

# Q2/H1 2023 Results

July 27, 2023

## Important cautionary statement regarding forward-looking statements

This presentation contains certain statements that are forward-looking. Forward-looking statements include, among other things, statements regarding: expectations regarding the cost to resolve the Group's legal proceedings and regulatory matters; strategies for value creation and operational goals; expected sales levels for particular products; product development pipeline and potential future products; expectations regarding regulatory approval of product candidates, future product pricing, the timing of such approvals, the timing of commercial launch of such product candidates, and eventual annual revenues of such future products; financial guidance for 2023 and medium- and long-term growth outlook; 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 substantia

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**

Chief Executive Officer

# Today's agenda

**Overview & Strategic Priorities Update** 

**R&D & Pipeline Update** 

Q2 / H1 Performance & FY 2023 Guidance

Conclusion

Q&A

Mark Crossley, CEO

Christian Heidbreder, Ph.D., CSO

Ryan Preblick, CFO

Mark Crossley, CEO

All participants



# Q2 / H1 2023 key messages



**Strong Q2 results** – total NR<sup>1</sup> \$276m, +25% YOY / SUBLOCADE® (buprenorphine extended-release) NR \$155m, +58% YOY / reported op. profit -3% YOY (+18% adjusted<sup>2</sup> basis)



**FY 2023 guidance raised** — total NR (\$1,060m mid-point, +18% YOY) / SUBLOCADE NR (\$610m mid-point, +50% YOY) / and higher adjusted op. profit YOY



**OPVEE**® (nalmefene) **nasal spray approved** – U.S. commercial launch projected for Q4 2023



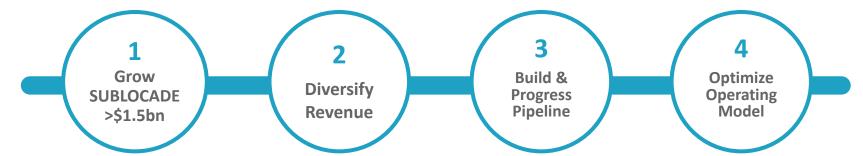
Successful U.S. listing on Nasdaq – trading under "INDV" commenced June 12th

<sup>&</sup>lt;sup>2</sup> See reconciliation page in appendix



<sup>&</sup>lt;sup>1</sup>NR=net revenue; Actual FX (foreign exchange) rates

# Executing clear strategies for value creation



- SUBLOCADE Q2 2023 NR of \$155m, +58%
- Ending patients<sup>1</sup> of 107.6k, +65% vs. Q2 2022 and +14% vs. Q1 2023; targeting 270k patients
- U.S. dispenses<sup>2</sup> of 124.8k, +65% vs. Q1 2022 and +16% vs. Q1 2023
- Increased access in U.S. justice system
- SUBLOCADE FY23 NR guidance increased to \$590m - \$630m (+50% at mid-point vs. FY 2022)

- PERSERIS® (risperidone for extended release)
   Q2 2023 NR of \$11m, +57% YOY
- PERSERIS FY 2023 NR guidance of \$45m - \$55m (+82% at mid-point vs. FY 2022)
- SUBLOCADE Q2 2023 ex-US NR \$10m, +67% YOY; now approved in UK
- OPVEE (nalmefene) nasal spray for emergency opioid overdose rescue induced by natural and synthetic opioids, like fentanyl) approved May 22, 2023 – projected Q4 2023 launch

- AELIS AEF0117 (CUD<sup>3</sup>): Phase 2B positive DSMB<sup>4</sup> with Last Subject Last Visit (LSLV) in Q1-2024 and final report projected in Q3-2024<sup>5</sup>
- INDV 2000 (OUD<sup>3</sup>): Phase 1 study MAD<sup>6</sup>
   LSLV in Q3-2023, End-of-Phase 1
   meeting with FDA projected Q4-2023<sup>5</sup>
- INDV 1000 (AUD<sup>3</sup>): Identified and profiling two backup compounds (Q3-2023 selection expected<sup>5</sup>)
- INDV 4002 (AUD<sup>3</sup>): Phase 2 data projected Q3-2023<sup>5</sup>
- INDV 5004 (ACO<sup>3</sup>): Currently funded by NIH/NCATS to optimize a parenteral drug product formulation and conduct additional studies

- \$782m of gross cash and investments<sup>7</sup> at June 30, 2023
- Settlement with 41 States and District of Columbia
- Additional contract manufacturing site projected for H2 2023
- U.S. trading on Nasdaq commenced June 12, 2023 (Nasdaq: INDV)

<sup>\*</sup>Note: % changes are vs. Q2 2022 unless otherwise specified

<sup>&</sup>lt;sup>1</sup> Rolling 12-month patients estimate using both Specialty Pharmacy and Specialty Distributor proxy data

