Indivior PLC

Q1 2022 Results
April 28, 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.

Q1 2022 key messages

Good start to the year; SUBLOCADE® drives top- and bottom-line growth

Reconfirming FY 2022 guidance

Returning value to shareholders with new $100m buyback;
Consultations on additional US listing underway

Strategic Priorities report card: Q1 2022

Grow SUBLOCADE® >$1 bil.

Q1 22 NR: $85m
+13% vs. Q4 21
+98% vs. Q1 21

Q1 22 US dispenses: 63.9k
+14% vs. Q4 21
+79% vs. Q1 21

Ending Q1 22 patients*: 57k
+16% vs. Q4 21
+78% vs. Q1 21

OHS Accessed: 430

Diversify Revenue

PERSERIS® Q1 22 NR: $5m
unch. vs. Q4 21; +67% vs. Q1 21; Expanded national sales force ramping up in FY 22

SUBUTEX® Prolonged Release (ROW):
Q1 22 NR: **$6m**
+20% vs. Q4 21
+100% vs. Q1 21

SUBOXONE® Film (ROW):
European launches progressing

Build Our Pipeline

SUBLOCADE®:
Publication of buprenorphine-fentanyl interaction study in JCI Insight (peer reviewed journal).

Aelis Farma (AEF 0117): Phase 2b study beginning Q2 22; study completion estimated for Q4 23

INDV-1000 (w/ ADDEX): Two lead molecules chosen for optimization; synthesizing to enable dosage studies

INDV-2000 (w/ C4X):
Completed Phase 1 study; additional toxicology and dosing studies expected in Q2 22 to re-initiate MAD study in H2 22

A complete R&D update may be found here.

Optimize Operating Model

Adj. Operating Profit: $54m**
(vs. adj. $51m Q1 21)

Net Cash & Investments: $776m
(vs. 853m FYE 2021)

Consulting shareholders for potential additional US listing

New $100m Share Repurchase Program Announced

*Rolling 12-month patients estimate using both Specialty Pharmacy and Specialty Distributor proxy data; ** See adjusted reconciliations in Appendix

Additional US listing – formal shareholder consultations proceeding

Spring / Summer 2022

Shareholder consultations

July 2022

Board decision whether to proceed with formal shareholder vote (decision to proceed expected with the Group's H1 22 results in late July)

September 2022

Early September:
EGM circular published

Late September:
Shareholder vote

Spring 2023

Implementation and commencement of additional US listing

Ryan Preblick

Chief Financial Officer

INDIVIOR

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%
Total Net Revenue	**$207**	**$180**	**15%**
Key product NR			
SUBLOCADE NR	$85	$43	98%
PERSERIS NR	$5	$3	67%
Adj. Gross Profit	**$170**	**$148**	**15%**
	82%	82%	
Adj. Op Exp	($117)	($97)	21%
SG&A	($109)	($88)	24%
R&D	($8)	($9)	-11%
Other Operating Income	1	1	-
Adj. Operating Income	**$54**	**$51**	**6%**
Cash & Investments	**$1,024**	$945	+79
Total Net Cash & Investments	**$776**	$711	+65

* Adjusted – see Appendix for reconciliations

Cash & Borrowing position

Cash & Borrowing table

($ in mil.)	Q1 22	FY 21
Cash & Cash Equivalents	$874	$1,102
ST & LT Investments	$150	NM
Total Cash & Investments	$1,024	$1,102
Current Borrowings	(3)	(3)
Long-term Borrowings	(238)	(239)
Loan issuance costs	(7)	(7)
Total Net Cash & Investments	$776	$853

Takeaways

Total net cash & investments of $776m:

- Timing differences for government rebates
- Annual settlement payments for DOJ and RB in Q1
- Cash optimization strategy with portion of cash invested in short-term, investment-grade fixed-income securities

Maintaining disciplined & consistent capital allocation:

- Deliver against SUBLOCADE® NR 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

FY 2022 guidance unchanged

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**

(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) [2]
  - 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 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

(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.

