

Indivior PLC

YTD / Q3 2019 Results
October 31, 2019



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 2019 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 this release): factors affecting sales of Indivior Group's products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; 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; 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; 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 ongoing investigative and antitrust litigation matters and the pending DOJ indictment; 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; 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.



YTD 2019 snapshot

YTD Financial Performance

2019 vs. 2018 (adjusted basis⁽¹⁾)

Net Rev.	\$652m	-15%
Op. Profit	\$248m	-2%
Net Inc.	\$213m	+4%
Cash	\$1,023m	(\$924m at FY18)
Net Cash	\$783m	(\$681m at FY18)

FY 19 Guidance⁽²⁾

Net Rev.	\$750m to \$790m
Net Inc.	\$160m to \$190m

(1) See Appendix for reconciliation

(2) See slide No. 14 for more detail

YTD 19 Operating Discussion (adjusted basis⁽¹⁾)

- **BMAT market:** Continued double-digit growth in U.S. mainly driven by government channels
- **Net Revenue:** U.S. NR decline (-16%) reflected SUBOXONE® (buprenorphine/naloxone) Film share loss partially offset by underlying market growth and SUBLOCADE™ (buprenorphine extended-release) Injection NR contribution; ROW NR decline (-10%) in-line with expectations
- **SUBLOCADE™:** NR of \$48m; dispense yield of 64%; KPIs continue to improve
- **Op. Profit:** Modest decline YOY (-2%) reflects OPEX savings from significant cost base reductions that partially offset the decline in net revenue
- **Net Income:** Modest increase (+4%) reflects net finance income earned on cash balance
- **Auth. generic buprenorphine / naloxone sublingual film:** Indivior has discontinued the authorized generic buprenorphine/naloxone film program due to increased mandatory rebating to US Government channels as required by recent legislative changes regarding “best price” which results in Indivior selling SUBOXONE® Film at a gross profit loss in most US government channels
- **R&D / Pipeline Update:** [click here](#)



DOJ matter

- On April 9, 2019, a federal grand jury in the Western District of Virginia indicted the Company on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the Company's marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE® Film and/or SUBOXONE® Tablet by certain physicians. On August 14, 2019, a federal grand jury in the Western District of Virginia returned a Superseding Indictment that did not add to or change the charges, but changed certain factual allegations. DOJ is seeking to recover \$3 billion in monetary forfeitures and all assets derived from the commission of the alleged offenses. The Company believes it has strong defences to the government's charges and will vigorously defend itself. It is not possible to predict with any certainty the potential impact of this litigation on the Group or to quantify the ultimate cost of a verdict or resolution.
- Please see Notes 9, 10 and 11 in press release [Indivior Announces 2019 Third Quarter and Nine Months YTD Results](#) beginning on page 21 for further details on Provisions, Contingent Liabilities and Legal Proceedings.



SUBLOCADE™

(buprenorphine extended-release) Injection



ONCE-MONTHLY

Sublocade™
*(buprenorphine extended-release)
injection for subcutaneous use* Ⓒ

Unique SUBLOCADE™ patients injected increasing month over month; Dispense yield achieves mid-sixties target range, comparable with Suboxone Film

Closed Case Performance (1)(2)(5)

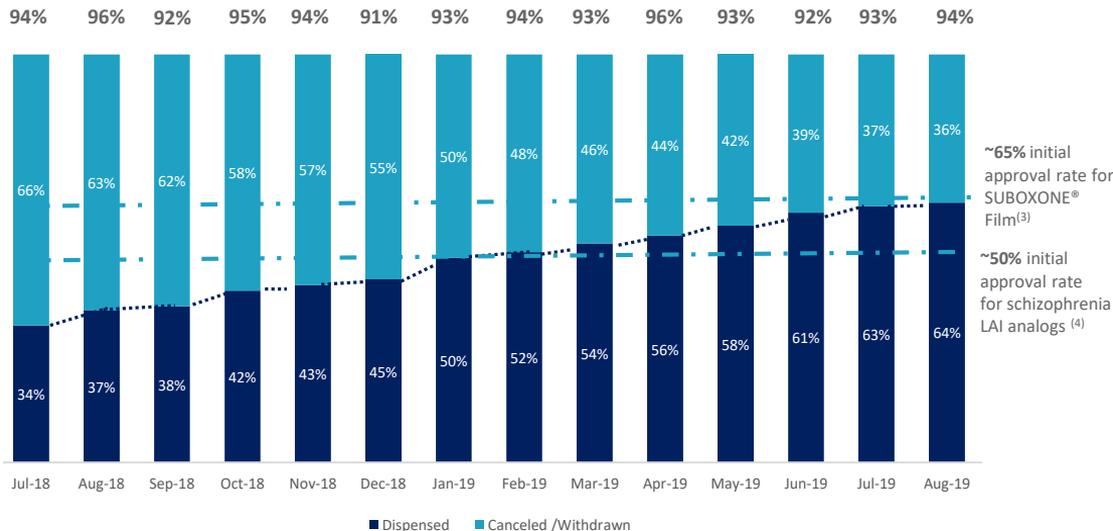
Cumulative Launch to 9/30/19 (1)