<sup>&</sup>lt;sup>2</sup> Total number of dispenses within the quarter (new and refill)

<sup>&</sup>lt;sup>3</sup> CUD = cannabis use disorder; OUD = opioid use disorder, AUD = alcohol use disorder; ACO: Acute Cannabinoid Overdose; GLP = Good Laboratory Practice

<sup>&</sup>lt;sup>4</sup> Data Safety Monitoring Board

<sup>&</sup>lt;sup>5</sup> Estimated timing, may be subject to change

<sup>&</sup>lt;sup>6</sup> multiple ascending dose

<sup>7</sup> See discussion of obligations in Notes 10 and 11, including our term debt and other payment obligations and liabilities from the Q2 2023 Results press release dated July 27, 2023

# Anti-trust MDL update

- Settlement with 41 States and District of Columbia \$102.5m paid in June 2023
- \$187.5m provision continues to be our best estimate for remaining classes
- Trial date for remaining classes (end payors and direct purchasers) is scheduled for October 30, 2023
- The Group's disclosures have been updated to reflect the status of the litigation as well as the proximity of the trial date



# **Christian Heidbreder**

**Chief Scientific Officer** 

# SUBLOCADE® studies

## → 5 Phase IV studies:

rapid induction in the era of synthetics; alternate injection sites; long-term outcomes; treatment cessation; ROAD

## → 4 Collaborations:

RECOVER Long-Term (US); CoLAB (AUS); Nonfatal overdose (CAN); EXPO (UK)

## → 21 RWE studies

(1) health disparity; (2) recovery; (3) harm reduction.

## $\rightarrow$ 9 ESS

(1) high-risk opioid overdose; (2) Criminal Justice System (CJS); (3) rapid initiation in different treatment settings; (4) co-morbidities; (5) long-term efficacy & safety.

<u>ROAD</u>: Recovery from OUD Open Access Data; <u>CoLAB</u>: Community Long-Acting Buprenorphine; <u>EXPO</u>: Extended-release pharmacotherapy for Opioid Use Disorder; <u>RWE</u>: Real World Evidence; ESS: Externally Sponsored Studies

## OPVEE® status

- → FDA approval granted May 22, 2023.
- → 28-month shelf life approved.
- Section 12 (Clinical Pharmacology) of the Prescribing Information shows the pharmacokinetics of OPVEE as well as its reversal of remifentanil-induced respiratory depression (pharmacodynamics).
- → Required pediatric studies in juvenile rats to support clinical study in children <12 years of age.</li>

- → Post-marketing requirement studies to assess the potential effects of dodecyl maltoside (DDM – nasal absorption enhancer) on development and reproductive toxicity.
- → Enhanced Pharmacovigilance request: Submission (as 15-day "Alert reports" for 5 years) of all serious and nonserious occurrences of severe, prolonged, and/or precipitated opioid withdrawal in cases where more than two doses of OPVEE are used in a single rescue.

# Pipeline status

PRODUCT NAME	MECHANISM OF ACTION	INDICATION	PCL	Ph1	Ph 2	Ph 3	APPROVAL	LAUNCH	
OPIOID USE DISORDER (OUD) & RESCUE FROM OPIOID OVERDOSE									
OPVEE®	Intranasal nalmefene (opioid receptor antagonist)	Emergency treatment of known or suspected overdose induced by natural or synthetic opioids						>	
INDV-2000*	Selective Orexin-1 (OX1) receptor antagonist	Non-opioid treatment for moderate/severe OUD			MAD Study: LSL	V Q3-2023; EoP1	meeting with FD	A: Q4-2023	
ALCOHOL USE DISORDE	ALCOHOL USE DISORDER (AUD)								
INDV-4002	Intranasal naltrexone (opioid receptor antagonist)	Treatment of AUD - Reduction in WHO drinking risk levels with associated health benefits			Phase	2 study results: C	23-2023		
INDV-1000**	Gamma-aminobutyric acid subtype B (GABAB) positive allosteric modulator (PAM)	Treatment of AUD		Selection	of two new lead r	molecules: Q3-20	23		
CANNABIS USE DISORD	CANNABIS USE DISORDER (CUD) & ACUTE CANNABINOID OVERDOSE (ACO)								
AEF0117***	Cannabinoid-1 receptor synthetic Signaling Specific inhibitor (SSi)	Treatment of CUD			P	hase 2B: LSLV Q1	L-2024; CSR: Q3-2	024	
INDV-5004	Drinabant – CB1 receptor antagonist	Treatment of ACO		IND-enabl	ng activities fund	ded by NIH/NCAT	'S grant		

