Indivior PLC

Q4 / FY 2021 Results
February 16, 2022

Mark Crossley

Chief Executive Officer

INDIVIOR

Forward-looking statements

This announcement contains certain statements that are forward-looking. 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. Forward-looking statements include, among other things, statements regarding the Indivior Group's financial guidance for 2022 and its medium- and long-term growth outlook, its operational goals, its product development pipeline, ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "potential", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

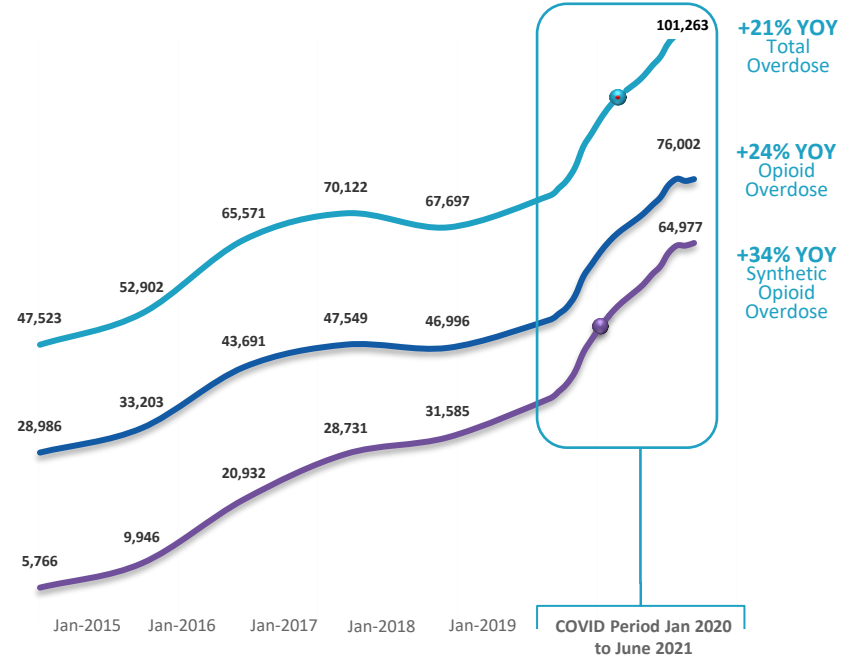
Various factors may cause differences between Indivior's expectations and actual results, including, among others, the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases, and: factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing and in the supply chain; disruptions in or failure of information technology systems; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; challenges in commercial execution; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including the Indivior Group's compliance with its agreements with the U.S. Department of Justice and with the Office of Inspector General of the Department of Health and Human Services, non-compliance with which could result in potential exclusion from participating in U.S. Federal health care programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; risks related to the evolving COVID-19 pandemic and the potential impact of COVID-19 on the Indivior Group's operations and financial condition, which cannot be predicted with confidence; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

Consequently, 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. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. 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.

US opioid crisis worsening with elevated overdose deaths

US Overdose Deaths Accelerated During COVID

(2015 – June 2021)



Source (updated 1/28/2021): Products - Vital Statistics Rapid Release - Provisional Predicted Drug Overdose Data (cdc.gov)

US Opioid Use Disorder (OUD) Disease State

10 mil.+ people(1)
Engage in non-medical misuse & illicit opioid use

3 mil.+ patients(1)
Diagnosed with OUD

1.2 mil.+ patients(2)
Treated with oral buprenorphine medication-assisted treatment (BMAT)

(1) SAMSHA
(2) Symphony Health and Indivior analytics

FY 2021 execution against our Strategic Priorities

Financial

- **Strong FY 2021 results**
  - ✓ Total NR +22% to $791m; total adj. op. income* +113% to $187m
  - ✓ SUBLOCADE® FY 21 NR +88% to $244m; FY 21 PERSERIS® NR +21% to $17m
  - ✓ Ending cash of $1.1 bn; net cash of $853m; refinanced debt maturity to 2026
- **FY 2022 guidance introduced**
  - ✓ Solid top-line growth; adj. operating profit expected to be similar to FY 2021
  - ✓ Continued meaningful SUBLOCADE® growth expected: +56% at mid-point

