

# Indivior PLC

Jefferies Healthcare Conference  
June 8, 2022



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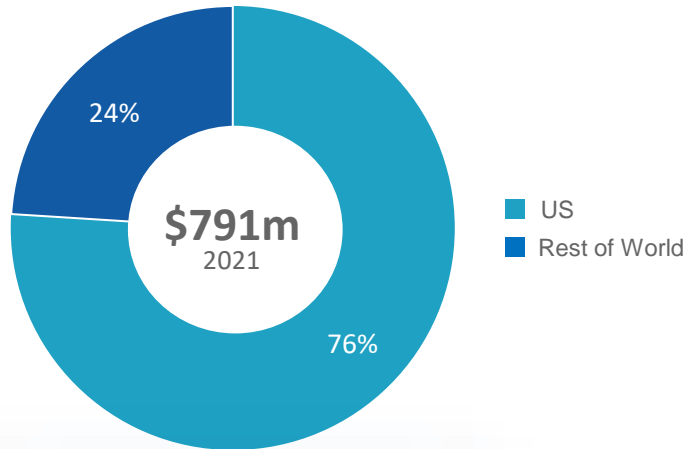
## Why Indivior?

- Pioneering life-transforming treatments for addiction and serious mental illness; uniquely positioned to address US opioid epidemic
- Strong cash generation + financial flexibility to fuel growth, share buybacks and potential business development
- Refreshed and energized management team and Board
- Good business momentum with further upside potential from multiple growth drivers



# Indivior – the basics

## FY 2021 Year Net Revenue (NR)



**+32%**

US NR growth in FY 2021

## Key Facts

- > **Global leader** in medication-assisted treatment (MAT) for opioid use disorder (OUD)
- > **No. 1 position** in largest market (U.S.) for >15 years
- > **Direct presence in >40 countries**, with operations in Canada, Europe and Australia
- > **Key Product (SUBLOCADE®) NR growth of 98%** in Q1 2022 versus Q1 2021
- > **Profitable w/ ~\$1bn of cash (\$776m net cash)** to fuel strategy
- > **~900 highly-engaged employees**



# Major approved treatments for growing disease spaces

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(s)



- Long-acting injectable for moderate to severe opioid use disorder (OUD)

U.S. Addressable Patients & Market Growth

~3.0 mil. patients<sup>(1)</sup>



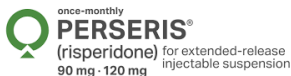
Mid- to high-single digits

Market Position

No. 1

Annual NR Goal

\$1bn+



- Long-acting injectable to treat schizophrenia

~2.6 mil. patients<sup>(2)</sup>



Mid- to high-single digits

Emerging

\$200m to \$300m



- Oral film medication taken daily to treat opioid dependence

~3.0 mil. patients<sup>(1)</sup>



Mid- to high-single digits

~20%  
(of daily market)

N.A.

(1) Symphony Health Analytica and Indivior analytics

(2) Source: Treatment Advocacy Center; "Schizophrenia - Fact Sheet"



# Our Vision and Strategic Priorities are clear



## Our Vision

For all **patients**  
around the **world** to  
**have access to**  
**evidence-based**  
**treatment** for the  
chronic **conditions**  
**and co-occurring**  
**disorders of**  
**addiction**

## Strategic Priorities

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- 1 Grow SUBLOCADE® >\$1bn
- 2 Diversify Revenue (PERSERIS® & ROW)
- 3 Build & Progress Pipeline
- 4 Optimize Operating Model

