# Indivior - Jefferies Global Healthcare Conference





#### Important Cautionary Note Regarding Forward-looking Statements

This presentation contains certain statements that are forward-looking. Forward-looking statements include, among other things, statements regarding strategic priorities, strategies for value creation, and operational goals; expected future revenue growth and the timing and amount of revenues for particular products; the Indivior Group's financial guidance including operating and profit margins for 2024, expected future earnings and cash flow growth, and its medium- and long-term revenue growth generally and in the rest-of-the-world region specifically; our product development pipeline and potential future products, expectations regarding regulatory approval of such product candidates, the timing of such approvals, and the timing of commercial launch of such products or product candidates, expected timing of future clinical trials and the results thereof, and eventual annual revenues of such future products; assumptions regarding expected changes in share; assumptions regarding the extent and impact of competition; assumptions regarding future exchange rates; expectations about our ability to leverage our cost base and achieve savings at our Raleigh manufacturing plant by 2027; expectations regarding the completion and timing of the potential transfer of our primary listing; the potential inclusion of our stock in U.S. indices over time; and other statements containing the words "believe," "anticipate," "plan," "expect," "intend," "estimate," "forecast," "strategy," "target," "guidance," "outlook," "potential," "project," "priority," "may," "will," "should," "could," "could," "could," "could," "could," "could," "could, "guidance," the negatives thereof, and variations thereon and similar expressions. By their nature, forward-looking statements involve risks and uncertainties as they relate to events or circumstances that may or may not occur in the future.

Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Various factors may cause differences between Indivior's expectations and actual results, including, among others, the material risks described in the most recent Indivior PLC Annual Report and in subsequent releases; the substantial litigation and ongoing investigations to which we are or may become a party; our reliance on third parties to manufacture commercial supplies of most of our products, conduct our clinical trials and at times to collaborate on products in our pipeline; our ability to comply with legal and regulatory settlements, healthcare laws and regulations, requirements imposed by regulatory agencies and payment and reporting obligations under government pricing programs; risks related to the manufacture and distribution of our products, most of which contain controlled substances; market acceptance of our products as well as our ability to commercialize our products and compete with other market participants; the fact that a substantial portion of our revenue derives from a small number of key proprietary products; competition; the uncertainties related to the development of new products, including through acquisitions, and the related regulatory approval process; our dependence on third-party payors for the reimbursement of our products and the increasing focus on pricing and competition in our industry; unintended side effects caused by the clinical study or commercial use of our products; our use of hazardous materials in our manufacturing facilities; our ability to successfully execute acquisitions, partnerships, joint ventures, dispositions or other strategic acquisitions; our ability to protect our intellectual property rights and the substantial cost of litigation or other proceedings related to intellectual property rights; the risks related to product liability claims or product recalls; the significant amount of laws and regulations that we are subject to, incl

Forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

## Our Company & Strategy

**Mark Crossley** 

CHIEF EXECUTIVE OFFICER



#### INDIVIOR INDIVIOR

# Why Indivior?



Global leader in addiction treatment with tremendous upside



Strong track record of execution and de-risking



Clear strategic priorities to create durable shareholder value



Scalable model to deliver attractive earnings and cash flow



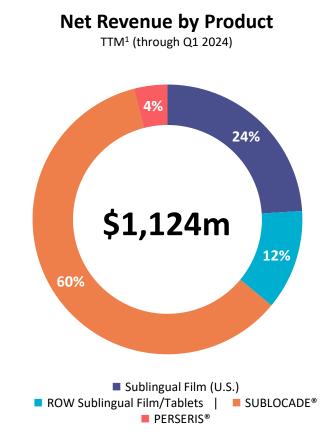
# Indivior is a Global Leader in Addiction Treatment

#### **Net Revenue by Geography**

TTM1 (through Q1 2024)







<sup>&</sup>lt;sup>1</sup> Trailing 4 quarters (Q2'23 – Q1'24)

<sup>&</sup>lt;sup>2</sup> See discussion of obligations in Note 9, 10 and 11, including our term debt and other payment obligations from the Q1 2024 Results press release dated April 25, 2024