Strategic

- **Investing for long-term profitable growth**
  - ✓ Expanding commercial capabilities to extend SUBLOCADE®'s leading position
  - ✓ Accelerating diversification with PERSERIS®
  - ✓ Funding R&D studies, progressing early-stage pipeline and increasing production capacity
  - ✓ Exclusive license for promising Phase 2 cannabis use disorder asset (Aelis Farma)

Capital

- **Completed $100m share repurchase program December 2021**
- **Exploring optimal listing structure for Indivior shares – potential additional US Listing**
- **Upholding compliance commitments and protecting our people**

* See Appendix for reconciliations

Strategic Priorities report card: FY 2021

1 Grow SUBLOCADE® >$1 bil.

- **FY 2021 NR: $244m**
  +88% vs. FY 2020
- **Q4 21 NR: $75m**
  +15% vs. Q3 21;
  +92% vs. Q4 20
- **FY 2021 US dispenses: 183K**
  +66% vs. FY 2020
- **Q4 21 US dispenses: 55.9k**
  +15% vs. Q3 21;
  +74% vs. Q4 20
- **Ending 2021 patients*: 49k**
  +14% vs. Q3 21;
  +70% vs. Q4 20

2 Diversify Revenue

- **PERSERIS® Q4 21 NR:** $5m flat vs. Q3 21; +25% vs. Q4 20; expanding sales force to gain US national coverage in FY 2022
- **SUBUTEX® Prolonged Release (ROW):**
  - ✓ Q4 21 NR: $5m (+25% vs. Q3 21)
  - ✓ FY 2021 NR:$16m (+300% vs. FY 2020)
- **SUBOXONE® Film (ROW):**
  - ✓ European launch underway

3 Build Our Pipeline

- **SUBLOCADE®:** Publication of results from Buprenorphine-Fentanyl interaction study in PLOS ONE (peer reviewed journal.
- **Aelis Farma (AEF 0117):** **Commencing** Phase 2b study end of Q1 2022.
- **INDV-1000 (w/ ADDEX):** Advancing optimization of the two lead molecules.
- **INDV-2000 (w/ C4X):** Completed Phase 1 single ascending dose (SAD) study.

R&D and pipeline update may be found here

4 Optimize Operating Model

- **Cash:** $1.102 bn
  (+$244m vs. FYE 2020)
- **Net Cash:** $853m
  (+$230m vs. FYE 2020)
- **$100m Share Repurchase Program (as of 12/31/21):** repurchased ~33.5 million shares at avg. daily weighted price of 219p for approx. $100m
- Terminated agreement with Pukang for the rights related to SUBOXONE® tablet (Sai Bo Song) in China

*Rolling 12-month patients estimate using both Specialty Pharmacy and Specialty Distributor proxy data

SUBLOCADE®: Extending our Leadership Position in OUD with a Differentiated Organized Health Systems (OHS) Platform

- **400+** 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 science into relevant patient benefits (fentanyl study)
- Pursuing further R&D studies to build evidence base

New Claims

Majority of prescribing HCPs are affiliated with an OHS

(1) Indivior analysis

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

Diversification opportunity:

- First commercial expansion outside OUD
- Co-morbid condition with OUD
  - ✓ Patients with OUD have been shown to have a higher risk of developing schizophrenia[1]
- US antipsychotic long-acting injectable (LAI) market is attractive:
  - ✓ $5.7 bil. gross sales; 6%+ CAGR over last 5 years[2]
  - ✓ Under-penetrated – only 15% of schizophrenia patients are on an LAI[1]
  - ✓ Schizophrenia is understood by payers as a disease area requiring vigilant management

What we are doing:

