INDIVIOR®

# Q4/FY 2022 Results

February 16, 2023

# Forward-looking statements

This presentation contains certain statements that are forward-looking. Forward-looking statements include, among other things, statements regarding the Indivior Group's financial guidance for 2023 and its medium- and long-term growth outlook; expectations for sales levels for particular products; the pending acquisition of Opiant; expectations regarding the Group's provisions, legal proceedings and matters, the planned additional US stock exchange listing; expected exceptional and recurring costs related to a US stock exchange listing; expected market growth rates; expected changes in market share; future exchange rates; operational goals; its product development pipeline and potential future products; ongoing litigation; and other statements containing the words "believe", "anticipate", "plan", "expect", "intend", "estimate", "forecast," "strategy," "target," "guidance," "outlook," "potential", "project", "priority," "may", "will", "should", "would", "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; 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; the substantial litigation and ongoing investigations to which we are or may become a party; 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 significant amount of laws and regulations that we are subject to, including due to the international nature of our business; macroeconomic trends and other global developments such as the COVID-19 pandemic; the terms of our debt instruments, changes in our credit ratings and our ability to service our indebtedness and other obligations as they come due; changes in applicable tax rate or tax rules, regulations or interpretations; and our ability to realize our deferred tax assets.

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.

# Agenda

| | |
|---|---|
| Mark Crossley | Overview & Strategic Priorities Update |
| Christian Heidbreder | R&D Update |
| Ryan Preblick | Q4/FY 2022 Performance & FY 2023 Guidance |
| Mark Crossley | Conclusion |
| All | Q&A |

# Mark Crossley

Chief Executive Officer

# FY 2022 key messages

- Continued strong execution in FY 2022 – Total NR[1] up 14% driven by SUBLOCADE®; SUBLOCADE NR grew 67% to $408m
- FY 2023 guidance introduced – expect top-line growth and positive operating leverage, consistent with medium-term profitable growth framework
- Pending Opiant Pharmaceuticals transaction anticipated to close early March
- Second $100m buyback largely complete; US listing on NASDAQ on track for Spring

[1] NR=net revenue; Actual FX (foreign exchange) rates
[2] See reconciliation page 19

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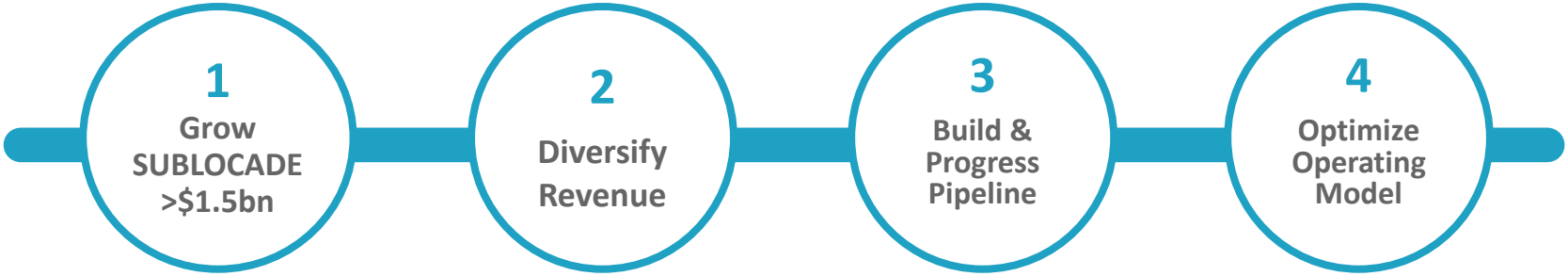
# Proactively addressing legacy litigation

Initial mediation sessions in late January 2023 regarding legacy civil multidistrict antitrust litigation provided the Group with new information on the previously disclosed contingent liability. Accordingly, the Group recorded an exceptional provision of $290m in FY 2022. Because these matters are in various stages, Indivior cannot predict with any certainty how these matters will ultimately be resolved, or the costs, or timing of such resolution. In particular, any final aggregate costs of these matters, whether resolved by settlement or trial, may be materially different from this provision. The Group cannot predict with any certainty whether it will reach settlement with the antitrust claimants (please see Note 12 for further information in the Group's FY 2022 Results Press Release dated February 16, 2023).

