

# Jefferies Healthcare Conference

June 7<sup>th</sup>, 2023

### 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 financial guidance for 2023 and its medium- and long-term growth outlook; strategies for value creation; expected sales levels for particular products; expectations regarding the cost to resolve the Group's legal proceedings and regulatory matters; the timing of our planned additional U.S. stock exchange listing; operational goals; our product development pipeline and potential future products; expectations regarding regulatory approval of product candidates, future product pricing, the timing of such approvals, and the timing of commercial launch of such product candidates, and eventual annual revenues of such future products; 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", "can", "outlook," "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, some of which are controlled substances; market acceptance of our products as well as our ability to commercialize our products and compete with other market participants; the uncertainties related to the development of new products, including through acquisitions, and the related regulatory approval process; our dependence on a small number of significant customers; our ability to retain key personnel or attract new personnel; 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 import, manufacturing and distribution of controlled substances; 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 signif

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.



# Mark Crossley

CEO

## Why Indivior?



Strengthening our global leadership in addiction treatment and science



Executing against attractive medium-term profitable growth framework



Elevating investor profile through additional U.S. listing on NASDAQ



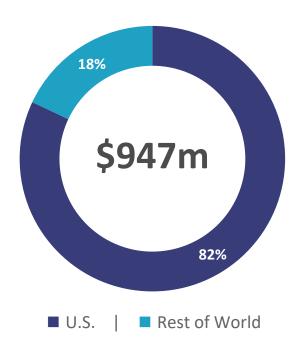
Actively addressing legacy litigation matters



### Indivior is the Global Leader in Addiction Treatment

### **Net Revenue by Geography**

TTM<sup>1</sup> (through Q1 2023)

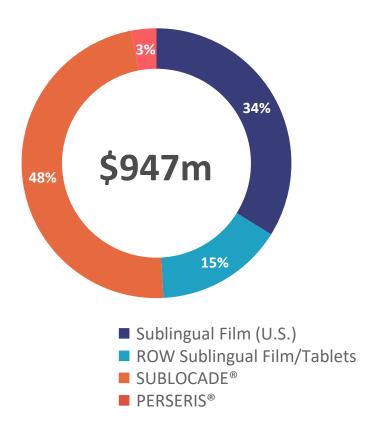






### **Net Revenue by Product**

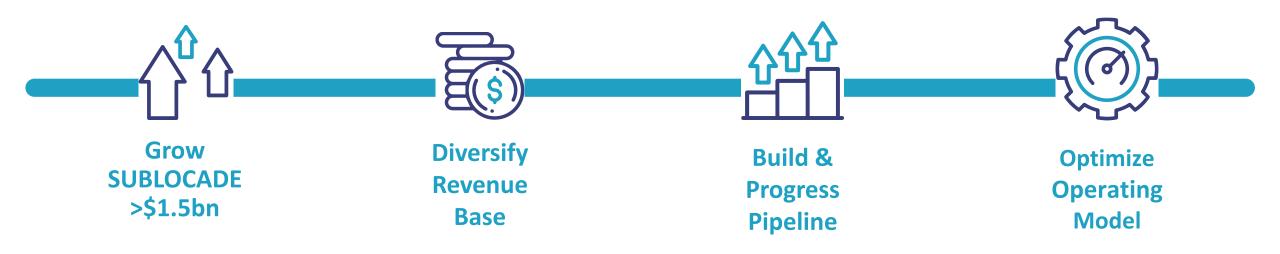
TTM<sup>1</sup> (through Q1 2023)





1. Trailing 4 quarters (Q1'22 – Q1'23)

# **Executing Clear Strategies for Value Creation**





### Addiction is a Global Crisis



**Opioids** 

**61m** people use opioids for non-medical purposes



**Cannabis** 

209m users



**Alcohol** 

**108m** people with Alcohol Use Disorder



Amphetamines & Cocaine

**56m** users





# A Significant Unmet Need Remains with High Overdose and Low Treatment Rates

## **10.1m** + people<sup>1</sup>

Engage in non-medical misuse & illicit opioid use

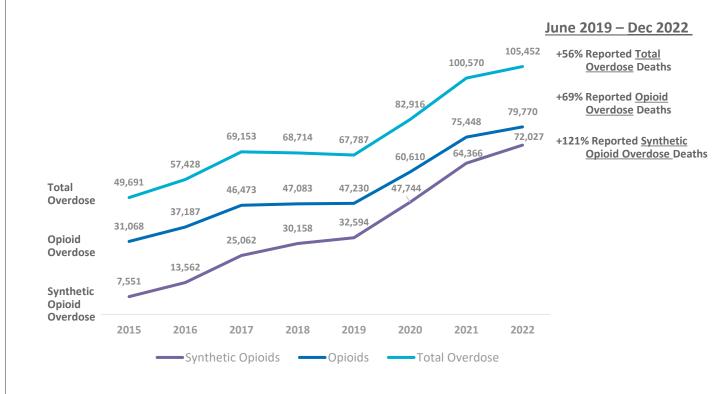
## 3.1m+ patients<sup>2</sup>

Diagnosed with Opioid Use Disorder (OUD)