- Doubled salesforce to achieve national commercial coverage
  - ✓ Focused institutional sales team added as part of the expansion
- Differentiating based on:
  - ✓ First and only subcutaneous LAI option
  - ✓ Initial peak plasma concentrations within 4-6 hours of initial dose
  - ✓ First and only LAI to achieve clinically relevant levels after first injection without use of a loading dose or any supplemental oral risperidone
- Positive anecdotal feedback in new territories supports investment

once-monthly
PERSERIS™
(risperidone)
for extended-release injectable suspension
90 mg · 120 mg

[1]Curr Opin Psychiatry 2020 May;33(3):219-224; [2]Symphony Healthcare METYS integrated Audit (Retail and Non Retail) accessed 1/31/2022

Rest of World (ROW): bringing new technologies to market

Current major ex.-US drug approvals (Feb. 2022)

		SUBLOCADE® (SUBUTEX® PR)	SUBOXONE® Film	PERSERIS®
North America	Canada	●	●	●*
Europe / Middle East	EU		○	
	France		○	
	Italy	○	●	
	Germany	○	●	
	Nordics (Sweden, Finland, Denmark, Norway)	●	●	
	UK		●	
	Israel	●	●	
Australasia	Australia	●	●	
	New Zealand	●	○	

● (available) ○ (approved)

* In exclusive partnership with HLS Therapeutics

Recently Launched Products

- **ROW SUBLOCADE (SUBUTEX® PR)**
  - Q4 21 NR: $5m
  - FY 21 NR: $16m
- **ROW SUBOXONE® Film**
  - European launch underway

Exploring optimal listing structure for Indivior shares

- Preliminary view of Board is that an additional listing in the US is likely to be beneficial
  - Better aligned with Group strategy and structure
    - ✓ Improved visibility in largest market (~80% of NR generated in US)
    - ✓ US market is the Group's highest value at-stake opportunity
    - ✓ Deeper pool of capital for bio-pharma opportunities
    - ✓ Leadership (CEO and CFO) based in US
    - ✓ ~40% of shareholders based in North America
- Intention is to consult with shareholders extensively; formal consultations expected to begin in Spring 2022

Indivior: Compelling Investment Case

Strong Market Fundamentals

- Unmet need / low treatment prevalence
- Upsurge in overdose deaths
- Continued volume growth expected in BMAT market

Transformational LAI Treatments

Sublocade™
(buprenorphine extended-release) injection for subcutaneous use Ⓒ
100mg·300mg

once-monthly
PERSERIS™
(risperidone)
for extended-release injectable suspension
90 mg · 120 mg

Investing for Growth

- Extending No. 1 position in OUD
- Accelerating diversification
- Bolstering science and pipeline

Committed to Value Creation

- Balanced capital allocation demonstrated
- First choice remains reinvestment
- Potential inorganic opportunities and other value enhancement opportunities
- Assessing optimal listing structure

R&D UPDATE FY-2021

FEBRUARY 16TH, 2022

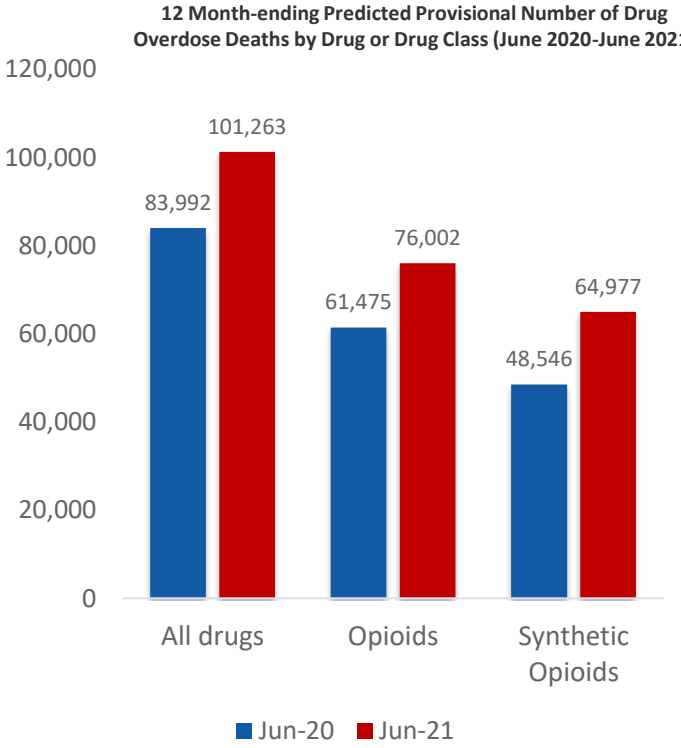
Christian Heidbreder, Chief Scientific Officer

