy drinks and, most recently, medical cannabis. Formerly President of Red Bull Canada, he was instrumental in restructuring the organisation and growing the business to \$150 MM in revenue.



#### Anthony Tennyson

**CO-FOUNDER &** CHIEF EXECUTIVE OFFICER

Anthony co-founded Awakn in 2020 and has built Awakn into a leading biotechnology company focused on developing therapeutics to treat addiction.

Prior to Awakn Anthony worked in financial services for 15 years with Aon, Merrill Lynch and Bank of Ireland.

Anthony holds an MBA in Strategy and Finance science companies. and an MSc in Technology.

Anthony leads Awakn's strategy development and execution.



#### Paul Carter

INDEPENDENT NON-EXECUTIVE DIRECTOR CORPORATE BOARD

Professor John Papastergiou is a highly regard-Paul Carter is a seasoned international Bio-Pharma leader with an outstanding and proven ed pharmacist and clinical research scientist track record. He has over 25 years of senior who has served as an advisor to several leadexecutive experience, having served as Execing pharmaceutical organisations including utive Vice-President and Chief commercial Bayer, Pfizer, GSK, and Astra Zeneca. He holds Officer of Gilead Sciences Inc. He also was faculty appointments at the schools of Pharmacy at both the University of Toronto and the the head of GSK China amongst many others executive positions. He currently sits on the University of Waterloo. In 2019, he was named board of several publicly listed and private bioby the International Forum on Advancement of Healthcare as one of the top 100 healthcare Nestor plc and Acorn Care and Education. leaders globally.





Prof. Celia Morgan

HEAD OF KETAMINE-ASSISTED THERAPY



Dr. Shaun **McNulty** CHIEF SCIENTIFIC OFFICER

Celia is a Professor of Psychopharmacology at the University of Exeter. Celia completed her undergrad and Ph.D at University College London and completed a scholarship program at Yale Celia was given a Chair in Psychopharmacology in 2015 in the University of Exeter.

Celia was PI on Awakn's acquired Phase II a/b trial and is the PI on Awakn's Phase III trial.

Celia leads Awakn's ketamine research.

Shaun is an experienced CNS drug discovery expert and biotechnology executive. Shaun has over 25 years of industry experience in the neuroscience drug discovery units of major pharmaceutical company, including Parke-Davis, Pfizer and GSK.

Shaun has worked to develop a range of CNS targeted drugs including Neurontin and Lvrica.

Shaun leads Awakn's R&D activity.

### Special advisor



### Dennis Purcell

SPECIAL ADVISOR TO THE CEO

Mr. Purcell is the Founder of Aisling Capital LLC, a major life sciences venture capital firm based in New York City and has previously served as the Fund's Senior Managing Partner and Advisor. Prior to the formation of Aisling Capital, Mr. Purcell served on the Executive Committee and as Managing Director of the Life Sciences Investment Banking Group at Chase H&Q, formerly Hambrecht and Quist. During his time in the industry, he has invested in, raised capital for, and advised hundreds of life sciences companies.

Mr. Purcell currently serves on the board of directors of Real Endpoints, Ichnos Pharmaceuticals, Summus Global, Shorla Oncology, and Embera Pharma. He is also an advisor to Better Health, Cellevolve and xCellerate. He has previously served on the Boards of public and private Life Sciences companies.

In addition, Mr. Purcell serves as an Executive-in-Residence at Columbia University and as an Endowment Committee member at the University of Delaware, where he also serves on the Pharmaceutical Innovation Board.



#### Prof. John Papastergiou

INDEPENDENT NON-EXECUTIVE DIRECTOR CORPORATE BOARD



#### Stephen Page

INDEPENDENT NON-EXECUTIVE DIRECTOR CORPORATE BOARD

Stephen Page has worked at Chief Executive and Board level in UK healthcare for over 30 year, most noticeably leading Priory Healthcare, the largest network of mental healthcare hospitals and clinics in the UK, through a period of rapid expansion and market dominance. He has led and successfully grown organisations in both public and private sectors including Oxleas NHS Trust in London,



# Investment Highlights

### Large Addressable Market

- 38.5 million people are affected by AUD in US and key international markets
- US AUD treatment market generates between US27bn and \$35bn per annum
- 75% treatment failure or relapse rates

### Highly Experienced Team

- Leading addiction experts in Prof. David Nutt and Prof. Celia Morgan
- Track record of successful research, development and commercialization
- Supportive 'blue chip' investor base



