

Indivior PLC

Q3 / YTD 2021 Results
October 28, 2021



Mark Crossley

Chief Executive Officer



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 2021 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "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 (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases): 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 the 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 compliance with the Indivior Group's 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.



Q3 2021 key messages

- Continued good SUBLOCADE® growth – 5th consecutive quarter of double-digit growth in net revenue and patient dispenses
- Organized Health Systems (OHS) strategy driving SUBLOCADE® momentum
- Raising FY 2021 Total NR and SUBLOCADE® NR guidance

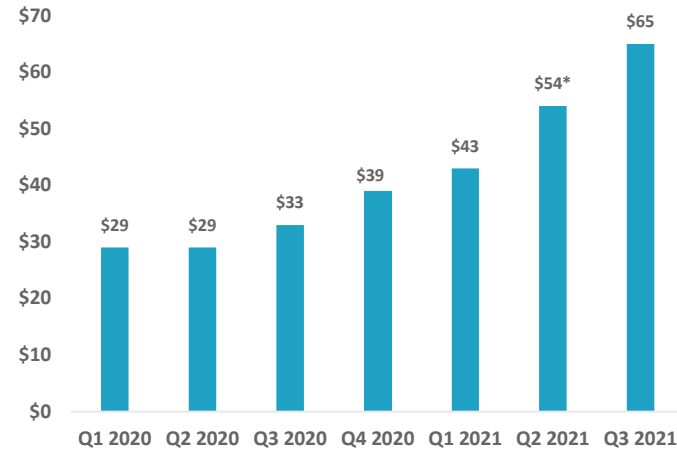


OHS strategy execution is driving SUBLOCADE® growth

- OHS strategy is now fully embedded
- OHS now accounts for ~55% of SUBLOCADE NR
- Activation in place with 300+ organizations (goal to activate 500+ priority organizations)
- In-person access continuing improve – ~70% in Q3, up from ~65% in Q2

SUBLOCADE® NR Growth through the COVID Period

(\$ in millions)



* Excludes \$7m CIS bulk order



Strategic Priorities report card: Q3 2021

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Grow SUBLOCADE® >\$1 bil.

- **Q3 21 NR: \$65m**
+7% vs. Q2 21 (+20% excl. \$7m CJS order in Q2 21);
+97% vs. Q3 20
- **Q3 21 US dispenses: 48.4k**
+13% vs. Q2 21*;
+66% vs. Q3 20
- **Q3 21 patients**: 43.0.k**
+17% vs. Q2 21;
+65% vs. Q2 20

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Diversify Revenue

- **PERSERIS® Q3 21 NR: \$5m**
+25% vs. Q2 21; +67% vs. Q3 20; expanding sales force to gain US national coverage in FY 2022
- **SUBUTEX® Prolonged Release (ROW):** Q3 21 NR: \$4m; unchanged vs. Q2 21 (\$11m YTD 21); available in Australia, Canada and Israel; approved in Germany, Italy, the Nordics and New Zealand
- **SUBOXONE® Film (ROW):** available in Canada, Israel, Germany, UK, Italy and the Nordics

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Build Our Pipeline

- **SUBLOCADE® label:** updated to include relevant fentanyl pharmacodynamic study (FDA approved).
- **Aelis Farma (AEF 0117):** Phase 2b study protocol finalized; commencement of study Q1 2022.
- **INDV-1000 (w/ ADDEX):** Two lead molecules and potential back-ups have been chosen for the late lead optimization phase.
- **INDV-2000 (w/ C4X):** Non-clinical toxicology study being planned in response to FDA. FDA's decision based on non-clinical findings from a separate (not sponsored by Indivior) development program.

R&D and pipeline update may be found [here](#)

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Optimize Operating Model

- **Cash:** \$1.005 billion
+\$147m vs. FYE 2020
- **Net Cash:** \$756m
+\$133m vs. FYE 2020
- **\$100m Share Repurchase Program (as of 9/30/21):** repurchased 11,730,087 shares at avg. daily weighted price of 189.87p for approx. \$31m

* Excludes units related to CJS order

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



Ryan Preblich

Chief Financial Officer



Q3/ YTD 2021 financial highlights

- > Strong top-line progression, FY 21 guidance raised*
 - Q3 YOY NR growth: +18% to \$187m; YTD YOY NR growth: +23% to \$568m
 - SUBLOCADE® Q3 YOY NR growth: +97% to \$65m; SUBLOCADE® YTD YOY NR growth: +86% to \$169m
- > Investing to accelerate LAI growth
 - SUBLOCADE® – digital marketing, CJS penetration
 - PERSERIS® – salesforce expansion
- > Maintained strong financial position
 - \$1 billion+ of cash
 - \$200m cash from operations YTD

* See slide 11 for FY21 guidance details



Profit & Loss Account*

	Q3			YTD		
	2021 Adjusted	2020 Adjusted	% change	2021 Adjusted	2020 Adjusted	% change
(\$ in mil. at actual FX)						
Net Revenues	187	159	18%	568	462	23%
Cost of Sales	(26)	(28)		(88)	(63)	
Gross Profit	161	131	23%	480	399	20%
<i>Gross Margin (%)</i>	86%	82%	+400bps	85%	86%	-100bps
Selling, General and Administration Expenses	(112)	(93)		(292)	(317)	
Research & Development Expenses	(11)	(8)		(33)	(26)	
Operating Profit	38	30	27%	155	56	NM
<i>Operating Margin (%)</i>	20%	19%	+100bps	27%	12%	NM
Net interest	(7)	(5)		(17)	(12)	
Taxation	(4)	(6)		(24)	(11)	
<i>Effective Tax Rate (%)</i>	13%	24%		17%	25%	
Net Income	27	19	42%	114	33	NM

* Please see Appendix for full reconciliation of Reported to Adjusted for periods indicated.