35,126 Unique prescriptions initiated

14,364 Unique patients injected

(1) Total includes estimate for patients with HCPs using Specialty Distributors (Buy and Bill)

Closed case run-rate:



(1) Proprietary Indivior SUBLOCADE™ data

(2) Closed cases unique to the month of enrollment. Tracking closed cases unique to the month of enrollment aligns with all other metrics (unique prescriptions and unique injections) and allows us to track developments over time

(3) Proprietary Indivior SUBOXONE® Film data

(4) Amundsen Consulting Analysis

(5) Data is measured 45 days after month close



SUBLOCADE™ KPIs – HCP Data & Patient Treatment Adherence

Cumulative Launch to 9/30/19 ⁽¹⁾

3,907 HCPs initiated prescription journeys

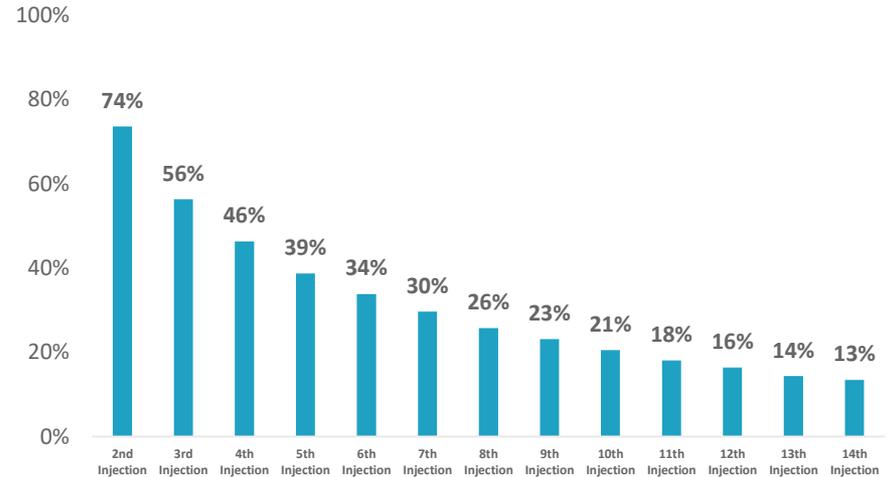
2,680 HCPs administered SUBLOCADE™

739 HCPs administered ≥ 5 patients

(1) Total includes HCPs using Specialty Distributors (Buy and Bill)

Treatment Adherence ⁽²⁾

(All patients with initial injection during March '18 to July '19)



(2) Excludes treatment by HCPs using Specialty Distributors (Buy and Bill)



PERSERIS™

(risperidone) for extended-release injectable suspension



once-monthly
PERSERIS™
(risperidone)
for extended-release
injectable suspension
90 mg · 120 mg

PERSERIS™ continues to progress

- Managed Care coverage now over 90% with solid parity access
- HCP / Patient experience with prescription journey and treatment remains positive
- Focused on continued awareness and experience with product
 - ✦ Mobilizing key external experts (KEEs)
 - ✦ Initiating peer-to-peer programs in-line with prescriber growth
 - ✦ Participating in full Medical Congress calendar

once-monthly
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Profit & Loss Account*