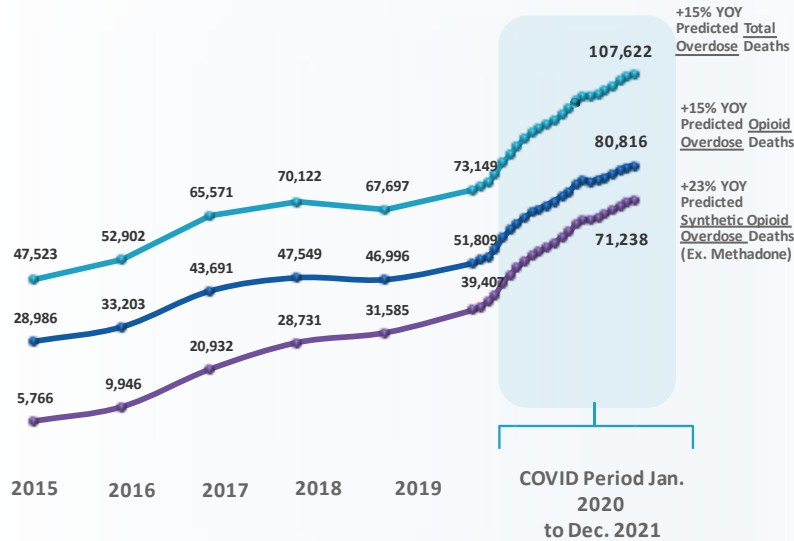


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# Significant unmet need – accelerating US overdose deaths

## US Overdose Deaths Accelerated During COVID

(2015 – Dec. 2021)



Source (updated 5/10/2022): [Products - Vital Statistics Rapid Release - Provisional Predicted Drug Overdose Data \(cdc.gov\)](#)

## US Opioid Use Disorder Disease State

**10 mil.+ people<sup>1</sup>**

Engage in non-medical misuse & illicit opioid use

**3.0 mil.+ patients<sup>1</sup>**

Diagnosed with OUD

**1.2 mil.+ patients<sup>2</sup>**

Treated with oral buprenorphine medication-assisted treatment (BMAT)

(1) SAMSHA

(2) Symphony Health and Indivior analytics



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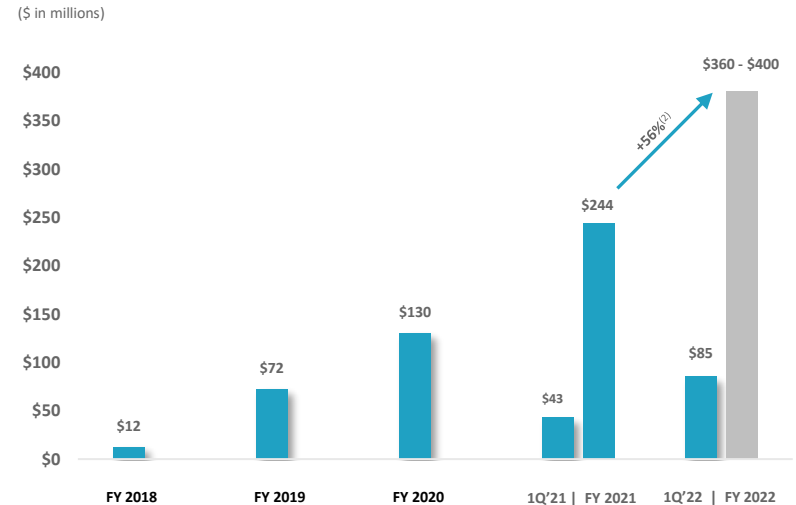
# SUBLOCADE<sup>®</sup>(1) is a paradigm shift in OUD treatment

## SUBLOCADE Key Attributes

- First buprenorphine-based long-acting injectable approved by U.S. FDA for the treatment of moderate to severe OUD
- Blocks the subjective and rewarding effects of opioids
- 1 treatment decision, 1 time per month
- Maintains buprenorphine plasma concentration  $\geq 2$  ng/mL threshold across entire monthly dosing interval
- Potential to help millions of patients based on FDA-approved indication
- Only available through a closed distribution system which decreases the risk of drug diversion and accidental pediatric exposure

(1) Please refer to full Prescribing Information for important safety information, including boxed warning: [www.SUBLOCADE.com](http://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.

## SUBLOCADE<sup>®</sup> Total Annual NR Growth is Strong



(2) FY 2022 SUBLOCADE NR mid-point of \$380m.





