

# BofA US Healthcare Conference

May 10, 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, 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", "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



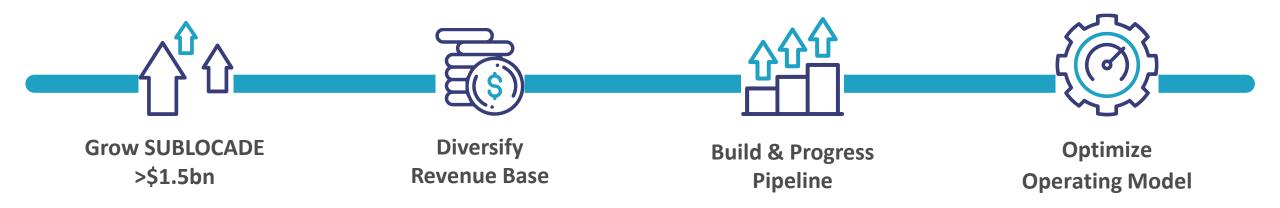
Actively addressing legacy litigation matters



## Indivior is the Global Leader in Addiction Treatment



## **Executing Clear Strategies for Value Creation**





## Addiction is a Global Crisis

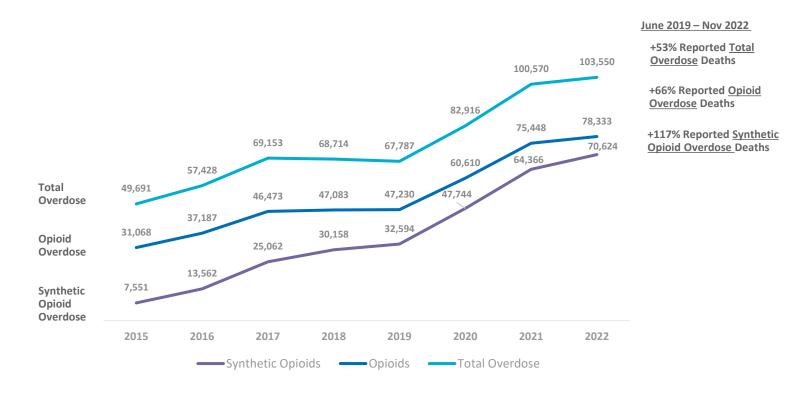


Source: UNODC, World Drug Report 2022 (United Nations publication, 2022); Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019 (GBD 2019) Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2021.



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

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



## 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



## Strong SUBLOCADE Net Revenue Growth Continues

## **SUBLOCADE Key Attributes**

# SUBLOCADE<sup>®</sup> 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

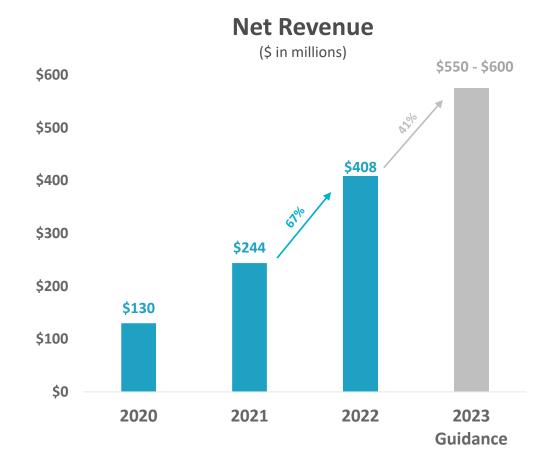
#### 1 treatment decision, 1 time per month

**Potential to help millions** of patients based on FDAapproved indication

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



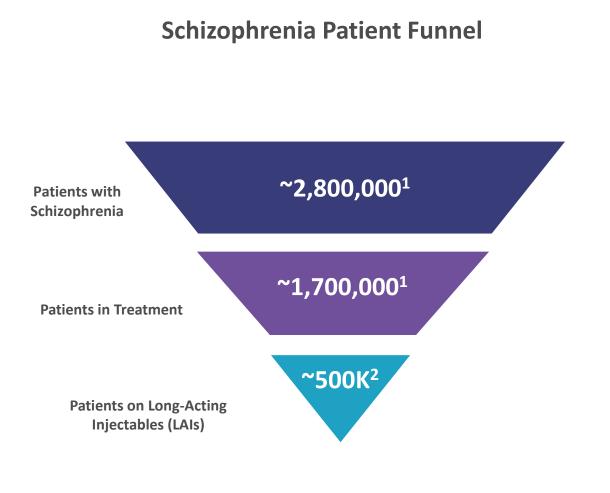
 (1) Please refer to full Prescribing Information for important safety information, including boxed warning: www.SUBLOCADE.com SUBLOCADE™ (buprenorphine extended-release) is indicated for the treatment of moderate to severe opioid use disorder in adults after initiation with transmucosal buprenorphine. SUBLOCADE™ should be used as part of a complete treatment program that includes counseling and psychosocial support.