## Addiction is a Global Crisis



#### **Opioids**

**60m** people use opioids for non-medical purposes



#### **Cannabis**

219m users



#### **Alcohol**

>100m people with Alcohol Use Disorder



# Amphetamines & Cocaine

58m users



## Clear Strategic Priorities to Drive Value Creation



#### **Grow SUBLOCADE >\$1.5Bn**

- → FY 2023 SUBLOCADE® NR +54% YoY
- → 136,900\* SUBLOCADE patients at FY 2023 (+66% vs. 2022)
- → Commercial investments to build on growth opportunities
- → Rest of World (ROW) SUBLOCADE NR of \$41m (+52% vs. 2022)



- → Acquisition and integration of Opiant
- → OPVEE® approved and launched
- → FY 2023 PERSERIS® NR +50% YoY
- → Continued ROW NR growth





#### **Build & Progress Pipeline**

- → SUD¹-focused pipeline development on track:
  - OUD<sup>2</sup>: INDV-2000
  - OUD: INDV-6001<sup>3</sup> (ALA-1000)
  - CUD<sup>4</sup>: AEF-0117 (partnership with Aelis Farma)

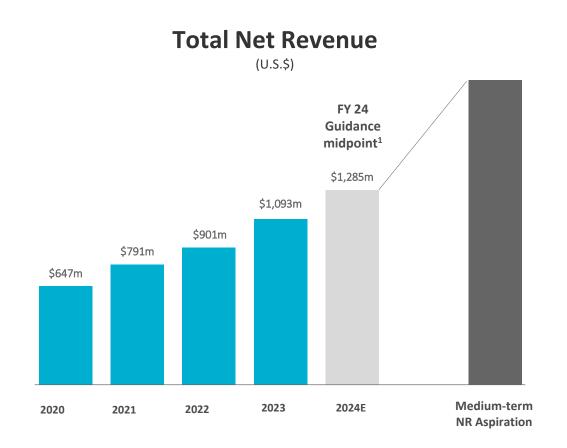
#### **Optimize Operating Model**

- → Successful NASDAQ listing in U.S.
- → Resolution of antitrust MDL<sup>5</sup>
- → Acquired wholly-owned sterile manufacturing site (Raleigh, NC) to secure supply for SUBLOCADE >\$1.5Bn
- → Executing \$100m share repurchase program
- → Effecting primary U.S. listing June 2024





# Confident in Medium-term Performance Goals – Double-Digit % NR CAGR & Margin Expansion



#### **Key Top-line Drivers:**

- SUBLOCADE >\$1.5 bn potential annual NR
   expected to reach \$1 bn NR run-rate by the end of 2025
- OPVEE peak \$150m \$250m potential annual NR
- PERSERIS peak \$200m \$300m potential annual NR
- ROW growth continues
- Assumes U.S. film share erodes to analogs
- Assumes existing competitive OUD LAI entrant