Licensing Agreement with: \*C4X Discovery; \*\*Addex Therapeutics; \*\*\*Aelis Farma

# AEF0117: Clinical Phase 1 & 2A Results Published by Aelis Farma in *Nature Medicine*

#### nature medicine



**Article** 

https://doi.org/10.1038/s41591-023-02381-w

# Signaling-specific inhibition of the $CB_1$ receptor for cannabis use disorder: phase 1 and phase 2a randomized trials

Accepted May 1, 2023
Published online June 8, 2023
https://www.nature.com/articles/s41591-023-02381-w

# Ryan Preblick

**Chief Financial Officer** 

# Q2 2023 financial highlights

#### Takeaways (vs. Q2 2022)

- Top-line NR growth of 25%
  - ✓ U.S. NR up 26%
  - ✓ ROW NR up 19% (up 20% excluding FX)
- Total SUBLOCADE NR of \$155m, up 58%; PERSERIS NR of \$11m, up 57%
- Reported gross margin of 82% down 1 pt. on intangible amortization; adjusted gross margin flat with improved product mix offset by inflationary impacts
- Reported operating profit down 3% to \$61m; Adjusted operating profit¹up 18% to \$71m

#### Operating Results – Reported and Adjusted<sup>2</sup>

\$ mil	Q2 23	Q2 22	<u>Change</u>	_	Adjust	ed
Net Revenue: U.S. ROW <sup>3</sup>	<b>276</b> 226 50	<b>221</b> 179 42	<b>25%</b> 26% 19%	Q2 23	Q2 22	Change
Gross Profit:	226	183	23%	228	183	25%
Gross Margin	82%	83%	-1 pt.	83%	83%	-
Op Expenses: SG&A R&D	(165) (133) (32)	(123) (109) (14)	34% 22% 129%	(125)	(107)	17%
Other Op. Income/(Expense):	-	3	NM	   -	(2)	NM
Operating Profit: Reported Adjusted <sup>2</sup>	61 71	63 60	-3% 18%	 		
Key product NR SUBLOCADE NR PERSERIS NR	Q2 23 155 11	Q2 22 98 7	<u>Change</u> 58% 57%			

<sup>&</sup>lt;sup>2</sup> See reconciliation pages in the appendix



<sup>&</sup>lt;sup>3</sup> Actual FX (foreign exchange) rates

# Cash & borrowing position

#### **Cash & Borrowing**

\$ in mil.)	Q2 23	<u>YE 22</u>
Cash & Cash Equivalents	\$592	\$774
ST & LT Investments	<u>\$190</u>	<u>217</u>
Total Cash & Investments <sup>1</sup>	\$782	\$991
Current Borrowings	(3)	(3)
Long-term Borrowings Loan issuance costs	(236) (6)	(237) (6)

#### **Takeaways**

#### Total gross cash & investments of \$782m<sup>1</sup>

- Cash and investments primarily held in USD
- Anti-trust settlement payment of \$102.5m in Q2 '23
- Opiant acquisition completed in Q1'23 for \$124m (net of transferred cash balance)
- Completed second \$100m share buyback in Q1'23

#### Disciplined and consistent capital allocation

- ▶ Deliver against SUBLOCADE NR goal of >\$1.5 billion
- Organically grow revenue base (PERSERIS, Ex.-US new products, OPVEE)
- Progress existing early-stage assets
- Consider inorganic growth opportunities ("bolt-on level")
- Regularly consider returns to shareholders



# FY 2023 guidance updated<sup>1</sup>

#### FY 2023 Revised Guidance<sup>2</sup> (\$ in mil.)

#### **Total Net Revenue**

#### **Key LAI<sup>2</sup> Products**

- SUBLOCADE NR (Total)
- PERSERIS NR

#### Adj. Gross Margin %

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

- SG&A
- R&D

#### Adj. Op. Profit

#### \$1,030m to \$1,090m (from \$970m to \$1,040m)

- \$590m to \$630 (+50% at mid-point; from \$550m to \$600m)
- \$45m to \$55m (+82% at mid-point; Unchanged)

#### Low to mid 80% range (unchanged)

#### \$620m to \$640m (unchanged)

- \$530m to \$540m (unchanged)
- \$90m to \$100m (unchanged)

#### Higher than FY 2022 level of \$212m

#### **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 (Buprenorphine/naloxone) Film
  - Accelerated share erosion in Q4 2023 reflecting underlying share loss due to anticipated formulary decisions together with assumed impact from a fourth film generic<sup>3</sup> entering the U.S. market in early Q4 2023 (from H2 2023)
  - The Group will continue to monitor the competitive environment and update the market accordingly

#### > ROW

- Growth from new products (SUBUTEX PR®, SUBOXONE Film) to more than offset 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 includes inflationary impacts:
  - SG&A
    - ✓ 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



<sup>&</sup>lt;sup>1</sup> As of July 27, 2023, before exceptional items.