INDIVIOR

Focus on you.

UNPRECEDENTED NUMBER OF REPORTED DRUG OVERDOSE DEATHS IN THE US:

→ *GROWING IMPACT OF FENTANYL & SYNTHETIC OPIOIDS*



Source (updated 1/2/2022: Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2022. Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov)

FOR THE FIRST TIME EVER, THE US EXCEEDED 100,000 OVERDOSE DEATHS

- → Fatal overdoses increased by 21% and reached the unprecedent number of 101,263 deaths in a 12-month timeframe (period ending June 2021).
- → Synthetic opioids incl. fentanyl accounted for ~65% of fatal overdoses.

THE OVERDOSE CRISIS DISPROPORTIONATELY AFFECTS INDIVIDUALS WITH CRIMINAL JUSTICE SYSTEM (CJS) INVOLVEMENT

- → The majority of individuals with OUD experience at least 1 episode of incarceration, typically in a county jail.
- → Most jails do not provide widely accepted medications for OUD (MOUD), which contributes to high rates of overdoses after release.
- → For those offering MOUD, treatment retention after release is a challenge.

EMERGENCY DEPARTMENTS (ED): A CORNERSTONE OF CARE TO CLOSE THE TREATMENT GAP

- → Few EDs are offering MOUD.
- → Only 1/3 of patients seen in the ED for nonfatal overdose received MOUD in the following year.

Source: Hawk K. et al. Consensus Recommendations on the Treatment of Opioid Use Disorder in the Emergency Department. J Ann Emerg Med.2021.04.023. DOI: https://doi.org/10.1016/j.annemergmed.2021.04.023

OUR RESPONSE TO THE OPIOID CRISIS: NEW EVIDENCE GENERATION IN SUPPORT OF SUBLOCADE®

Approval of US Label updates:

- → Buprenorphine-Fentanyl interaction: Open-label, cross-over study showing that treatment-relevant plasma concentrations of buprenorphine significantly decreased respiratory depression and resultant apnea (cessation of breathing) induced by escalating doses of fentanyl (FDA approval June 21, 2021).[1]

Collaborations:

