

# Indivior PLC

YTD 2020 Results Supplement  
October 29, 2020



# 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 2020, if any, 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 settlement with the U.S. Department of Justice and 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.



# CEO perspective: Q3 20

## Navigating the challenges of COVID-19 while building for the future

### Performance



- Q3 results were solid considering ongoing COVID-19 challenges
  - ✓ +ive adj. op. profit\*; SUBLOCADE® NR increase to \$33m (YTD NR: \$91m); PERSERIS® NR was \$3m (YTD NR: \$10m)
  - ✓ Organized Health System (OHS) strategy for SUBLOCADE® on track
  - ✓ Cash of \$929m; DOJ Agreement expected to be finalized November 12th
- Took actions to protect against ongoing COVID-19 impacts and provide for long-term growth
  - ✓ \$60m to \$70m in pre-tax savings in FY 2021 versus expected FY 2020 OPEX base (see FY 20 Guidance pg. 6)

### Outlook



- Assume COVID-19 challenges persist
  - ✓ HCPs continuing to significantly restrict in-person interactions
- Reinstating FY 20 guidance

### Priorities



- Maintain leading position in global OUD treatment
- Continue to build growth platform for depot treatments
- Execute savings actions to preserve financial flexibility
- Deliver on compliance commitments and protect our people

\* On an Adjusted basis. See Appendix for reconciliations.



# Profit & Loss Account (adjusted basis)\*

## Q3

	2020 Adjusted	2019 Adjusted	% change
(\$ in mil.)			
<b>Net Revenues</b>	<b>159</b>	<b>199</b>	<b>-20%</b>
Cost of Sales	(28)	(34)	
<b>Gross Profit</b>	<b>131</b>	<b>165</b>	<b>-21%</b>
<i>Gross Margin (%)</i>	82%	83%	
Selling, General and Administration Expenses	(93)	(97)	
Research & Development Expenses	(8)	(11)	
<b>Operating Profit</b>	<b>30</b>	<b>57</b>	<b>-47%</b>
<i>Operating Margin (%)</i>	19%	29%	
Net interest	(5)	(1)	
Taxation	(6)	(8)	
<i>Effective Tax Rate (%)</i>	24%	14%	
<b>Net Income</b>	<b>19</b>	<b>48</b>	<b>-60%</b>

## YTD

	2020 Adjusted	2019 Adjusted	% change
	<b>462</b>	<b>652</b>	<b>-29%</b>
	(63)	(97)	
	<b>399</b>	<b>555</b>	<b>-28%</b>
	86%	85%	
	(317)	(271)	
	(26)	(36)	
	<b>56</b>	<b>248</b>	<b>-77%</b>
	12%	38%	
	(12)	2	
	(11)	(37)	
	25%	15%	
	<b>33</b>	<b>213</b>	<b>-85%</b>

\* Please see Appendix for reconciliations of periods indicated.



## Cash & borrowing position

(\$ in mil.)	YTD 2020	FY 2019
Cash & Cash Equivalents	\$929	\$1,060
Current Borrowings	(4)	(4)
Long-term Borrowings	(231)	(233)
Loan issuance costs	(1)	(2)
Net cash	\$693	\$821

- Net cash of \$693m at YTD 2020
- Retaining cash on balance sheet:
  - ✓ Ability to continue resourcing depot technology growth initiatives
  - ✓ Manage through transition from SUBOXONE® Film (accrued rebating payables)
  - ✓ Provide for legal settlement and compliance commitments
- Escrowed \$100m of DOJ agreement payment to be paid in Q4



# FY 20 guidance reinstated

(\$ in mil.)	Guidance
Net revenue	\$595m — \$620m
Pre-tax income (adj. basis) <sup>(1)</sup>	Positive