# 1.8m+ patients<sup>2</sup>

Treated with buprenorphine medication-assisted treatment (BMAT) last 12 months

# 12 Month-ending Reported Number of Drug Overdose Deaths by Drug or Drug Class





## Strong SUBLOCADE Net Revenue Growth Continues

### **SUBLOCADE** Key Attributes

SUBLOCADE® is the first buprenorphine-based long-acting injectable approved by U.S. FDA for the treatment of moderate to severe OUD

Rationally designed to deliver therapeutic levels of buprenorphine of ≥2 ng/mL over the entire monthly dosing period resulting in >70% mu-receptor occupancy

Consistent and sustained levels

No daily ups and downs

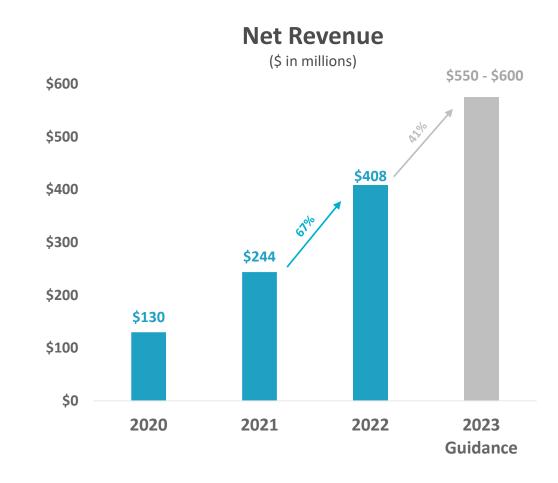
No supplemental or booster dosing

**Blocks** the subjective and rewarding effects of opioids

1 treatment decision, 1 time per month

**Potential to help millions** of patients based on FDA-approved indication

Proven Organized Health Systems (OHS) channel with approximately 90% of NR

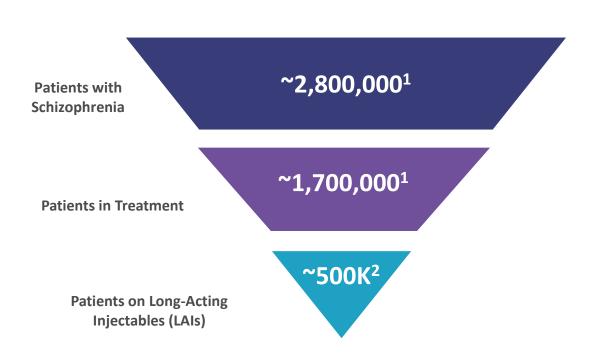


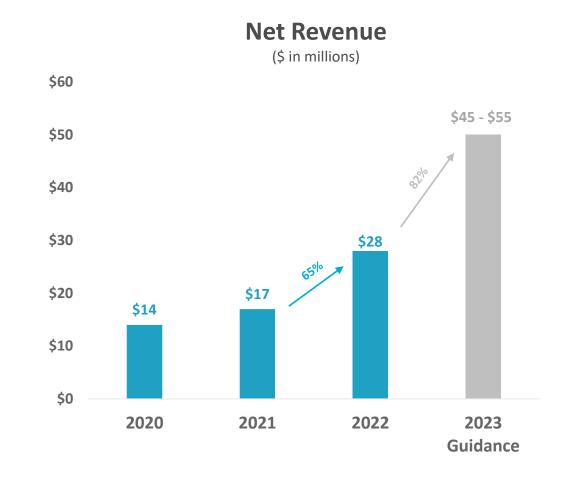
FY 23 NR Guidance +41%<sup>1</sup> vs. Prior Year



# PERSERIS Peak NR Target of \$200-\$300m

### **Schizophrenia Patient Funnel**





FY23 NR Guidance +82%<sup>1</sup> vs. Prior Year

<sup>1</sup> At mid-point of range – Guidance as of April 27, 2023





www.treatmentadvocacycenter.org

# **Opiant Acquisition**



Transaction closed March 2<sup>nd</sup>; integration completed



FDA approval for OPVEE® (nalmefene) nasal spray (opioid overdose rescue medicine for natural and synthetic opioids like fentanyl) May 22<sup>nd</sup>; anticipated Q4 2023 launch