### De-risked Pipeline

- Re-purposing approach reduces R&D risks and costs
- Partnership with UK Dept. of Health for AWKN-P001 reduces
   R&D costs and time to market
- AWKN-P001 Phase IIb complete, safety and efficacy proven, progressing into Phase III
- (S)-ketamine and MDMA/ Zydis<sup>®</sup> programs provides additional opportunities

### Commercialization Advantages

- Re-purposing approach and ILAP designation for AWKN-P001 reduces commercialization risk
- Partnership with UK Dept of Health increases probability of adoption at scale in the UK healthcare system
- Efficient treatment protocol and standardization of psycho-social support increases probability of acceptance by healthcare services industry



# Awakn's History & Near-term Catalysts

### Completed

#### 2021

**Q1:** Acquired Phase II a/b program for a novel combined therapeutic of ketami psycho-social support to treat SAUD

Q2: Listed on NEO

#### 2022

**Q1:** AWKN-P001 Phase II a/b trial data published, achieved 86% abstinence in the months post treatment

**Q2:** Signed exclusive agreement with Catalent for feasibility study of MDMA on Zydis<sup>®</sup> platform

**Q3:** Signed exclusive agreement with an established pharma co. for a Phase I (S program to enable testing of drug product for suitability in treating addiction

#### 2023

**Q1:** Secured grant funding for AWKN-P001 Phase III trial from UK state, Awakn contribution capped at approx. US\$1m

**Q1:** AWKN-P001 granted ILAP (FDA FastTrack equivalent) by UK regulator



	Near-term Catalysts
	2023 +
ine and	Secure regulatory and ethical approval for AWKN-P001 Phase III trial
	<ul> <li>First participant in AWKN-P001 Phase III trial</li> </ul>
	<ul> <li>Complete (S)-ketamine drug product assessment and potentially sign exclusive global licensing agreement for use in addiction</li> </ul>
	<ul> <li>Submit IND application to FDA for proprietary formulation of (S)-ketamine treat Mild and Moderate AUD (subject to in-licensing)</li> </ul>
ne 6	<ul> <li>Complete MDMA/Zydis<sup>®</sup> feasibility study and potentially sign global license agreement</li> </ul>
their	<ul> <li>Complete MDMA/Zydis<sup>®</sup> pre-clinical pharmacokinetic study</li> </ul>
)-ketamine	



# Cap Table

### Capital Structure

Common Shar

Warrants

Stock Options

DSU's

**Full Diluted** 

Management /

Locked Up Sha



AwaknLifeSciences.com

ires	36,923,339
	14,957,126
S	2,971,746
	35,172
	54,887,383
/ Insider Ownership	16.55%
nares	27.02%



# Awakn Analyst Coverage

### Awakn Contact

Anthony Tennyson, Co-Founder & CEO

Jonathan Held, Co-Founder & Chief Business Officer

### Awakn Coverage

Andrew Partheniou, Stifel Jason

Jason Mc Carthy, Maxim Group



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jmccarthy@maximgrp.com

om NEO: AWKN | OTCQB: AWKNF

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# References

In relation to references on slides 5

INDICATIONS	SCOPE	SOURCE
NUMBER OF PEOPLE WITH AUD	US	https://www.niaaa.nih.gov/publications/bro
TREATMENT	US	https://www.niaaa.nih.gov/publications/bro
ANNUAL DEATHS NUMBER	US	https://www.cdc.gov/alcohol/fact-sheets/a
ANNUAL ECONOMIC BURDEN	US	https://www.niaaa.nih.gov/publications/bro the%20United%20States%20about%20%24 in%202021.
NUMBER OF PEOPLE WITH AUD	UK & EU	https://pubmed.ncbi.nlm.nih.gov/2534259
TREATMENT	UK & EU	https://www.ncbi.nlm.nih.gov/pmc/articles
ANNUAL DEATHS NUMBER	UK & EU	https://www.oecd-ilibrary.org/sites/821292 9acda6e2be1b&itemIGO=oecd&itemConte
ANNUAL ECONOMIC BURDEN	UK & EU	https://www.uems.eu/data/assets/pdf_f
GLOBAL STATUS REPORT	GLOBAL	https://www.who.int/publications/i/item/9
GLOBAL ECONOMIC BURDEN	GLOBAL	https://pubmed.ncbi.nlm.nih.gov/17132572