#### **Key Bottom-line Drivers:**

- Leverageable cost base
- Gross margin trending to mid 80% range over time

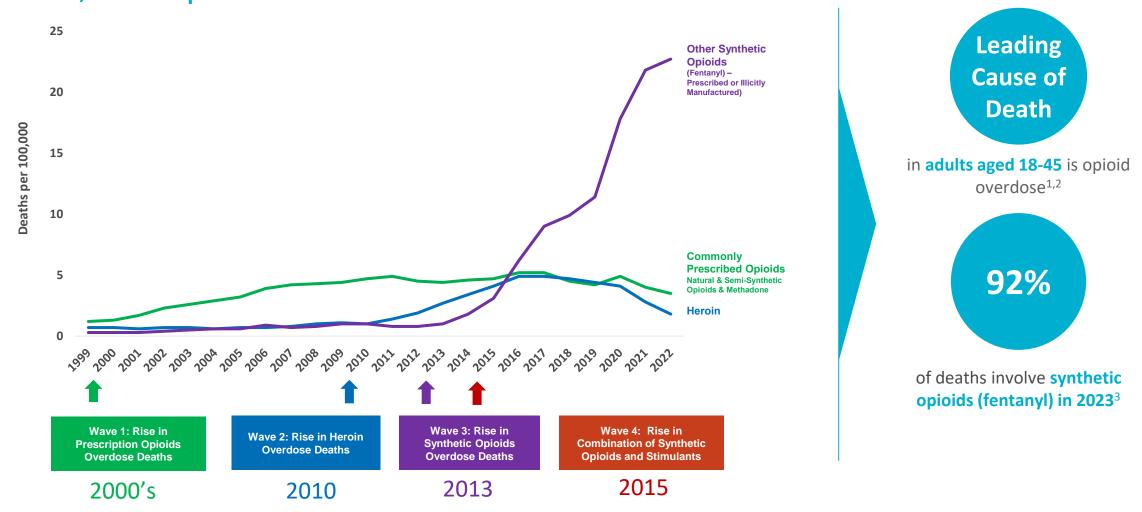
# SUBLOCADE®

UNLOCKING >\$1.5 BN POTENTIAL ANNUAL NR OPPORTUNITY





# Overdose Crisis is Being Driven by Synthetics: ~75,000 per Annum



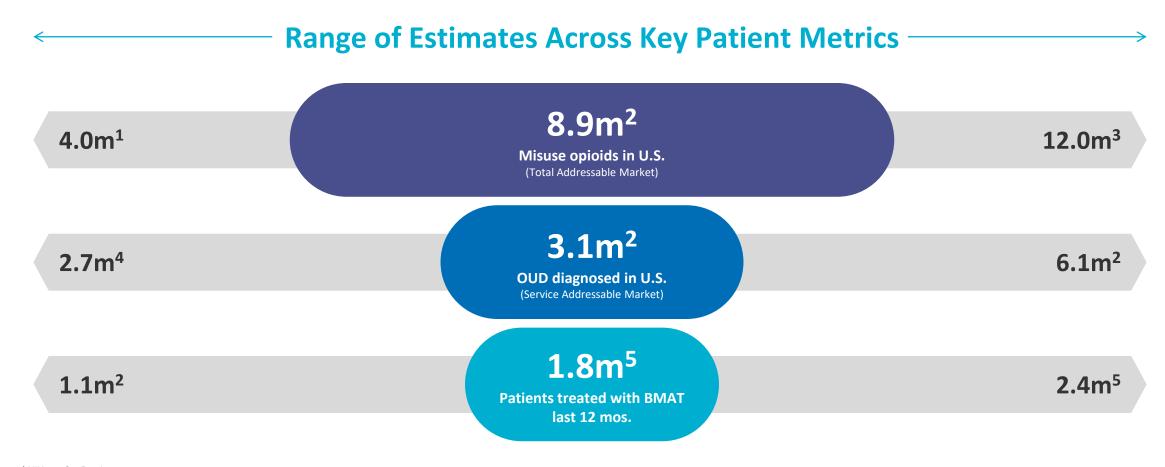
<sup>&</sup>lt;sup>1</sup> Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control. WISQARS leading causes of death reports. Centers for Disease Control and Prevention. https://wisqars.cdc.gov/fatal-leading. Published 2021. Accessed May 3, 2022. <sup>2</sup> CDC WONDER Online Database. Multiple cause of death, 2018-2020, single race results: deaths occurring through 2020. Centers for Disease Control and Prevention. 2021. Accessed May 11, 2022.

<sup>&</sup>lt;sup>2</sup> CDC WONDER Online Database. Multiple cause of death, 2018-2020, single race results: deaths occurring through 2020. Centers for Disease Control and Prevention. 2021. Accessed May 11, 2022. https://wonder.cdc.gov/controller/datarequest/D157;jsessionid=C003973203296DC9773978C0CF93

<sup>&</sup>lt;sup>3</sup> CDC: Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov)



## A Significant Treatment Gap Exists in the U.S.



<sup>&</sup>lt;sup>1</sup> NIH.gov StatPearls

<sup>&</sup>lt;sup>2</sup> 2022 NSDUH Annual National Report (SAMSHA)

<sup>&</sup>lt;sup>3</sup> The opioid crisis: a contextual, social-ecological framework (biomedcentral.com)

<sup>&</sup>lt;sup>4</sup> Opioid Use Disorder, Disease or Condition of the Week (CDC)

<sup>&</sup>lt;sup>5</sup> Symphony and Indivior analytics



## SUBLOCADE®1 Meets the Challenge of Today's Opioid Crisis



First monthly LAI buprenorphine treatment to consistently deliver at least 2ng/mL<sup>2</sup>