## Top-line:

- SUBOXONE® Film
  - ✓ Continued double-digit underlying BMAT market growth
  - ✓ SUBOXONE® Film share of 21% remains relatively unchanged for remainder of FY 2020
  - ✓ The Group continues to expect that SUBOXONE® Film share loss will ultimately revert to observed industry analogues<sup>(2)</sup>
- Rest of World
  - ✓ Continued competitive pressures in legacy W. European markets resulting in a mid-single digit NR decline compared to the previous year
- Net revenue expectations for SUBLOCADE® of \$120m to \$125m
  - ✓ Central net revenue case assumes modest new patient enrolments
  - ✓ Lower end of net revenue range considers tightened COVID-19 restrictions impacting new patient enrolments
- Net revenue expectations for PERSERIS® of \$12m to \$15m

## Expenses:

- OPEX (combined SG&A and R&D) of \$470m to \$480m

(1) Before F/X and exceptional costs

(2) 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 HIGHLIGHTED SAFETY INFORMATION

#### INDICATION

SUBOXONE® Film is indicated for the 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 should not be used by patients who have been shown to be hypersensitive to buprenorphine or naloxone.

#### WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: SUBOXONE Film 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. 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.

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 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 Signs 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.

For more information about SUBOXONE Film, please see the full Prescribing Information and Medication Guide at [www.suboxone.com](http://www.suboxone.com).



## SUBLOCADE® (BUPRENORPHINE EXTENDED-RELEASE) INJECTION FOR SUBCUTANEOUS USE (CIII)

### INDICATION AND HIGHLIGHTED SAFETY INFORMATION

#### 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.

#### 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.

#### HIGHLIGHTED SAFETY INFORMATION

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.

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 of 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](http://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 2020			Q3 2019*		
	2020 Actual	Adjustments	2020 Adjusted	2019 Actual	Adjustments	2019 Adjusted
(\$ in mil.)						
<b>Net Revenues</b>	<b>159</b>		<b>159</b>	<b>199</b>		<b>199</b>
Cost of Sales	(33)	5 <sup>1</sup>	(28)	(34)		(34)
<b>Gross Profit</b>	<b>126</b>		<b>131</b>	<b>165</b>		<b>165</b>
Selling, General and Administration Expenses	(100)	7 <sup>2</sup>	(93)	(97)		(97)
Research & Development Expenses	(8)		(8)	(11)		(11)
<b>Operating Profit</b>	<b>18</b>		<b>30</b>	<b>57</b>		<b>57</b>
Net interest	(5)		(5)	(1)		(1)
Taxation	(3)	(3) <sup>3</sup>	(6)	(8)		(8)
<b>Net Income</b>	<b>10</b>		<b>19</b>	<b>48</b>		<b>48</b>

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

\* There were no exceptional adjustments in the period



# YTD Profit & Loss Account Reconciliation

	YTD 2020			YTD 2019		
	2020 Actual	Adjustments	2020 Adjusted	2019 Actual	Adjustments	2019 Adjusted
(\$ in mil.)						
<b>Net Revenues</b>	<b>462</b>		<b>462</b>	<b>652</b>		<b>652</b>
Cost of Sales	(74)	11 <sup>1</sup>	(63)	(97)		(97)
<b>Gross Profit</b>	<b>388</b>		<b>399</b>	<b>555</b>		<b>555</b>
Selling, General and Administration Expenses	(509)	192 <sup>2</sup>	(317)	(299)	28 <sup>1</sup>	(271)
Research & Development Expenses	(26)		(26)	(36)		(36)
<b>Operating Profit</b>	<b>(147)</b>		<b>56</b>	<b>220</b>		<b>248</b>
Net interest	(12)		(12)	2		2
Taxation	24	(35) <sup>3</sup>	(11)	(33)	(4) <sup>2</sup>	(37)
<b>Net Income</b>	<b>(135)</b>		<b>33</b>	<b>189</b>		<b>213</b>

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

1 YTD 2019 adjusted exclude \$20m of exceptional restructuring costs and \$8m of exceptional legal expense for ongoing IP-related litigation

2 Excludes tax effect on exceptional items in YTD 2019 period