Intention to price OPVEE responsibly considering innovation and access



Targeting "public interest" market with highly-focused commercial strategy



Confident in potential to achieve annual NR in range of \$150-\$250 million



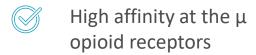
# OPVEE shown to provide fast onset and long duration reversal of opioid-induced respiratory depression

# OPVEE (opioid overdose rescue medicine for natural and synthetic opioids like fentanyl)

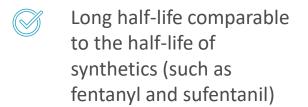
### OPVEE (2.7mg)

Affinity at μ opioid receptors	<b>1.0</b> <sup>(1)</sup>
Plasma concentrations at 5 minutes (ng/ml)	<b>4.43</b> <sup>(3)</sup>
Tmax (minutes)	<b>15</b> <sup>(3)</sup>
Cmax (ng/ml)	<b>10</b> <sup>(3)</sup>
Half-life (hours)	<b>11</b> <sup>(3)</sup>

### Nalmefene shows:







### **OPVEE Device:**





<sup>1.</sup>K values were estimated using [3H]alvimopan binding to cloned humanmopioid receptors (Cassel, et al., 2005). The ~5-fold higher affinity of nalmefene compared naloxone is consistent with both K values obtained (0.13 and 0.62 nM, respectively) using [3H]DAMGO as a radioligand in monkey brain membranes (Emmerson, et al., 1994) and pA2values of 9.38 and 8.51, respectively, in functional assays using guinea pig ileum and mouse vas deferens (Toll, et al., 1998).

<sup>2.</sup> Krieter, et al. ,2016

<sup>3.</sup> Data on file: NCT04759768

<sup>4.</sup> Data from FDA, 2015(https://www.accessdata.fda.gov/drugsatfda\_docs/label/2015/208411lbl.pdf)

<sup>5.</sup> Data compiled in separate studies on normal healthy volunteers

### **Ex.-US Business**

Leveraging Indivior's presence in 39 countries to bring new technologies to key Ex.-US markets:



**SUBUTEX PR** – Approved in 11 countries Ex-US Pending approval in UK



**SUBOXONE Film** – Approved in 36 countries Ex-US Filings under review in Kuwait, Kingdom of Saudi Arabia and Colombia



+5% Q1 2023 ROW NR vs. Q1 2022 including FX (up 13% excluding FX)

### **Current major ex.- US drug approvals**

**SUBLOCADE®** 

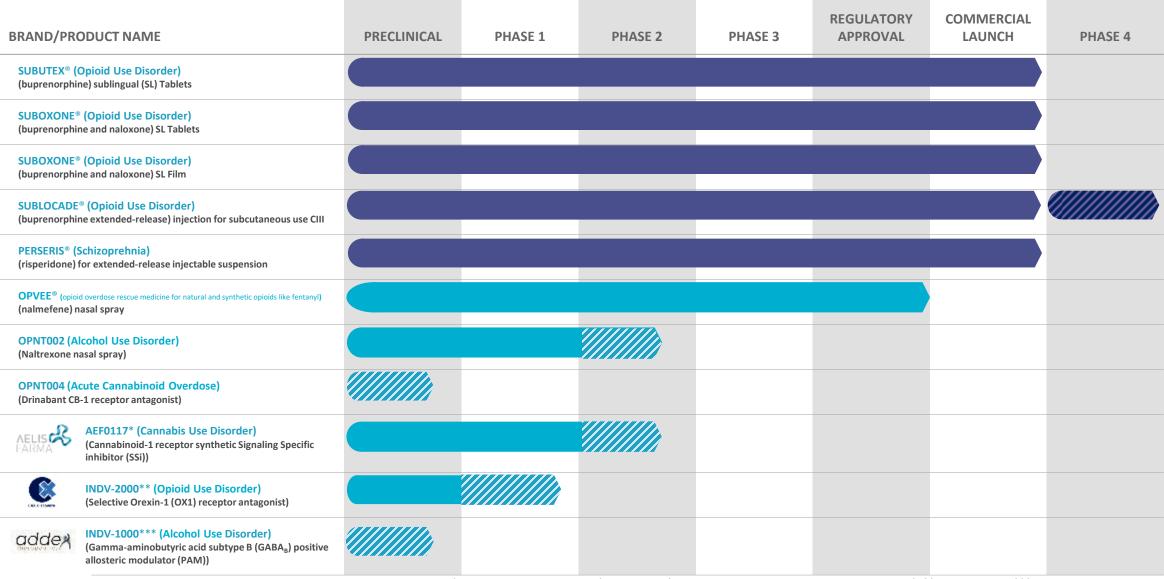
		(SUBUTEX®PR)	20ROXONE <sub>®</sub> FIIM
N. America	Canada	•	•
	EU		
	France		
Europe & Middle East	Italy		
	Germany		
	Denmark, Norway		
	Sweden		
	Finland		
	Switzerland		
	UK		
	Israel		
Australasia	Australia	•	•
	New Zealand		