#### **SUPPRESS**

the high

- No daily fluctuations
- Consistent sustained therapeutic levels



#### **REDUCE**

illicit opioid use

 Backed by robust clinical trial results and 6 years of RWE



#### **EXTEND**

effect vs. higherpotency opioids<sup>3</sup>

- Blocks high in most patients after 1st dose
- Continued effect for 8 weeks after 2<sup>nd</sup> dose
- ✓ Broad indication in moderate-to-severe OUD
- One treatment decision, once a month
- ✓ Only LAI delivering buprenorphine levels up to 6 ng/mL<sup>4</sup>

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<sup>&</sup>lt;sup>1</sup> 1 Please refer to full Prescribing Information for important safety information, including boxed warning: www.SUBLOCADE.com

<sup>&</sup>lt;sup>2</sup> For Moderate to Severe OUD patients; consistently delivers 2ng/mL throughout the dosing interval in majority of patients after the second injection of SUBLOCADE 300mg

<sup>&</sup>lt;sup>3</sup> Blockade demonstrated vs. hydromorphone

<sup>&</sup>lt;sup>4</sup> 6.32ng/mL buprenorphine plasma exposure at steady state with 300mg dose



## Enabling U.S. Treatment Backdrop

DATA 2000 requirement removed December 2022

15 U.S. states offering comprehensive MAT in jails and prisons<sup>1</sup>

Telehealth expansion begun during pandemic continues to be extended<sup>2</sup>

\$50 bn+ in global opioid settlement funds<sup>3</sup>

\$45 bn U.S. budget request for National Drug Control Policy agencies<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> A Review of Medication Assisted Treatment (MAT) in United States Jails and Prisons (June 2023)

<sup>&</sup>lt;sup>2</sup> Telehealth.HHS.gov

<sup>3</sup> www opioidsettlementtracker com

<sup>&</sup>lt;sup>4</sup> U.S. FY 2024 budget request for National Drug Control Policy agencies



## U.S. Expansion in Place —ASOC¹, CJS, Medical

# Increased Field Capabilities

+50% Sales Force (OHS-affiliated & Indep. HCPs)

+25% CJS Team (Federal, State Prisons & County Jails)

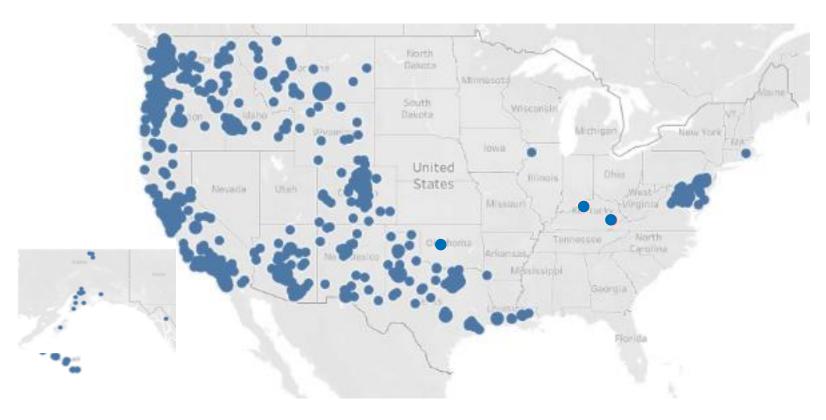
# Added Medical & Govt. Affairs Capabilities

+10 MSLs<sup>2</sup>

+5 County Govt. Affairs<sup>3</sup>

#### U.S. Counties with One or More Alternative Sites of Care

(~1,160 ASOCs across 21 states)



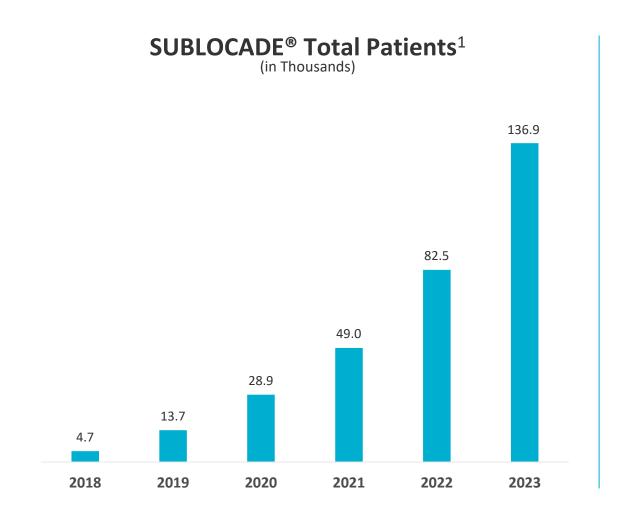
<sup>&</sup>lt;sup>1</sup> ASOC = alternate sites of care