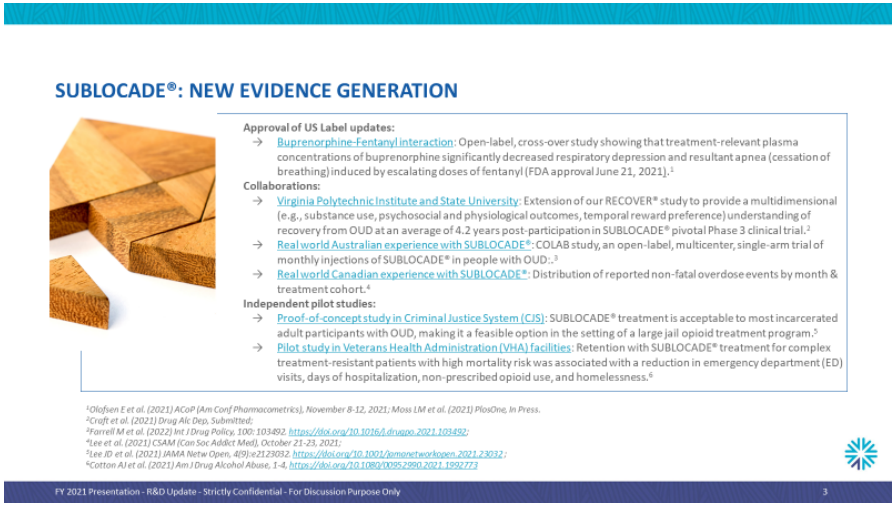
- → Virginia Polytechnic Institute and State University: Extension of our RECOVER® study to provide a multidimensional (e.g., substance use, psychosocial and physiological outcomes, temporal reward preference) understanding of recovery from OUD at an average of 4.2 years post-participation in SUBLOCADE® pivotal Phase 3 clinical trial.[2]
- → Real world Australian experience with SUBLOCADE®: COLAB study, an open-label, multicenter, single-arm trial of monthly injections of SUBLOCADE® in people with OUD.[3]
- → Real world Canadian experience with SUBLOCADE®: Distribution of reported non-fatal overdose events by month & treatment cohort.[4]

Independent pilot studies:

- → Proof-of-concept study in Criminal Justice System (CJS): SUBLOCADE® treatment is acceptable to most incarcerated adult participants with OUD, making it a feasible option in the setting of a large jail opioid treatment program.[5]
- → Pilot study in Veterans Health Administration (VHA) facilities: Retention with SUBLOCADE® treatment for complex treatment-resistant patients with high mortality risk was associated with a reduction in emergency department (ED) visits, days of hospitalization, non-prescribed opioid use, and homelessness.[6]

[1]*Olofsen E et al. (2021) ACoP (Am Conf Pharmacometrics), November 8-12, 2021; Moss LM et al. (2022) PlosOne, Published online January 27, 2022. https://doi.org/10.1371/journal.pone.0256752 .*
[2]*Craft et al. (2021) Drug Alc Dep, Submitted;*
[3]*Farrell M et al. (2022) Int J Drug Policy, 100: 103492. https://doi.org/10.1016/j.drugpo.2021.103492;*
[4]*Lee et al. (2021) CSAM (Can Soc Addict Med), October 21-23, 2021;*
[5]*Lee JD et al. (2021) JAMA Netw Open, 4(9):e2123032. https://doi.org/10.1001/jamanetworkopen.2021.23032 ;*
[6]*Cotton AJ et al. (2021) Am J Drug Alcohol Abuse, 1-4, https://doi.org/10.1080/00952990.2021.1992773*

OUR RESPONSE TO THE OPIOID CRISIS: NEW R&D INVESTMENT IN 2022



- **Generate further evidence regarding the use of SUBLOCADE®:**
  - → Fentanyl and synthetic opioids' users
  - → Initiation in CJS to determine if decreases the risk of overdose after release and improves linkage to care
  - → Early initiation at ED to determine if decreases the rates of relapse and overdose and facilitate transitions to community-based care
- **Evolve the treatment paradigm:**
  - → Longer treatment duration may lead to improved patients' outcomes
  - → Treatment cessation strategy

PROGRESS OUR PIPELINE ACTIVITIES IN OPIOID USE DISORDER (OUD), ALCOHOL USE DISORDER (AUD) & CANNABIS USE DISORDER (CUD)

CUD Clinical Phase 2b

AEF0117
CB1 -VE ALLOSTERIC MODULATOR

- → Phase IIb study design and protocol finalized for start by end of Q1-2022/Q2-2022.
- → Other CMC, nonclinical toxicology and clinical workstreams progressing as planned.

OUD Clinical Phase 1

INDV-2000
SELECTIVE OX1 RECEPTOR ANTAGONIST

- → Completion of Phase I SAD trial.
- → Phase I MAD on clinical hold (FDA letter September 1, 2021), based on nonclinical findings from another similar development program not sponsored by Indivior.
- → Clinical hold waiver contingent upon favorable outcome of an additional repeat-dose toxicology study in sexually mature male dogs. Final study report tentatively in Q2-2022 pending duration of study recovery phase.
- → Major progress on the formulation and chemical development fronts.