SUBOXONE® Film

# Approved Products & Pipeline for a Growing Disease Space





### Attractive Medium-Term Profile



# Attractive Growth Profile

#### **Expected Double-digit % NR CAGR**

- SUBLOCADE® building to >\$1.5 bn potential annual NR
- PERSERIS® \$200-300m potential annual NR
- Modest ROW growth

#### **KEY ASSUMPTIONS**

- Underlying BMAT growth: mid- to high-single digits
- SUBLOCADE® competitor entry
- SUBOXONE® Film share trends to analogs (not promoted in US)



### Positive Operating Leverage

Gross margin mid-80%s

Scalable business model

#### **KEY ASSUMPTIONS**

- Managing inflationary environment
- Investments primarily focused on US commercial and R&D / pipeline



# Positive Cash Flow

Capital-light business model
Disciplined capital allocation approach

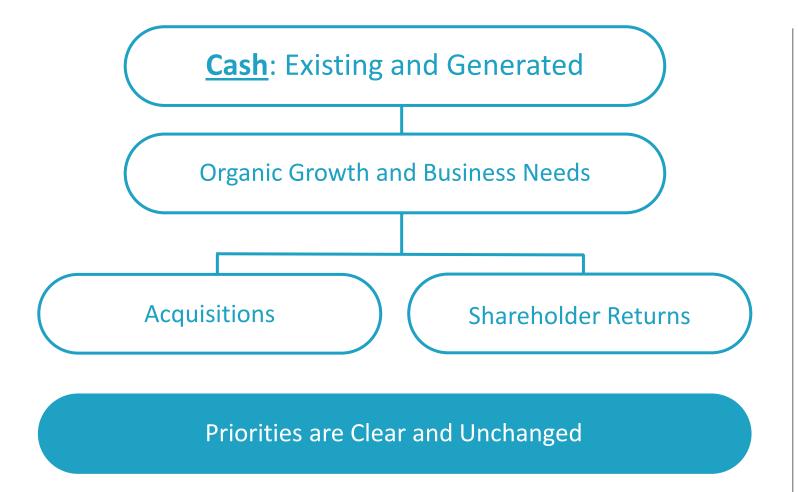
#### **KEY ASSUMPTIONS**

Self-sustaining business

**Expect Operating Margin Expansion and Positive Free Cash Generation Over the Medium-Term** 



## **Capital Allocation Priorities**





#### **Selling & General Expenses**

 FY 2022=\$218m (FY 2021=\$192m) – Increased investments to drive SUBLOCADE/PERSERIS LAIs

#### **Research & Development**

 FY 2022 = \$72m (FY 2021=\$52m) – SUBLOCADE studies and capacity expansion

#### **Completed Opiant Acquisition**

Approximately \$145m Cash + CVRs

#### **Share buyback**

Q1 2023 - completed 2<sup>nd</sup> \$100m share buyback

#### Additional listing in the U.S. expected June 12th

 Investment to improve awareness of Indivior among a broader pool of investors and analysts

#### **Continuing to meet obligations**

Working to resolve legacy legal matters





# Q1 2023 Results

## Q1 2023 financial highlights

### Takeaways (vs. Q1 2022)

- Top-line NR growth of 22%
  - ✓ U.S. NR up 27%
  - ✓ ROW NR up 5% including FX (up 13% excluding FX)
- Total SUBLOCADE NR up 55%; PERSERIS NR up 60%
- Gross Profit % increase of 3 pts. primarily on SUBLOCADE mix, favorable FX and lower manufacturing write-offs
- Reported operating profit up 6% to \$57m; Adjusted operating profit¹ up 31% to \$71m, excluding exceptional Opiant transaction costs and U.S. listing costs
- Gross cash & investments \$803m² at the end of Q1 2023