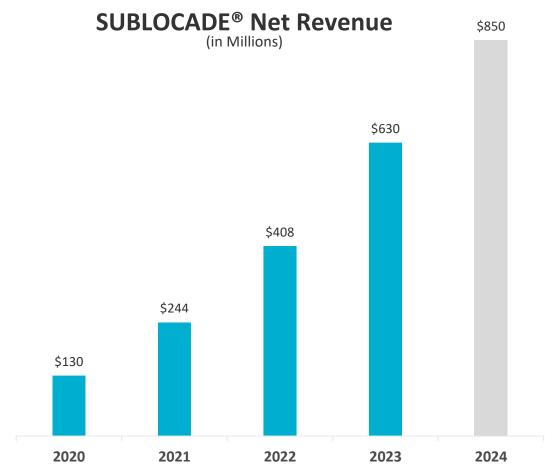
<sup>&</sup>lt;sup>2</sup> MSL = medical science liaison

<sup>&</sup>lt;sup>3</sup> County Government Affairs Role



## SUBLOCADE is Helping Reshape Patients' Lives







# SUBLOCADE: Confident in Delivering >\$1.5 bn NR Target

8.9m

Misuse opioids in U.S. <sup>1</sup>

3.1m

OUD diagnosed in U.S. <sup>1</sup>

~270,000

**Target SUBLOCADE patients** 

**Undertreated Disease & Enabling Market Backdrop** 

- ~20% treatment rate<sup>2</sup>
- Increasing access and de-regulation of MOUD prescribing
- Growing awareness and funding

**Leading Treatment Based on Powerful Science** 

- Category leader with six years of LAI treatment experience
- Paradigm-changing treatment in face of synthetic opioid crisis
- Delivery of at least 2ng/mL buprenorphine for a full 28 days

Proven & Successful Go-to-Market Strategy

- Meeting patients where they are in OHS and CJS settings
- Expanding footprint with ASOC<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> 2022 NSDUH Annual National Report (SAMSHA)

<sup>&</sup>lt;sup>2</sup> See slide 22: 1.8m patients treated with BMAT / 8.9m misuse opioids

## OPVEE<sup>®</sup>

UNIQUELY POSITIONED TO HELP COMBAT TODAY'S OPIOID EPIDEMIC





# OPVEE Squarely Addresses the Current Wave of Synthetic Opioid Overdoses

Triple Threat of Synthetic Opioid Pharmacology such as Fentanyl

Rapid

**Potent** 

**Long-Lasting** 



#### **Key treatment attributes:**

- Rapid absorption and proven nasal spray device
- Fast, strong and long-lasting reduction of respiratory depression<sup>1</sup>
- Uniquely suited for today's synthetically-driven (fentanyl) opioid crisis
- OPVEE development supported through federal grants from BARDA<sup>2</sup> and NIDA<sup>3</sup>



<sup>&</sup>lt;sup>1</sup>The Journal of Clinical Pharmacology Authors: Mark Ellison PhD, Emily Hutton, MSci, Lynn Webster, MD, and Phil Skolnick PhD, DSc (hon.).

<sup>&</sup>lt;sup>2</sup> BARDA: Biomedical Advanced Research and Development Authority

<sup>&</sup>lt;sup>3</sup> NIDA: National Institute on Drug Abuse

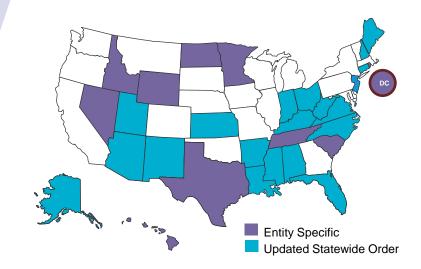


# Combination of Top Down (State-Level) and Bottom Up (First-Line Users) Approach is Required



#### **Standing Orders:**

• 31 states' standing orders include OPVEE or are entity-specific. Recent successes in Veterans Affairs & legislation passage in GA.