# Executing clear strategies for value creation




- Peak NR increased to >$1.5bn (expect >$1bn NR run-rate exiting 2025)
- FY22 NR of $408m, +67%
- Ending patients[1] of 82.5k, +68%; targeting 270k patients
- US dispenses[2] of 316.2k, + 73%
- Achieved access to 500+ Organized Health Systems (OHS) in the US
- Increased access in US justice system
- SUBLOCADE FY23 NR guidance of $550m-$600m (+41% at mid-point vs. FY22)

- 11/14/22 agreement to acquire Opiant Pharmaceuticals (close expected in early March); Opiant's OPNT003 PDUFA[3] date May 22, 2023;
- SUBLOCADE FY22 ex-US NR $27m, +69%
- PERSERIS® FY22 NR of $28m, +65%
- PERSERIS patients in FY22 of 5,400; targeting 40k patients
- PERSERIS FY23 NR guidance of $45m-$55m (+82% at mid-point vs. FY22)

- AELIS AEF0117 (CUD[4]): Phase 2b study recruitment initiated in May 2022; on track to report results in 2024[5]
- INDV 2000 (OUD[4]): Phase 1 study[6] start Sept. 2022; pursuing formulation development and manufacturing
- INDV 1000 (AUD[4]): Selected two lead molecules and two back-ups; expect to recommend lead molecule in Q1 2023

- Maintained financial flexibility; $991m of gross cash and investments[7] at end-2022
- Repurchased ~4.8m of INDV shares at ~$90m through 12/31/22 (second $100m repurchase program)
- Expect start-up of additional SUBLOCADE contract manufacturing site in H2 2023
- US listing planned for Spring 2023
- Published inaugural Sustainability Report

*Note: % changes are vs. FY 2021 unless otherwise specified
[1] Rolling 12-month patients estimate using both Specialty Pharmacy and Specialty Distributor proxy data
[2] Total number of dispenses within the quarter (new and refill)

[3] PDUFA= prescription drug user fee act

[4] CUD = cannabis use disorder; OUD = opioid use disorder, AUD = alcohol use disorder
[5] Estimated timing, may be subject to change
[6] multiple ascending dose

[7] See discussion of obligations in Notes 9 and 10, including our term debt and other payment obligations and liabilities from the Q4 2022 Results press release dated February 16, 2023

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# Medium-term profitable growth framework

**Attractive Growth Profile**

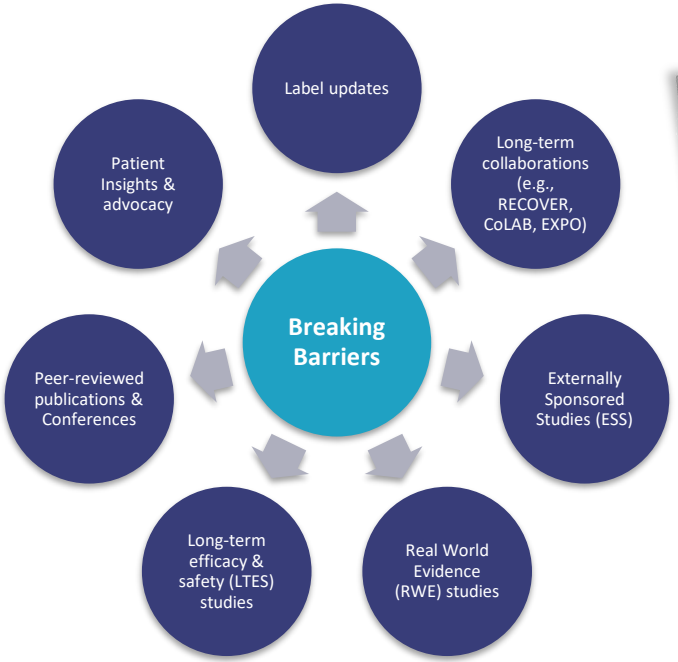
**Positive Operating Leverage**

**Strengthening Cash Flow**

# Christian Heidbreder

Chief Scientific Officer

# SUBLOCADE strategic R&D and medical priorities 2023




# Most recent peer-reviewed publications

Received: 15 April 2022 | Accepted: 18 November 2022
DOI: 10.1111/add.16115

RESEARCH REPORT

ADDICTION SSA

**Long-term recovery from opioid use disorder: recovery subgroups, transition states and their association with substance use, treatment and quality of life**