1

# SUBLOCADE<sup>®</sup>: Extending our Leadership Position in OUD with a Differentiated Organized Health Systems (OHS) Platform



- **430+** OHS accessed (vs. 500+ target)
- **75%+** of SUBLOCADE NR growth from OHS channel

## Broadened Platform



- Dedicated Criminal Justice System team (National coverage)
- Added 12 MSLS (national coverage)

## Growing Capabilities



- Translating patient insights into real world evidence (fentanyl study)
- Pursuing further R&D studies to build evidence base

## New Insights/Evidence



Majority of prescribing HCPs are affiliated with an OHS



# 1 Path to \$1bn+ goal for SUBLOCADE® is achievable

**>10 mil.**

Misuse opioids in US<sup>(1)</sup>

**>3.0 mil.**

OUD diagnosed in US<sup>(1)</sup>

**~180,000**

Target SUBLOCADE® patients

Market growth



Sustained U.S. market growth: mid- to high-single digits

HCPs & patients



57,000 total SUBLOCADE® patients<sup>(2)</sup>

Relevance & Evidence



Ongoing studies to support SUBLOCADE® (RECOVER® and fentanyl)

(1) SAMSHA

(2) Rolling 12-month patients estimate using both Specialty Pharmacy and Specialty Distributor proxy data (Q1 2022)



## 2

## Diversify revenue

**PERSERIS®: Peak NR Objective \$200m to \$300m**

### Diversification opportunity:

- First commercial expansion outside OUD
- Co-morbid condition with OUD
- US antipsychotic long-acting injectable market is attractive

### What we are doing:

- Doubled salesforce to achieve national commercial coverage
- Differentiating based on product attributes
- Positive anecdotal feedback in new territories supports investment

## ROW: Bringing new technologies to market

### Current major ex.-US drug approvals (April 2022)

		SUBLOCADE® (SUBUTEX® PR)	SUBOXONE® Film	PERSERIS®
<b>N. America</b>	Canada	●	●	●*
	EU		●	
	France		●	
<b>Europe &amp; Middle East</b>	Italy	●	●	
	Germany	●	●	
	Nordics Sweden, Finland, Denmark, Norway	●	●	
	UK		●	
	Israel	●	●	
<b>Australasia</b>	Australia	●	●	
	New Zealand	●	●	

● (available) ● (approved/Not Marketed) ● (approved)

\* In exclusive partnership with HLS Therapeutics



# 3 Build and progress pipeline



**Cannabis-Related Disorders (CrD)**  
AEF0117 (Synthetic CB1 Specific Signaling Inhibitor)

- Strategic collaboration with **Aelis Farma**
- First Indivior-Aelis **Joint Steering Committee (JSC)** held July 19, 2021
- **Clinical Phase 2B study** design & protocol finalized and scheduled to start in Q2-2022



**Opioid Use Disorder (OUD)**  
INDV-2000 (Selective Orexin-1 Receptor Antagonist)

- Strategic collaboration with **C4X Discovery**
- **Phase 1 Multiple Ascending Dose (MAD) study** currently planned and scheduled to start Q3-2022 after completion of additional nonclinical toxicology study required by the FDA



**Alcohol Use Disorder (AUD)**  
INDV-1000 (Selective GABA<sub>B</sub> Positive Allosteric Modulator)

- Strategic collaboration with **Addex Therapeutics**
- Two **lead molecules chosen** for optimization
- **Synthesizing** to enable dosage studies



## Optimize operating model

### Maintain a disciplined and consistent approach

- Deliver against SUBLOCADE® NR long-term goal of >\$1 billion
- Organically diversify revenue base (PERSERIS®, Ex.-US new products)
- Deliver on existing early-stage assets
- Announced new \$100m share repurchase program
- Potential inorganic growth opportunities

### Exploring optimal listing structure

- An additional US listing is better aligned with Group strategy, structure and opportunities
- Formal shareholder consultations underway
- Decision whether to seek formal shareholder approval to be announced with H1 2022 results late July
- Formal shareholder vote late September 2022 (if sufficient shareholder support)