#### **Funding:**

- SAMHSA grants updated to include all FDA-approved OORM products
- State and local opioid abatement funds can also be used to purchase OORMs including OPVEE



#### **Existing Opioid Overdose Reversal Markets**

- Single state authorities / Grant administrators
- Naloxone Coordinators
- State/County/City Dept. of Health
- Veterans Affairs
- Community-based orgs/Harm groups
- Substance abuse centers/OTPs
- Law Enforcement
- Department of Corrections
- Fire/Emergency services
- State/County/City Opioid task forces



#### **Experience Program underway**

OPVEE offered free of charge to qualifying public interest entities in local communities to build experience

- Potential to drive significant impact on OPVEE adoption, as seen in Oakland County Pilot Program
- >180 organizations enrolled in program within first 3 weeks



# Confident in Delivering \$150m to \$250m Peak NR Goal for OPVEE

Differentiated product targeting synthetic (fentanyl) overdose crisis

Highly experienced commercial team

Expansive experience program expected to lead to adoption

# Indivior Pipeline





# **Growing Pipeline**

BRAND/PRODUCT NAME	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	REGULATORY APPROVAL	COMMERCIAL LAUNCH
SUBLOCADE® (Opioid Use Disorder) (buprenorphine extended-release) injection for subcutaneous use CIII						
OPVEE® (Opioid Overdose Rescue) (nalmefene) nasal spray						
PERSERIS® (Schizophrenia) (risperidone) for extended-release injectable suspension						
AELIS AEF0117 (Cannabis Use Disorder) (CB1 receptor synthetic Signaling Specific inhibitor (SSi))						
INDV-6001 (Opioid Use Disorder) <sup>1</sup> (3-month long-acting buprenorphine)						
INDV-2000 (Opioid Use Disorder) (Selective Orexin-1 (OX1) receptor antagonist)						
INDV-1000 (Alcohol Use Disorder)  GABA <sub>B</sub> positive allosteric modulator (PAM))						
INDV-5004 (Acute Cannabinoid Overdose) (Drinabant – CB1 receptor antagonist)						

<sup>1</sup> Licensed for the entire world other than the People's Republic of China, Hong Kong, Taiwan, or Macau

# Operational Excellence





# Margin Expansion from Scalable Business Model

#### Adj Op Profit (\$m) & Margin %



#### **Scalable Business Model**

- Mix improvement driven by SUBLOCADE
- Leveraging growth investments behind commercial assets
- Focused R&D spend
- Disciplined expense management
- Raleigh, N.C. site Manufacturing savings beginning in 2027

# Expect to deliver ~300 bps\* of margin improvement in 2024

\*Mid-point of FY 2024 guidance issued (as of May 23, 2024)



## Balanced Capital Allocation Framework

**Cash**: Existing and Generated

#### Organic Growth and Business Needs:

- Maintain flexibility and meet obligations<sup>1</sup>
- Reinvest in growth (current products)
- R&D / Supply

Business Development / Acquisitions

Shareholder Returns

#### **Organic Growth and Business Needs**

- Growth investments to drive SUBLOCADE, PERSERIS and launch OPVEE
- Pipeline advancement and strengthening

#### **Business Development / Acquisitions**

- Completed Opiant acquisition
- Acquired Raleigh, N.C. manufacturing site
- Pipeline expansion through acquisition of full rights to INDV-2000 and in-licensing of Alar long-acting buprenorphine portfolio<sup>1</sup>

#### **Shareholder Return**

 \$100m share repurchase program announced in November'23 (since 2021, approximately \$265m spent on share buybacks through April 19, 2024)

<sup>1</sup> Licensed for the entire world other than the People's Republic of China, Hong Kong, Taiwan, or Macau