Cash & borrowing position

(\$ in mil.)	YTD 2021	FY 2020
Cash & Cash Equivalents	\$1,005	\$858
Current Borrowings	(3)	(4)
Long-term Borrowings	(239)	(230)
Loan issuance costs	(7)	(1)
Net cash	\$756	\$623

- Net cash growth to \$756m (vs. \$623m at FY 2020):
 - ✓ Stronger YTD operating performance
 - ✓ Stable government payables
 - ✓ 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; small early-stage acqs. possible (low double-digit \$millions)
 - ✓ Returning capital to shareholders via \$100m share repurchase program



Upgrading FY 2021 total net revenue and SUBLOCADE® guidance

Revised FY 2021 Guidance (\$ in mil.)

Total NR:	\$750m to \$770m; +18% YOY at mid-point (previously \$705m to \$740m)
SUBLOCADE NR:	\$235m to \$245m; +85% YOY at mid-point (previously \$210m to \$230m)
PERSERIS NR:	\$17m to \$20m (No change)
Adj. gross margin:	Low 80% range (No change)
Adj. OPEX (SG&A + R&D):	\$470m to \$480m (No change)
Adj. Pre-tax income:	Higher than previously expected

Additional top-line items:

- Continued underlying BMAT market growth
- Relatively stable SUBOXONE® Film share levels in the US* for the remainder of FY 2021
- Rest of World
 - ✓ New product (SUBUTEX PR®, SUBOXONE® Film) contribution slightly offset by continued competitive pressure in the legacy tablet business in Western Europe

Margin & Expense detail:

- Adj. gross margin in low 80% range; target remains mid-80% range as mix of SUBLOCADE NR expected to increase as a % of total NR
- Adj. OPEX (combined SG&A and R&D) of \$470m to \$480m
 - ✓ Commercial investments to grow the Group's LAI technologies, principally in the US

* The Group continues to expect that SUBOXONE® Film share loss will ultimately revert to observed industry analogues according to the IMS Institute Report, January 2016: "Price Declines after Branded Medicines Lose Exclusivity in the U.S."



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 pruritus 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 ELDERLY 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 ($\geq 5\%$ and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions ($\geq 5\%$) 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



Q3 Profit & Loss Account Reconciliation

	Q3 2021			Q3 2020		
	Q3 2021 Actual	Adjustments	Q3 2021 Adjusted	Q3 2020 Actual	Adjustments	Q3 2020 Adjusted
(\$ in mil.)						
Net Revenues	187		187	159		159
Cost of Sales	(26)		(26)	(33)	5 ¹	(28)
Gross Profit	161		161	126		131
Selling, General and Administration Expenses	(112)	nil ⁽¹⁾	(112)	(100)	7 ²	(93)
Research & Development Expenses	(11)		(11)	(8)		(8)
Operating Profit	38		38	18		30
Net interest	(7)		(7)	(5)		(5)
Taxation	(4)		(4)	(3)	(3) ³	(6)
Net Income	27		27	10		19

(1) Excludes net exceptional items – \$19m benefit related to sale of legacy Temgesic / Buprex / Buprex business outside the US, \$5m benefit related to releases of provisions related to DOJ matters and -\$24 related to an increase in the provision for ANDA litigation.

1 Related to inventory provisions due to COVID-19
 2 Related to restructuring costs for strategic alignment announced Sept. 24, 2020
 3 Excludes tax effect on exceptional items in Q3 2020



YTD Profit & Loss Account Reconciliation

	YTD 2021			YTD 2020		
	YTD 2021 Actual	Adjustments	YTD 2021 Adjusted	YTD 2020 Actual	Adjustments	YTD 2020 Adjusted
(\$ in mil.)						
Net Revenues	568		568	462		462
Cost of Sales	(88)		(88)	(74)	11 ¹	(63)
Gross Profit	480		480	388		399
Selling, General and Administration Expenses	(279)	(13) ⁽¹⁾	(292)	(509)	192 ²	(317)
Research & Development Expenses	(33)		(33)	(26)		(26)
Operating (Loss) / Profit	168		155	(147)		56
Net interest	(18)	1 ⁽²⁾	(17)	(12)		(12)
Taxation	19	(43) ⁽³⁾	(24)	24	(35) ³	(11)
Net (Loss) / Income	169		114	(135)		33

(1) Excludes \$13m of exceptional items – \$19m benefit related to sale of legacy Temgesic / Buprex / Buprex business outside the US, \$18m benefit related to releases of provisions related to DOJ matters and -\$24 related to an increase in the provision for ANDA litigation.

(2) Excludes \$1m write-off of historical deferred financing costs

(3) Excludes tax benefit related to development credits for SUBLOCADE and impact of settlement costs with RB

1 Related to inventory provisions due to COVID-19

2 Related to exceptional legal provision (\$183m) related to the DOJ matter, strategic alignment restructuring announced Sept. 24, 2020 (\$7m) and lease disposal costs (\$2m)

3 Excludes tax effect on exceptional items in YTD 2020 period



Upcoming events

- **November 15th:** Stifel Virtual Healthcare Conference
 - ✓ Fireside chat and 1x1's
- **November 16th:** Jefferies London Healthcare Conference
 - ✓ Presentation and 1x1's