<sup>&</sup>lt;sup>2</sup> LAI=long-acting injectable.

<sup>&</sup>lt;sup>3</sup> Apotex generic buprenorphine/naloxone sublingual film approved by FDA June 2022.

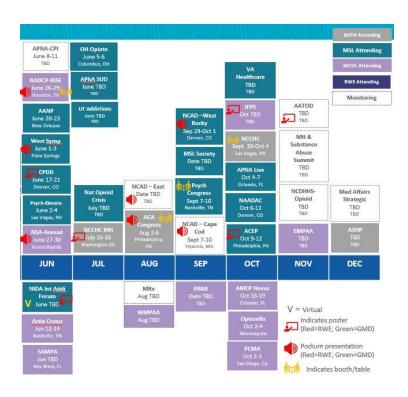
Q&A

# **Appendix**

# H2 2023 Capital Markets Calendar

Date	Key Event
Sept. (dates TBD)	Northland Securities "Teach-in" and non-deal roadshow
Sept. 11 <sup>th</sup> – 12 <sup>th</sup>	Morgan Stanley Healthcare Conference (New York)
Sept. 22 <sup>nd</sup>	Jefferies "Back to School" Event (virtual)
Late Oct. / Early Nov.	Q3 23 Results Earnings Call & Investor Roadshow
Nov. 9 <sup>th</sup>	Truist Healthcare Conference (New York)
Nov. 14 <sup>th</sup>	Stifel Healthcare Conference (New York)
Nov. 28 <sup>th</sup> – 30 <sup>th</sup>	Piper Healthcare Conference (New York)

# Peer-Reviewed Publications & Conferences



#### Peer-Reviewed Publications YTD

→ 6 published & 2 in press

#### **Conference Presentations YTD**

→ Association of Military Surgeons of the United States (AMSUS); Academy of Managed Care Pharmacy (AMCP); American Society for Clinical Pharmacology & Therapeutics (ASCPT); College of Psychiatric and Neurologic Pharmacists (CPNP); American Association of Psychiatric Pharmacists (AAPP); International Society for Pharmacoeconomic and Outcomes Research (ISPOR)

#### **Priority Conferences (Q3-2023):**

→ College on Problems of Drug Dependence (CPDD); National Commission on Correctional Health Care (NCCHC); Annual International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE); American Correctional Association (ACA); Psych Congress, American Academy of Nurse Practitioners (AANP), National Association of Drug Court Professionals (NADCP-Rise)

# Financial Reconciliation: Adjusted Results

	Q2 2023	Q2 2022	H1 2023	H1 2022
For the three and six months ended June 30	\$m	\$m	\$m	\$m
Exceptional items and other adjustments within costs sales				
Amortization of acquired intangible assets	(2)	_	(2)	
Total exceptional items and other adjustments within cost of sales	(2)	_	(2)	-
Exceptional items and other adiustments within SG&A				
Acquisition-related costs	(4)	_	(16)	_
US listing costs <sup>3</sup>	(4)	(2)	(6)	(2)
Total exceptional items and other adjustments within SG&A	(8)	(2)	(22)	(2)
Exceptional items and other adjustments within net other operating incom				
Insurance reimbursement	_	5	_	5
Total exceptional items and other adjustments within net other operatin income	_	5	_	5
Total exceptional items and other adjustments before taxes	(10)	3	(24)	3
Tax on exceptional items and otherdjustments	1	_	3	_
Exceptional tax item's	(8)	_	(8)	_
Total exceptional items and other adjustments	(17)	3	(29)	3

- With the acquisition of Opiant and approval of OPVEE, the Group reported adjusted cost of sales to exclude amortization of acquired
  intangible assets on a prospective basis from Q2 2023. Prior period adjusted results have not been restated as the impact is not material.
- 2. In H1 2023 and Q2 2023, the Group recognized \$16m and \$4m of exceptional costs related to the acquisition of Opiant (refer to Note 16).
- In H1 2023 and Q2 2023, the Group recognized \$6m and \$4m of exceptional costs in preparation for a potential additional listing of Indivior shares on a major US exchange (H1 2023 and Q2 2023: \$2m).
- The Group recognized \$5m of exceptional income in Q2 2022 related to the proceeds received from a Directors' & Officers' insurance reimbursement claim.
- 5. Exceptional tax items are comprised of \$5m write off of deferred tax assets and tax expense due to I.R.C. limitation on the deduction of executive compensation by U.S. publicly traded companies and \$3m change in estimate as to the tax benefit of legal provisions booked in the prior year.