William H. Craft[1,2] | Hwasoo Shin[3] | Allison N. Tegge[1,3] | Diana R. Keith[1] | Liqa N. Athamneh[1] | Jeffrey S. Stein[1] | Marco A. R. Ferreira[3] | Howard D. Chilcoat[4,5] | Anne Le Moigne[4] | Angela DeVeaugh-Geiss[4] | Warren K. Bickel[1]

Long-term recovery from opioid use disorder: recovery subgroups, transition states and their association with substance use, treatment and quality of life - Craft - Addiction - Wiley Online Library

frontiers | Frontiers in Pharmacology

**Buprenorphine exposure levels to optimize treatment outcomes in opioid use disorder**

Celine M. Laffont[1]*, Eliford Ngaimisi[2], Mathangi Gopalakrishnan[2], Vijay Ivaturi[2], Malcolm Young[1], Mark K. Greenwald[3] and Christian Heidbreder[1]

[1]Indivior Inc., North Chesterfield, VA, United States, [2]Center for Translational Medicine, University of Maryland, Baltimore, MD, United States, [3]Department of Psychiatry and Behavioral Neurosciences, Wayne State University School of Medicine, Detroit, MI, United States

Frontiers | Buprenorphine exposure levels to optimize treatment outcomes in opioid use disorder (frontiersin.org)

Journal of Current Medical Research and Opinion
Received 03-10-2022 | Revised 12-10-2022 | Accepted 17-10-2022 | Published Online 19-10-2022
DOI: https://doi.org/10.52845/CMRO/2022/5-10-2
ISSN (O) 2589-8779 | (P) 2589-8760
CMRO 05 (10), 1426-1438 (2022)

CMRO

Research Article

**Impact of Medications for Opioid Use Disorder on Healthcare Resource Utilization and Costs for Patients Served By a State Medicaid Program**

Orsolya Lunacsek, PhD, MBA[1*]; Maher Abdel-Sattar, PharmD, MS[1]; Augustina Ogbonnaya, MPH[1]; William Mullen, PA-C, MPH[2]; Ann Wheeler, PharmD[2]; Christian Heidbreder, PhD, MA[2]; Bryan Amick, PharmD, MBA, MS[3]

Impact of medications for opioid use disorder on healthcare resource utilization and costs for patients served by a state Medicaid program | Journal of Current Medical Research and Opinion (cmro.in)

Drug and Alcohol Dependence Reports 6 (2023) 100133

ELSEVIER

Contents lists available at ScienceDirect

Drug and Alcohol Dependence Reports

journal homepage: www.elsevier.com/locate/dadr

**History of the discovery, development, and FDA-approval of buprenorphine medications for the treatment of opioid use disorder**

Christian Heidbreder[a,*], Paul J. Fudala[a], Mark K. Greenwald[b]

[a] Indivior Plc, North Chesterfield, VA, United States of America
[b] Department of Psychiatry and Behavioral Neurosciences, Wayne State University School of Medicine, Detroit, Michigan, United States of America

History of the discovery, development, and FDA-approval of buprenorphine medications for the treatment of opioid use disorder - ScienceDirect

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# SUBLOCADE, SUBOXONE Film (ex-US) & PERSERIS

## SUBUTEX® prolonged-release (PR) solution for injection

- Regulatory approvals granted in 11 MoW countries including Canada, Australia, New Zealand, Israel, Sweden, Finland, Denmark, Norway, Germany, Italy and Switzerland
- Pending approval in the UK
- Geo-expansion submissions planned in Kuwait, KSA, UAE, and Qatar

## SUBOXONE film (Ex US)

- Regulatory approvals granted in Canada, Israel, all EU Member States (+ UK, Iceland, Norway, and Liechtenstein), New Zealand, Qatar, and UAE.
- Under review in Kuwait, Kingdom of Saudi Arabia, and Columbia.