### **Operating Results – Reported and Adjusted<sup>3</sup>**

\$ mil	Q1 23	Q1 22	<b>Change</b>
Net Revenue: U.S. ROW <sup>4</sup>	<b>253</b> 209 44	<b>207</b> 165 42	<b>22%</b> 27% 5%
Gross Profit:	<b>214</b> 85%	<b>170</b> 82%	<b>26%</b> +3 pts
Op Expenses: SG&A R&D	(158) (131) (27)	(117) (109) (8)	35% 20% NM
Other Op. Income/(Expense):	1	1	0%
Operating Profit: Reported Adjusted <sup>3</sup>	57 71	54 54	6% 31%
<b>Key product NR</b> SUBLOCADE NR PERSERIS NR	Q1 23 132 8	<u>Q1 22</u> 85 5	<u>Change</u> 55% 60%

<sup>&</sup>lt;sup>1</sup> Excluding exceptional SG&A items as detailed in Note 4 from the Q1 2023 Results press release dated April 27, 2023

<sup>&</sup>lt;sup>2</sup> See discussion of obligations in Notes 11 and 12, including our term debt and other payment obligations and liabilities from the Q1 2023 Results press release dated April 27, 2023

<sup>&</sup>lt;sup>3</sup> See reconciliation page in the appendix

<sup>&</sup>lt;sup>4</sup> Actual FX (foreign exchange) rates

## FY 2023 guidance (Reflects guidance provided April 27, 2023)

Guidance includes the impact from the closed transaction with Opiant Pharmaceuticals and continued SUBOXONE Film resilience in US

### FY 2023 Guidance<sup>1</sup> (\$ in mil.)

#### **Total Net Revenue**

### **Key LAI Products**

- SUBLOCADE NR (Total)
- PERSERIS NR

#### Adj. Gross Margin %

### Adj. OPEX (SG&A + R&D)

- SG&A
- R&D

#### Adj. Op. Profit

### \$970m to \$1,040m

- \$550m to \$600 (+41% at mid-point)
- \$45m to \$55m (+82% at mid-point)

### Low to mid 80% range

### \$620m to \$640m

- \$530m to \$540m
- \$90m to \$100m

#### Slightly below FY 2022 level of \$212m

<sup>&</sup>lt;sup>2</sup> Apotex generic buprenorphine/naloxone sublingual film approved by FDA on 2 June 2022.



### **Additional Top-Line Assumptions**

- Underlying BMAT market growth of mid- to high-single digits
- OPVEE NR impact immaterial reflecting anticipated Q4 launch timing
- U.S. SUBOXONE Film
  - Accelerated share erosion in H2 2023 reflecting underlying share loss due to anticipated formulary decisions together with assumed impact from a fourth film generic<sup>2</sup> entering the U.S. market in the second half of FY 2023
  - The Group will continue to monitor the competitive environment and update the market accordingly

#### > ROW

- Broadly stable with growth in new products (SUBUTEX PR®, SUBOXONE Film), largely offset by continued pressure on legacy products
- Minimal FX translation impacts, based on current rates

### **Margin & Expense Considerations**

- ➤ Adj. gross margin: increased SUBLOCADE mix offset by higher inflation
- > Adj. OPEX :
  - SG&A
    - ✓ Inflationary impacts
    - ✓ Commercial initiatives supporting SUBLOCADE leadership including Justice Team and Key Account Director build out
    - ✓ Opiant commercial expenses including expenses associated with anticipated Q4 launch of OPVEE
  - R&D
    - ✓ Ongoing long-term efficacy and safety studies for SUBLOCADE
    - ✓ Early-stage asset advancement
    - ✓ Integration of Opiant R&D personnel and pipeline assets
    - ✓ Inflationary impacts

<sup>&</sup>lt;sup>1</sup> Before exceptional items. LAI=long-acting injectable.



Q&A

# Appendix



## Financial Reconciliation: Q1 2023 & Q1 2022

	Q1 2023	Q1 2022	
(\$ in mil. at Actual FX )			
Net Income / (Loss)	44	41	
Net interest (expense) / income	(1)	6	
Taxation	14	7	
Operating Profit / (Loss)	57	54	
Adjustments	14	N/A	
Adjusted Operating Profit / (Loss)	71	54	

#### Q1 2023 Notes:

\$12m exceptional transaction and deal costs related to the acquisition of Opiant Pharmaceuticals, Inc. \$2m exceptional costs in preparation for a potential listing of Indivior shares on a major U.S. exchange

#### Q1 2022 Notes:

N/A