SUBOXONE® (BUPRENORPHINE AND NALOXONE) SUBLINGUAL FILM (CIII)

INDICATION AND USAGE
SUBOXONE® Film is indicated for treatment of opioid dependence. SUBOXONE Film should be used as part of a complete treatment plan that includes counseling and psychosocial support

HIGHLIGHTED SAFETY INFORMATION
Prescription use of this product is limited under the Drug Addiction Treatment Act.

CONTRAINDICATIONS
SUBOXONE Film is contraindicated in patients with a history of hypersensitivity to buprenorphine or naloxone.

WARNINGS AND PRECAUTIONS
Addiction, Abuse, and Misuse: Buprenorphine can be abused in a manner similar to other opioids and is subject to criminal diversion. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits.

Respiratory Depression: Life-threatening respiratory depression and death have occurred in association with buprenorphine use. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with SUBOXONE Film. Strongly consider prescribing naloxone at the time SUBOXONE Film is initiated or renewed because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and, if naloxone is prescribed, how to treat with naloxone.

Unintentional Pediatric Exposure: Store SUBOXONE Film safely out of the sight and reach of children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children.

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Risk of Opioid Withdrawal with Abrupt discontinuation: If treatment is temporarily interrupted or discontinued, monitor patients for withdrawal and treat appropriately.

Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events.

Precipitation of Opioid Withdrawal Sign and Symptoms: An opioid withdrawal syndrome is likely to occur with parenteral misuse of SUBOXONE Film by individuals physically dependent on full opioid agonists, or by sublingual or buccal administration before the agonist effects of other opioids have subsided.

Risk of Overdose in Opioid Naïve Patients: SUBOXONE Film is not appropriate as an analgesic. There have been reported deaths of opioid naïve individuals who received a 2 mg sublingual dose

ADVERSE REACTIONS
Adverse events commonly observed with the sublingual/buccal administration of the SUBOXONE Film are oral hypoesthesia, glossodynia, oral mucosal erythema, headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.

DRUG INTERACTIONS
Benzodiazepines: Use caution in prescribing SUBOXONE Film for patients receiving benzodiazepines or other CNS depressants and warn patients against concomitant self-administration/misuse.

CYP3A4 Inhibitors and Inducers: Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over- or under- dosing.

Antiretrovirals: Patients who are on chronic buprenorphine treatment should have their dose monitored if NNRTIs are added to their treatment regimen. Monitor patients taking buprenorphine and atazanavir with and without ritonavir. Dose reduction of buprenorphine may be warranted.

Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue SUBOXONE Film if serotonin syndrome is suspected.

USE IN SPECIFIC POPULATIONS
Lactation: Buprenorphine passes into the mother's milk.

Geriatric Patients: Monitor geriatric patients receiving SUBOXONE Film for sedation or respiratory depression.

Moderate or Severe Hepatic Impairment: Buprenorphine/naloxone products are not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment.

To report pregnancy or side effects associated with taking SUBOXONE Film, please call 1-877-782-6966.

For more information about SUBOXONE Film, the full Prescribing Information, and Medication Guide visit www.suboxone.com. For REMS information visit www.suboxoneREMS.com.

SUBLOCADE (buprenorphine extended-release) injection, for subcutaneous use (CIII)

INDICATION

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

HIGHLIGHTED SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- **Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.**
- **Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.**

Prescription use of this product is limited under the Drug Addiction Treatment Act.

CONTRAINDICATIONS

SUBLOCADE should not be administered to patients who have been shown to be hypersensitive to buprenorphine or any component of the ATRIGEL® delivery system

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

Respiratory Depression: Life threatening respiratory depression and death have occurred in association with buprenorphine. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with SUBLOCADE.

Opioids can cause sleep-related breathing disorders e.g., central sleep apnea (CSA), sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. Consider decreasing the opioid using best practices for opioid taper if CSA occurs.

Strongly consider prescribing naloxone at SUBLOCADE initiation or renewal because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and how to treat with naloxone if prescribed.

Risk of Serious Injection Site Reactions: The most common injection site reactions are pain, erythema and pruritis with some involving abscess, ulceration, and necrosis. The likelihood of serious injection site reactions may increase with inadvertent intramuscular or intradermal administration.

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome is an expected and treatable outcome of prolonged use of opioids during pregnancy.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off the opioid.