In relation to references on slides 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



rochures-and-fact-sheets/understanding-alcohol-use-disorder

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/alcohol-use.htm

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9230-en/1/3/2/2/4/index.html?itemId=%2Fcontent%2Fpublication%2F82129230-en&csp\_=e7f5d56a7f4dd03271a5 ItentType=book

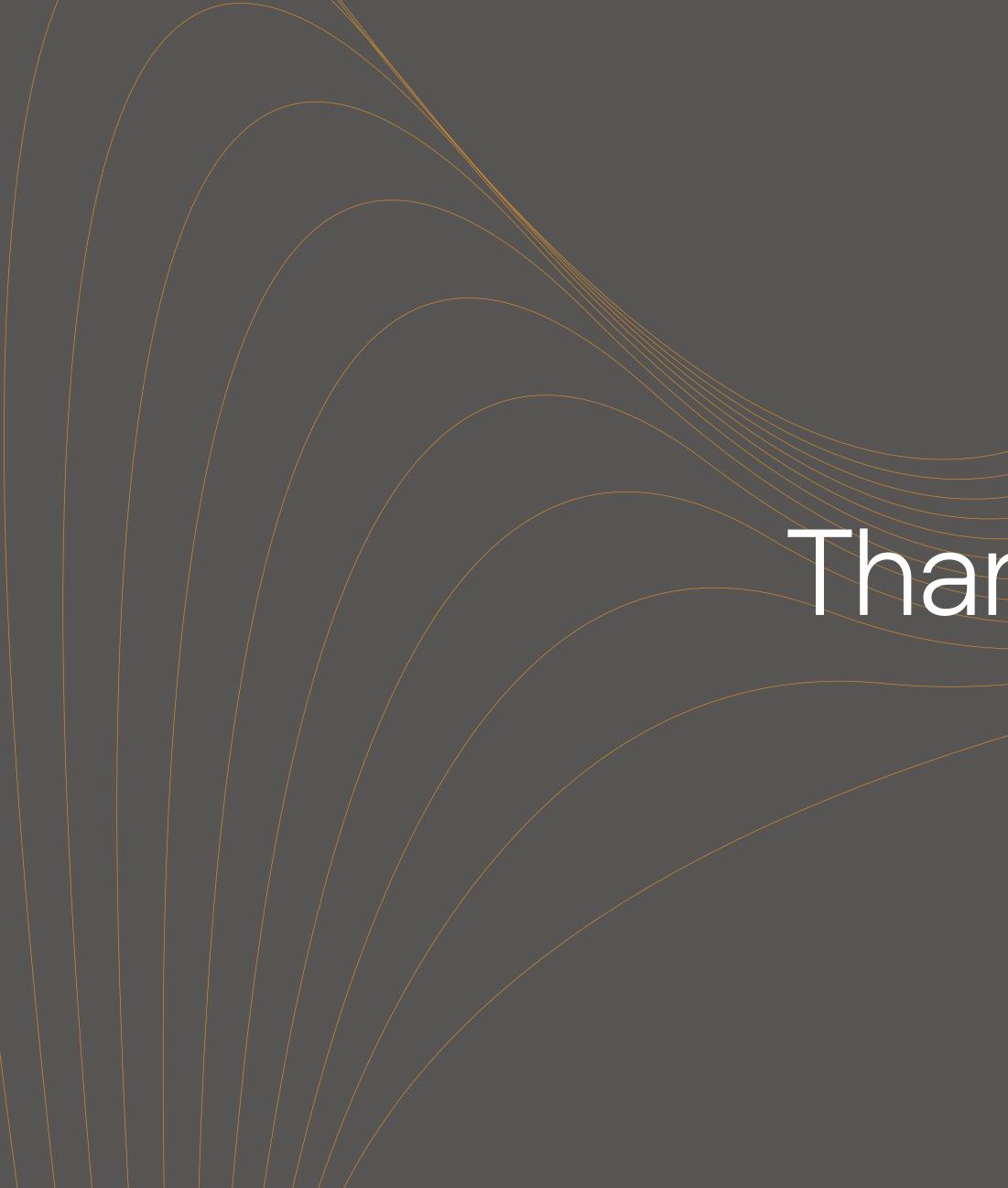
\_file/0011/1550/Summary\_Report\_Interventions\_for\_Alcohol\_Dependence\_in\_Europe.pdf

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# Thank You