# U.S. Listing Update & Closing Remarks



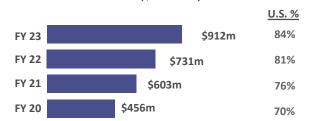


## U.S. Primary Listing Update

#### **Net Revenue by Geography**



### U.S. Net Revenue Progression (\$-in mil.)



#### **Background & Context**

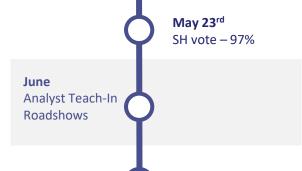
- U.S. NR represents 84% of total NR (FY 2023)
- U.S. expected to continue to increase as proportion of total NR, driven by proprietary growth products (SUBLOCADE, PERSERIS and OPVEE)
- Group's headquarters and leadership team based in the U.S. (Richmond, Va.)
- U.S. shareholders

   approaching 50% of Group's
   total investor base; U.K.
   investors represent ~33%
- U.S. GAAP financials (incl. Form 10-K) targeted for March 2025

#### **Expected Benefits**

- Elevate profile as addiction treatment leader with a promising pipeline to further attract U.S. investors
- U.S. index inclusion over time
- Fully leverage existing organizational capabilities (reporting, controls, legal)
- U.K. investors to retain liquidity through secondary U.K. listing

# Q4 Feb 22<sup>nd</sup> Announcement March/April SH Consultations Q1 Apr 25<sup>th</sup> Move to SH Vote



**Targeting June 27th** 

Effectiveness



# Confident in our Ability to Transform Patient Lives and Create Durable Shareholder Value

We are a global leader in addiction treatment

SUBLOCADE is a transformational asset with >\$1.5 bn global opportunity<sup>1</sup>

We are pursuing diversification opportunities in addiction & its comorbidities

We will maintain our operational excellence & expect to generate significant free cash

Q&A

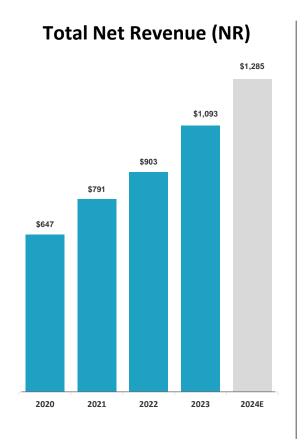


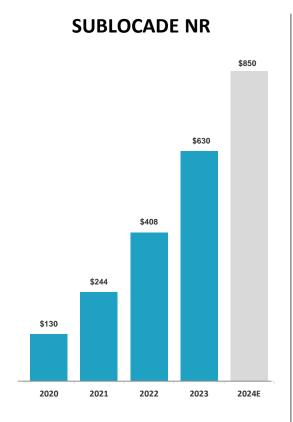
# Appendix

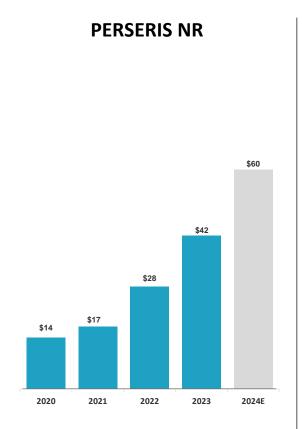


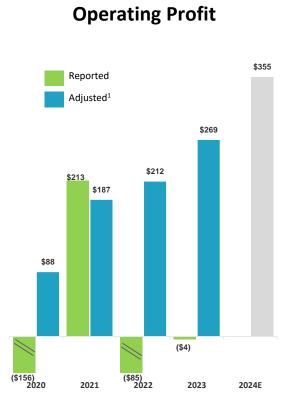


# Delivering on Our Profitable Growth Thesis (\$ in mil.)









<sup>&</sup>lt;sup>1</sup> See appendix for reconciliation



## Financial Reconciliations

	2023	2022	2021	2020
For the twelve months ended December 31	\$m	\$m	\$m	\$m
Gross profit	907	742	664	550
Exceptional items and other adjustments in cost of sales	8	_	_	5
Adjusted gross profit	915	742	664	555
	2023	2022	2021	2020
For the twelve months ended December 31	\$m	\$m	\$m	\$m
Selling, general and administrative expenses	(811)	(763)	(431)	(666)
Exceptional items and other adjustments in selling, general and administrative expenses	268	302	6	239
Adjusted selling, general and administrative expenses	(543)	(461)	(425)	(427)
	2023	2022	2021	2020
For the twelve months ended December 31	\$m	\$m	\$m	\$m
Net other operating income	6	8	32	
Exceptional items and other adjustments in Other Operating Income	(3)	(5)	(32)	
Adjusted Net other operating income	3	3	_	_
	2023	2022	2021	2020
For the twelve months ended December 31	\$m	\$m	\$m	\$m
Operating profit/(loss)	(4)	(85)	213	(156)
Exceptional items and other adjustments in cost of sales	8	_	_	5
Exceptional items and other adjustments in selling, general and administrative	268	302	6	239
expenses				
Exceptional items and other adjustments in net other operating income	(3)	(5)	(32)	
Adjusted operating profit	269	212	187	88
	2023	2022	2021	2020
For the twelve months ended December 31	\$m	\$m	\$m	\$m
Reported operating profit/(loss) / Net Revenue	(0.4)%	(9.4)%	26.9 %	(24.1)%
Exceptional items and other adjustments in cost of sales	25.0 %	33.0 %	(3.3)%	37.7 %
Adjusted operating profit/(loss) / Net Revenue	24.6%	23.5%	23.6%	13.6%