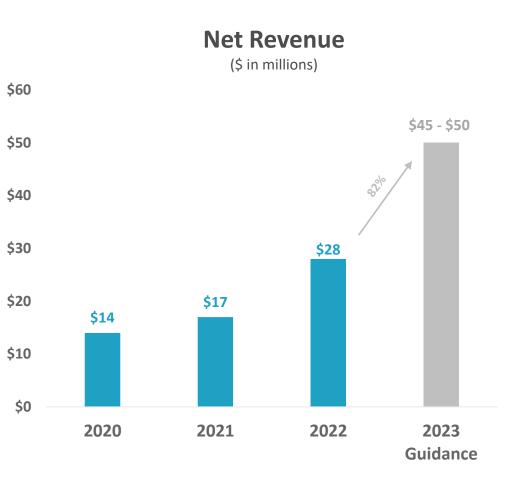


## FY 23 NR Guidance +41%<sup>1</sup> vs. Prior Year

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

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





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

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



<sup>2</sup> ncbi.nlm.nih.gov/33906481

# **Opiant Acquisition Update**



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



May 22<sup>nd</sup> PDUFA for OPNT003 (emergency treatment of known or suspected opioid overdose); anticipated Q4 2023 launch (if approved)



Intention to price OPNT003 responsibly considering innovation



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



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



# Scientific evidence confirms OPNT003's potential to improve and sustain reversal of opioid overdose

#### OPNT003 (emergency treatment of known or suspected opioid overdose) compared with 4mg nasal naloxone

	<b>OPNT0003 (3mg)</b>	Naloxone (4mg)
Affinity at $\mu$ opioid receptors	<b>1.0</b> <sup>(1)</sup>	<b>5.4</b> <sup>(1)</sup>
Plasma concentrations at 5 minutes (ng/ml)	<b>4.43</b> <sup>(3)</sup>	<b>1.5</b> <sup>(2)</sup>
Tmax (minutes)	<b>15</b> <sup>(3)</sup>	<b>30</b> <sup>(4)</sup>
Cmax (ng/ml)	<b>10</b> <sup>(3)</sup>	<b>4.83</b> <sup>(4)</sup>
Half-life (hours)	<b>11</b> <sup>(3)</sup>	<b>2.08</b> <sup>(4)</sup>

1.K values were estimated using [3H]alvimopan binding to cloned humanmopioid receptors (Cassel, et al., 2005). The ~5-fold higher affinity of nalmefene comparedto naloxone is consistent with both Kivalues 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).

2.Krieter, et al. ,2016

3. Data on file: NCT04759768

4. Data from FDA, 2015(https://www.accessdata.fda.gov/drugsatfda\_docs/label/2015/208411lbl.pdf) 5. Data compiled in separate studies on normal healthy volunteers

## 

### Compared with Naloxone, Nalmefene shows:



Higher affinity at the  $\mu$  opioid receptors



Reduced Tmax and higher Cmax



Longer half-life comparable to the halflife of synthetics (such as fentanyl and sufentanil)

## Ex. - US Business

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



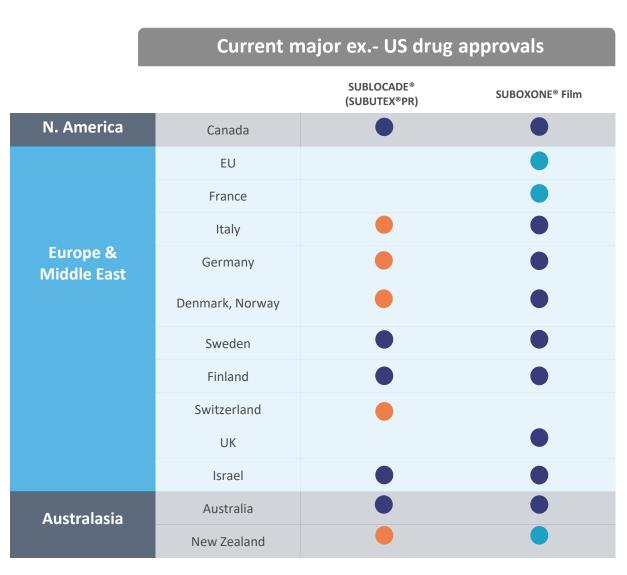
**SUBUTEX PR** – Approved in 11 countries Ex-US Pending approval in UK



**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)





(approved)

# Approved Products & Pipeline for a Growing Disease Space

BRAND/PRODUCT NAME	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	REGULATORY APPROVAL	COMMERCIAL LAUNCH	PHASE 4
SUBUTEX® (buprenorphine) sublingual (SL) Tablets							
SUBOXONE <sup>®</sup> (buprenorphine and naloxone) SL Tablets							
SUBOXONE <sup>®</sup> (buprenorphine and naloxone) SL Film							
SUBLOCADE <sup>®</sup> (buprenorphine extended-release) injection for subcutaneous use CIII							
<b>PERSERIS®</b> (risperidone) for extended-release injectable suspension							
OPNT003 (Nalmefene nasal spray)							
OPNT002 (Naltrexone nasal spray)							
OPNT004 (Drinabant CB-1 receptor antagonist)							
AEF0117* (Cannabinoid-1 receptor synthetic Signaling Specific inhibitor (SSi))							
(Selective Orexin-1 (OX1) receptor antagonist)							
(Gamma-aminobutyric acid subtype B (GABA <sub>B</sub> ) positive allosteric modulator (PAM))							