## PERSERIS (risperidone) for extended-release injectable suspension

- Two FDA approvals of Prior Approval Supplement (PAS) in 2022:
- extension of shelf-life to 36 months and time out of fridge from current 7 days to 30 days on August 29, 2022
- alternate injection sites (back of the arm) on December 15, 2022.

# Pipeline activities

## AUD Nonclinical

**INDV-1000**
**GABA-B +VE ALLOSTERIC MODULATOR**

- Characterization of two lead molecules, two additional back-up molecules, and scale-up and manufacture of one lead
- Finalization of primary and secondary *in vivo* profiling studies for lead molecules
- Decision for candidate selection of one lead molecule Q1 2023

## OUD Clinical Phase 1

**INDV-2000**
**SELECTIVE OX1 RECEPTOR ANTAGONIST**

- Objectives for 2023 are to:
- Progress nonclinical toxicology studies
- Complete Multiple Ascending Dose (MAD) study as planned per protocol for delivery in Q4 2023
- Complete the CYP3A4 Induction Clinical Study in Q4 2023
- Progress tablet formulation development and manufacturing
- Progress CMC stability work

## CUD Clinical Phase 2b

**AEF0117[1]**
**CB1 -VE ALLOSTERIC MODULATOR**

- Aelis Farma achieved first subject first visit (FSFV) with AEF0117 in the Phase 2B trial on May 23, 2022.
- Estimated Last Subject Last Visit and Database Lock in H1 2024 with final CSR in H2 2024.
- Other CMC, nonclinical toxicology and clinical workstreams progressing as planned

[1] *Aelis Farma (Indivior has exclusive license to this technology)*

# Ryan Preblick

Chief Financial Officer

# FY 2022 financial highlights

## Takeaways

- Top-line NR growth of 14% vs. FY 2021
  - ✓ US NR up 21%
  - ✓ ROW NR down 10% including FX (up 1% excluding FX)
- Total SUBLOCADE NR up 67% vs. FY 2021; PERSERIS NR up 65% vs. FY 2021
- Reported operating expenses include $290m exceptional legacy antitrust multidistrict litigation provision; adjusted operating expenses[1] up 12% vs. FY 2021 driven by sales and marketing and R&D investments
- Reported operating profit includes the above exceptional litigation provision; adjusted operating profit[2] up 13% vs. FY 2021

[1] Excluding exceptional SG&A items as detailed in Note 4 from the Q4 2022 Results press release dated February 16, 2023

## Operating Results – Reported and Adjusted[2]

| $ mil | FY 22 | FY 21 | Change | Adjusted FY 22 | Adjusted FY 21 | Adjusted Change |
|---|---|---|---|---|---|---|
| **Net Revenue:** | **901** | **791** | **14%** | | | |
| US | 731 | 603 | 21% | | | |
| ROW[3] | 170 | 188 | (10%) | | | |
| **Gross Profit:** | **742** | **664** | **12%** | | | |
| | 82% | 84% | | | | |
| **Op Expenses:** | **(835)** | **(483)** | **73%** | **(533)** | **(477)** | **12%** |
| **SG&A** | **(763)** | **(431)** | **77%** | **(461)** | **(425)** | **8%** |
| Selling | (218) | (192) | 14% | (218) | (192) | 14% |
| Administrative | (545) | (239) | 128% | (243) | (233) | 4% |
| **R&D** | **(72)** | **(52)** | **38%** | **(72)** | **(52)** | **38%** |
| **Other Op. Income/(Expense):** | **8** | **32** | **(75%)** | **3** | **0** | **NM** |
| **Operating Profit:** | | | | | | |
| Reported | **(85)** | **213** | **NM** | | | |
| Adjusted[2] | **212** | **187** | **13%** | | | |

| **Key product NR** | FY 22 | FY 21 | Change |
|---|---|---|---|
| SUBLOCADE NR | 408 | 244 | 67% |
| PERSERIS NR | 28 | 17 | 65% |

[2] See reconciliation page 19 in the appendix
[3] Actual FX (foreign exchange) rates
NM: not meaningful