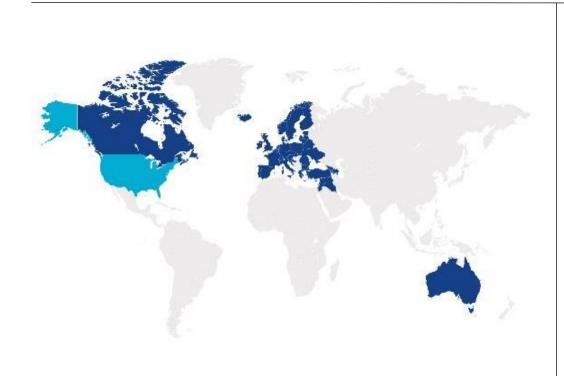


## Indivior is a Global Leader in Addiction

Strengthening our position in the U.S. behind SUBLOCADE

Continuing to expand our footprint across Rest of World

Unique product pipeline expected to address broader addiction types



		SUBLOCADE (SUBUTEX®PR (ROW))	SUBOXONE Film <sup>2</sup>	PERSERIS	OPVEE
North America	U.S.	•	•	•	•
	Canada	•	•		
Europe & Middle East	France		•		
	Italy	•	•		
	Germany	•	•		
	Denmark, Norway	•	•		
	Sweden	•	•		
	Finland	•	•		
	Switzerland	•			
	UK	•	•		
	Israel	•	•		
Australasia	Australia	•	•		
	N Zealand	•	•		

(approved/Not Marketed)

<sup>1</sup> SUBUTEX® (buprenorphine) tablets used to treat OUD are taken daily by sublingual administration and are available in non-U.S. markets.

<sup>&</sup>lt;sup>2</sup> The Group does not promote **SUBOXONE Film** in the US

# PERSERIS®

SIGNIFICANT OPPORTUNITY TO DIFFERENTIATE IN SCHIZOPHRENIA

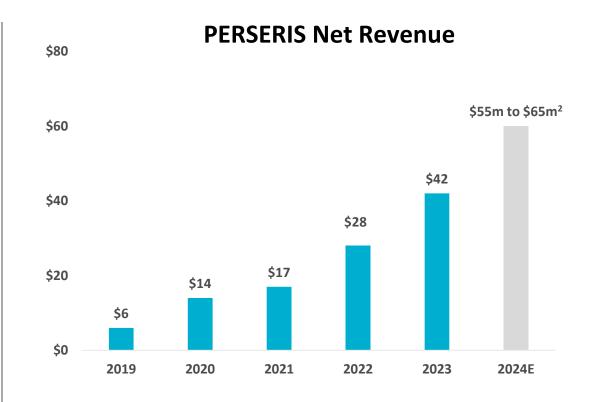




# PERSERIS<sup>1</sup> — Differentiation is Clear and Understandable

#### **PERSERIS Differentiated Profile**

- First approved subcutaneous risperidone LAI
- 4 to 6 hours peak plasma concentrations of risperidone
- No loading dose / oral supplementation recommended
- Optimal dopamine receptor occupancy over entire month
- Safety consistent with known profile of oral risperidone



2. Mid-point of PERSERIS FY 2024 guidance as of May 23, 2024

Source: INDV market research (PERSERIS® Message Testing Qualitative Research conducted by IPSOS, February 2022; n:25).

<sup>&</sup>lt;sup>1</sup> P-RAG-US-00415 (PERSERIS® IVA)