AUD Nonclinical

INDV-1000
GABA-B +VE ALLOSTERIC MODULATOR

- → Identification of two lead molecules going through primary and secondary in vivo profiling studies for IND-readiness.

SAD: Single Ascending Dose; MAD: Multiple Ascending Dose

Ryan Preblick

Chief Financial Officer

INDIVIOR

Full Year 2021 financial highlights*

- Top- and bottom-line improvement
- Maintained strong financial position
- Positive cash flow from operations
- Investing to accelerate LAI growth

FY 2021 vs. FY 2020
($m actual F/X)

	2021	2020	Change
US Net Revenue	$603	$456	32%
ROW Net Revenue	$188	$191	-2%
Total Net Revenue	**$791**	**$647**	**22%**
Key product NR:			
SUBLOCADE NR	$244	$130	88%
PERSERIS NR	$17	$14	21%
Adj. Gross Profit	**$664** *84%*	**$555** *86%*	**20%**
Adj. Op Exp (SG&A + R&D)	($477)	($467)	2%
Adj. Operating Income	**$187**	**$88**	**113%**
Cash	**$1,102**	$858	+$244
Net Cash	**$853**	$623	+$230

* Adjusted – see Appendix for reconciliations

Cash & Borrowing position

($ in mil.)	FY 2021	FY 2020
Cash & Cash Equivalents	$1,102	$858
Current Borrowings	(3)	(4)
Long-term Borrowings	(239)	(230)
Loan issuance costs	(7)	(1)
Net cash	$853	$623

- Net cash growth to $853m:
  - ✓ Stronger FY operating performance
  - ✓ SUBOXONE Film resiliency = stable government payables balance
  - ✓ BUPREX® / BUPREXX / Temgesic® sale proceeds
- Maintaining disciplined & balanced cash stance:
  - ✓ Deliver against SUBLOCADE® net rev. goal of >$1 billion
  - ✓ Organically diversify revenue base (PERSERIS®, Ex.-US new product launches)
  - ✓ Deliver on existing early-stage assets
  - ✓ Returned capital to shareholders via $100m share repurchase program
  - ✓ Potential inorganic growth opportunities and consideration of other value enhancement options

FY 2022 guidance introduced

FY 22 Guidance [1] ($ in mil.)	
Total Net Revenue	**$840m to $900m**
Key LAI products:	
• SUBLOCADE NR	• $360m to $400m (+56% at mid-point vs. FY21)
• PERSERIS NR	• $27m to $32m (+74% at mid-point vs. FY21)
Adj. gross margin %	**Low to mid 80% range**
Total OPEX (SG&A + R&D)	**$520m to $540m**
• SG&A	• $440m to $455m
• R&D	• $80m to 85m
Adj. op. income	**Similar to FY21 levels**

FY 2022 Assumptions

- Near-term constraints in the US healthcare system ease as the Omicron wave of COVID-19 subsides
- Growth for SUBLOCADE and PERSERIS is expected to be stronger in the second half of 2022 compared to the first half of 2021

Additional top-line items:

- Underlying BMAT market growth of mid- to high-single digits
- SUBOXONE® Film
  - ✓ Assumes share erosion continues to diverge from analogs in 2022; anticipate a similar erosion rate to 2021 (just over 1pp) [2]
- Rest of World
  - ✓ 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

Margin & Expense detail:

- Expected adj. gross margin: low- to mid-80% range mainly due to expected continued relative strength of SUBOXONE Film and higher cost inflation
- Total Adj. OPEX (combined SG&A and 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

(1) Before exceptional items

(2) Historically, erosion rates were based on industry analogs. However, SUBOXONE® Film share has continued to outperform analogs. Therefore, we have changed our 2022 modelling 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.

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