# Cash & borrowing position

## Cash & Borrowing

| ($ in mil.) | FY 22 | FY 21 |
|---|---|---|
| Cash & Cash Equivalents | $774 | $1,102 |
| ST & LT Investments | $217 | NA |
| Total Cash & Investments | $991 | $1,102 |
| | | |
| Current Borrowings | (3) | (3) |
| | | |
| Long-term Borrowings | (237) | (239) |
| Loan issuance costs | (6) | (7) |

## Takeaways

**Total gross cash & investments of $991m[1]:**

- Cash and investments primarily held in USD
- Approximately $90m used for share repurchases during FY 2022 at an average price of 1,537p

**Disciplined and consistent capital allocation in FY 22:**

- Deliver against SUBLOCADE NR goal of >$1.5 billion
- Organically diversify revenue base (PERSERIS, Ex.-US new products)
- Progress existing early-stage assets
- $100m share repurchase program almost complete
- Inorganic growth opportunities (pending acquisition of Opiant Pharmaceuticals)

[1] See discussion of obligations in Notes 9 and 10, including our term debt and other payment obligations and liabilities from the Q4 2022 Results press release dated February 16, 2023

# FY 2023 guidance introduced

Excludes impacts from the pending transactions with Opiant Pharmaceuticals

| FY 2023 Guidance[1] ($ in mil.) | |
|---|---|
| **Total Net Revenue** | **$950m to $1,020m (+9% at mid-point vs. FY22)** |
| **Key LAI products:** | |
| • SUBLOCADE NR (Total) | • $550m to $600 (+41% at mid-point vs. FY22) |
| • PERSERIS NR | • $45m to $55m (+82% at mid-point vs. FY22) |
| **Adj. gross margin %** | **Low to mid 80% range** |
| **Adj. OPEX (SG&A + R&D)** | **$570m to $590m** |
| • SG&A | • $490m to $500m |
| • R&D | • $80m to $90m |
| **Adj. op. profit** | **Higher than FY 2022 level (with expected margin expansion)** |

[1] Before exceptional items. LAI=long-acting injectable.
[2] 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**
- **US SUBOXONE Film**
  - Anticipated formulary decisions expected to impact share by approximately 2 points, similar to recent years
  - Additional impact assumed from a fourth buprenorphine/naloxone sublingual film generic[2] entering the US market in Q2 2023.
  - The Group will continue to monitor the competitive environment and update the market accordingly
- **ROW**
  - Broadly stable with traction for new products (SUBUTEX PR®, SUBOXONE Film) 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
  - R&D
    - ✓ Ongoing long-term efficacy and safety studies for SUBLOCADE
    - ✓ Early-stage asset advancement
    - ✓ Inflationary impacts

# Appendix

# Financial Reconciliation: FY 2022 & FY 2021

| ($ in mil. at Actual FX ) | FY 2022 | FY 2021 |
|---|---|---|
| **Net Income / (Loss)** | **(53)** | **205** |
| Net interest (expense) / income | 10 | 23 |
| Taxation | (42) | (15) |
| **Operating Profit / (Loss)** | **(85)** | **213** |
| Adjustments | 297 | (26) |
| **Adjusted Operating Profit / (Loss)** | **212** | **187** |

FY 2022 Notes:

$290m impact from the exceptional provision related to anti-trust litigation and consumer protection claims
$6m impact from the exceptional provision related to a dispute over reimbursement of legal costs with a supplier
$6m impact from exceptional consulting costs related to an additional listing in the US.
($5m) benefit related to the proceeds received from a Directors' and Officers' insurance reimbursement claim

FY 2021 Notes:

$1m benefit from a provision release related to a prior accrual for restructuring cost
$12m benefit related to a Directors and Officers insurance reimbursement claim
$18m benefit from a provision release related to DOJ matters
($24m) impact from increased provision from intellectual property related matters – ANDA Litigation
($1m) impact from the write-off of unamortized deferred financing cost related to the extinguishment and settlement of the previous term loan
$20m benefit from the net gain on disposal of the TEMGESIC franchise and proceeds from the out license of nasal naloxone opioid overdose patents