Risk of Opioid Withdrawal With Abrupt Discontinuation: If treatment with SUBLOCADE is discontinued, monitor patients for several months for withdrawal and treat appropriately.

Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to and during treatment.

Risk of Withdrawal in Patients Dependent on Full Agonist Opioids: Verify that patient is clinically stable on transmucosal buprenorphine before injecting SUBLOCADE.

Treatment of Emergent Acute Pain: Treat pain with a non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect.

ADVERSE REACTIONS

Adverse reactions commonly associated with SUBLOCADE (in ≥5% of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.

For more information about SUBLOCADE, the full Prescribing Information including BOXED WARNING, and Medication Guide, visit www.sublocade.com.

ABOUT PERSERIS® (risperidone) for extended-release injectable suspension

INDICATION
PERSERIS® (risperidone) is indicated for the treatment of schizophrenia in adults.

WARNING: INCREASED MORTALITY IN ELDERY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

See full prescribing information for complete boxed warning.

* **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**

* **PERSERIS is not approved for use in patients with dementia-related psychosis.**

CONTRAINDICATIONS
PERSERIS should not be administered to patients with known hypersensitivity to risperidone, paliperidone, or other components of PERSERIS.

WARNINGS AND PRECAUTIONS
Cerebrovascular Adverse Reactions, Including Stroke in Elderly Patients with Dementia-Related Psychosis: Increased risk of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities. PERSERIS is not approved for use in patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): Manage with immediate discontinuation and close monitoring.

Tardive Dyskinesia: Discontinue treatment if clinically appropriate.

Metabolic Changes: Monitor for hyperglycemia, dyslipidemia and weight gain.

Hyperprolactinemia: Prolactin elevations occur and persist during chronic administration. Long-standing hyperprolactinemia, when associated with hypogonadism, may lead to decreased bone density in females and males.

Orthostatic Hypotension: Monitor heart rate and blood pressure and warn patients with known cardiovascular disease or cerebrovascular disease, and risk of dehydration or syncope.

Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts (CBC) in patients with a history of a clinically significant low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing PERSERIS if a clinically significant decline in WBC occurs in absence of other causative factors.

Potential for Cognitive and Motor Impairment: Use caution when operating machinery.

Seizures: Use caution in patients with a history of seizures or with conditions that lower the seizure threshold.

ADVERSE REACTIONS
The most common adverse reactions in clinical trials (≥ 5% and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions (≥ 5%) were injection site pain and erythema (reddening of the skin).

For more information about PERSERIS™, the full prescribing information, including BOXED Warning, visit https://www.perseris.com.

Appendix

Income statement: Q1 2022 vs. Q1 2021

	Q1 2022			Δ	Q1 2021		
	Q1 2022 Actual	Adjustments	Q1 2022 Adjusted	Y-o-Y (adjusted basis)	Q1 2021 Actual	Adjustments	Q1 2021 Adjusted
($ in mil. at Actual FX)							
Net Revenues	**207**		**207**		**180**		**180**
Cost of Sales	(37)		(37)		(32)		(32)
Gross Profit	**170**		**170**		**148**		**148**
Gross Margin (%)	*82%*		*82%*		*82%*		*82%*
Selling, General and Administration Expenses	(109)		(109)		(83)	(5)[1]	(88)
Research & Development Expenses	(8)		(8)		(9)		(9)
Other Operating Income	1		1		1	(1)[2]	0
Profit (Loss) on Ordinary Activities before interest & taxation	**54**		**54**		**57**		**51**
Operating Margin (%)	*26%*		*26%*		*32%*		*28%*
Net interest (expense) / income	(6)		(6)		(4)		(4)
Taxation	(7)		(7)		27	(36)[3]	(9)
Effective Tax Rate (%)	*15%*		*15%*		*51%*		*(19%)*
Net Income / (loss)	**41**		**41**		**80**		**38**

Q1 2022 Notes:

Q1 2021 Notes:
(1) Excludes $5m of benefit related to a legal provision release
(2) Excludes $1m related to proceeds from out-licensing of nasal naloxone patents
(3) Excludes $36m benefit related to development credits for SUBLOCADE

THANK YOU