\*Licensing Agreement with: \*Aelis Farma (Indivior has exclusive license to this technology); \*\*C4X Discovery; \*\*\*Addex Therapeutics

## Attractive Medium-Term Profile



### Attractive Growth Profile

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

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

#### **KEY ASSUMPTIONS**

- Underlying BMAT growth: mid- to high-single digits
- SUBLOCADE<sup>®</sup> competitor entry
- SUBOXONE<sup>®</sup> 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

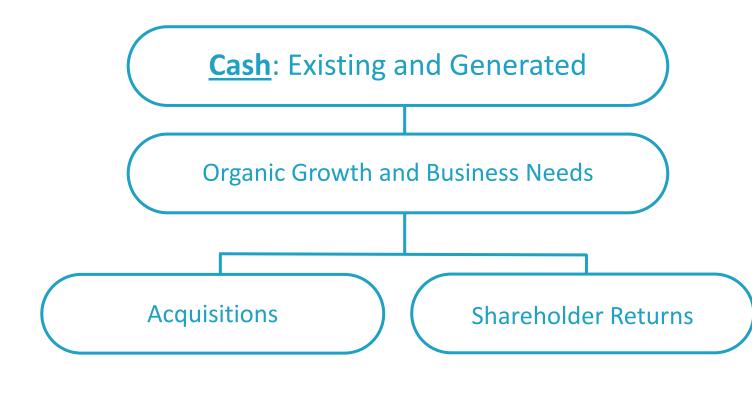
**KEY ASSUMPTIONS** 

Self-sustaining business

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



## **Capital Allocation Priorities**



Priorities are Clear and Unchanged



#### **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.

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

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

Resolution of 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 profit<sup>1</sup> up 31% to \$71m, excluding exceptional Opiant transaction costs and U.S. listing costs
- Gross cash & investments \$803m<sup>2</sup> at the end of Q1
   2023



<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>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

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

\$ mil	<u>Q1 23</u>	<u>Q1 22</u>	<u>Change</u>
Net Revenue:	253	207	22%
U.S.	209	165	27%
ROW <sup>4</sup>	44	42	5%
Gross Profit:	214	170	26%
	85%	82%	+3 pts
<b>Op Expenses:</b>	(158)	(117)	35%
SG&A	(131)	(109)	20%
R&D	(27)	(8)	NM
		<b>X</b> - 7	
Other Op.			201
Income/(Expense):	1	1	0%
<b>Operating Profit:</b>			
Reported	57	54	6%
Adjusted <sup>3</sup>	71	54	31%
Key product NR	<u>Q1 23</u>	<u>Q1 22</u>	<u>Change</u>
SUBLOCADE NR	132	85	55%
PERSERIS NR	8	5	60%

<sup>3</sup> See reconciliation page in the appendix <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

\$ in mil.)		<ul> <li>OPNT003 NR impact immaterial reflecting anticipated Q4 launch timing</li> <li>U.S. SUBOXONE Film</li> </ul>
	<ul> <li>\$970m to \$1,040m</li> <li>\$550m to \$600 (+41% at mid-point)</li> <li>\$45m to \$55m (+82% at mid-point)</li> </ul>	<ul> <li>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</li> <li>The Group will continue to monitor the competitive environment and update the market accordingly</li> <li>ROW</li> <li>Broadly stable with growth in new products (SUBUTEX PR<sup>®</sup>, SUBOXONE Film), largely offset by continued pressure on legacy products</li> <li>Minimal FX translation impacts, based on current rates</li> </ul>
	Low to mid 80% range	Margin & Expense Considerations
	<ul> <li>\$620m to \$640m</li> <li>\$530m to \$540m</li> <li>\$90m to \$100m</li> <li>Slightly below FY 2022 level of \$212m</li> </ul>	<ul> <li>Adj. gross margin: increased SUBLOCADE mix offset by higher inflation</li> <li>Adj. OPEX :         <ul> <li>SG&amp;A</li> <li>Inflationary impacts</li> <li>Commercial initiatives supporting SUBLOCADE leadership including Justice Team and Key Account Director build out</li> <li>Opiant commercial expenses including expenses associated with anticipated Q4 launch of OPNT003</li> </ul> </li> </ul>
		• R&D

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

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

**INDIVIOR**<sup>®</sup>

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

Underlying BMAT market growth of mid- to high-single digits

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d
DNE
h

✓ Inflationary impacts





## 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