	Q3			YTD		
	2019 Adjusted	2018 Adjusted	% change	2019 Adjusted	2018 Adjusted	% change
(\$ in mil.)						
Net Revenues	199	245	-19%	652	768	-15%
Cost of Sales	(34)	(35)		(97)	(93)	
Gross Profit	165	210	-21%	555	675	-18%
<i>Gross Margin (%)</i>	83%	86%		85%	88%	
Selling, General and Administration Expenses	(97)	(123)		(271)	(371)	
Research & Development Expenses	(11)	(16)		(36)	(50)	
Operating Profit	57	71	-20%	248	254	-2%
<i>Operating Margin (%)</i>	29%	29%		38%	33%	
Net interest	(1)	(3)		2	(14)	
Taxation	(8)	(10)		(37)	(35)	
<i>Effective Tax Rate (%)</i>	14%	15%		17%	15%	
Net Income	48	58	-17%	213	205	+4%

* Please see Appendix for full reconciliation for periods indicated.



FY 2019 guidance (revised October 15th)

(\$ in mil.)	Revised Guidance	Previous Guidance
Net revenue	\$750m — \$790m	\$670m — \$720m
Net income (adj.)	\$160m — \$190m	\$80m — \$130m

Top-line:

- U.S. buprenorphine/ naloxone film market conditions
 - ✓ Continued double-digit underlying BMAT market growth
 - ✓ SUBOXONE® film share above observed industry analogues⁽¹⁾
 - ✓ Authorized generic contribution in the tens of \$-million
 - ✓ Includes adverse net revenue impact from recent legislation change regarding “best price” which results in Indivior selling SUBOXONE® Film at a negative gross profit through most US government channels, if it continues to supply Sandoz Inc. with its authorized generic product. As such, the Group has given notice and will discontinue its authorized generic program at the end of 2019
 - ✓ Competitive pressures in legacy W. European markets and Canada, partially offset by modest growth in Australia
- Net revenue expectations for SUBLOCADE™ & PERSERIS™
 - ✓ SUBLOCADE NR range of \$60m to \$70m
 - ✓ Modest PERSERIS NR contribution

Expenses:

- OPEX of \$440m to \$460m, including current Litigation/Investigative Matters⁽²⁾
- Ongoing investments to drive the progression of SUBLOCADE™ and PERSERIS™
- A tax rate in the high-single to low double-digits
- Before F/X and exceptional costs

(1) IMS Institute Report, January 2016: “Price Declines after Branded Medicines Lose Exclusivity in the U.S.”

(2) See page 22 in YTD 2019 press release dated Oct. 31, 2019 – Note 11.



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.



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.



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 2019 ⁽¹⁾			Q3 2018		
	2019 Actual	Adjustments	2019 Adjusted	2018 Actual	Adjustments	2018 Adjusted
(\$ in mil.)						
Net Revenues	199		199	245		245
Cost of Sales	(34)		(34)	(35)		(35)
Gross Profit	165		165	210		210
Selling, General and Administration Expenses	(97)		(97)	(123)		(123)
Research & Development Expenses	(11)		(11)	(16)		(16)
Operating Profit	57		57	71		71
Net interest	(1)		(1)	(3)		(3)
Taxation	(8)		(8)	21	31 ²	(10)
Net Income	48		48	89		58

¹ There were no Exceptional Items in the period

² One-time claim for US orphan drug credits



YTD Profit & Loss Account Reconciliation

	YTD 2019			YTD 2018		
	2019 Actual	Adjustments	2019 Adjusted	2018 Actual	Adjustments	2018 Adjusted
(\$ in mil.)						
Net Revenues	652		652	768		768
Cost of Sales	(97)		(97)	(93)		(93)
Gross Profit	555		555	675		675
Selling, General and Administration Expenses	(299)	(28) ¹	(271)	(354)	(17) ³	(371)
Research & Development Expenses	(36)		(36)	(50)		(50)
Operating Profit	220		248	271		254
Net interest	2		2	(14)		(14)
Taxation	(33)	4 ²	(37)	(6)	29 ⁴	(35)
Net Income	189		213	251		205

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

² Excludes tax effect on exceptional items in YTD 2019 period

³ YTD 2018 adjusted results exclude the effects of exceptional items related to out-licensing of the intranasal naloxone opioid overdose patents.

⁴ One-time claim for US orphan drug credits, partially offset by \$2 mil. charge on exceptional income related to out-licensing of the intranasal naloxone opioid overdose patents.