# Q1 2022 Financial Highlights & FY 2022 Guidance



# Q1 2022 financial highlights

## Takeaways

- ▶ Double-digit top-line growth
- ▶ SUBLOCADE NR up 98% YOY
- ▶ Maintained strong financial flexibility
- ▶ On track to achieve FY 2022 financial guidance

## Profit & Loss (\$ in mil. actual F/X)

	Q1 22	Q1 21	Change
US Net Revenue	\$165	\$131	26%
ROW Net Revenue	\$42	\$49	-14%
<b>Total Net Revenue</b>	<b>\$207</b>	<b>\$180</b>	<b>15%</b>
<b>Key product NR</b>			
SUBLOCADE NR	\$85	\$43	98%
PERSERIS NR	\$5	\$3	67%
<b>Adj. Gross Profit</b>	<b>\$170</b>	<b>\$148</b>	<b>15%</b>
	82%	82%	
<b>Adj. Op Exp</b>	(\$117)	(\$97)	21%
SG&A	(\$109)	(\$88)	24%
R&D	(\$8)	(\$9)	-11%
Other Operating Income	1	1	-
<b>Adj. Operating Income</b>	<b>\$54</b>	<b>\$51</b>	<b>6%</b>
<b>Cash &amp; Investments</b>	<b>\$1,024</b>	\$945	+79
<b>Total Net Cash &amp; Investments</b>	<b>\$776</b>	\$711	+65



# FY 2022 guidance\*

\*Confirmed on April 28, 2022. This information is provided as of that date and shall not constitute an update of prior guidance.

## FY 22 Guidance<sup>1</sup> (\$ in mil.)

<b>Total Net Revenue</b>	<b>\$840m to \$900m</b>
<b>Key LAI products:</b>	
• SUBLOCADE NR	• \$360m to \$400m (+56% at mid-point vs. FY21)
• PERSERIS NR	• \$27m to \$32m (+74% at mid-point vs. FY21)
<b>Adj. gross margin %</b>	<b>Low to mid 80% range</b>
<b>Total OPEX (SG&amp;A + R&amp;D)</b>	<b>\$520m to \$540m</b>
• SG&A	• \$440m to \$455m
• R&D	• \$80m to \$85m
<b>Adj. op. income</b>	<b>Similar to FY21 levels</b>

(1) Before exceptional items

## FY 22 Assumptions

- Near-term constraints in the US healthcare system ease as impact of COVID-19 pandemic subsides
- Growth for SUBLOCADE and PERSERIS expected to be stronger in the second half of 2022 compared to the first half of 2022

## Additional top-line items

- **Underlying BMAT market growth of mid- to high-single digits**
- **SUBOXONE® Film**
  - Assumes share erosion continues to diverge from analogs; anticipate similar erosion rate to 2021 (just over 1pp)<sup>2</sup>
  - Traction for new products (SUBUTEX PR, SUBOXONE Film) more than offset by continued austerity measures in legacy Western European markets and pricing on legacy products; F/X at Jan. 2022 rates

(2) Historically, erosion rates were based on industry analogs. However, SUBOXONE® Film share has continued to outperform analogs. Therefore, we have changed our 2022 modeling assumption to reflect the actual SUBOXONE® Film share performance over the last two-plus years. Indivior will report any material formulary changes that could impact SUBOXONE® Film share erosion assumptions.

## Margin & Expense detail

- **Expected adj. gross margin: low- to mid-80% range mainly due to expected relative strength of SUBOXONE Film & higher cost inflation**
- **Total Adj. OPEX (SG&A + R&D) of \$520m to \$540m reflects:**
  - SG&A range of \$440m to \$455m
    - ✓ Annualization of investments to grow SUBLOCADE® and PERSERIS®
    - ✓ Costs associated with US listing review
  - R&D range of \$80m to \$85m
    - ✓ Further SUBLOCADE® Lifecycle Management studies
    - ✓ Manufacturing capacity expansion
    - ✓ Early-stage asset advancement



# THANK YOU

