

Indivior PLC

H1 2020 Results
July 30, 2020



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 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, 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.



AGENDA

Overview/SUBLOCADE®/PERSERIS®

Mark Crossley

Financial Review

Ryan Preblich

R&D Update

Christian Heidbreder

Conclusion

Mark Crossley

Q & A



A clear Vision and growth path

Our Vision

For all **patients** around the **world** to have access to **evidence-based treatment** for the chronic conditions and co-occurring disorders of addiction

Near-term focus

- ✔ Depot technologies
- ✔ US core market
- ✔ Advance current pipeline
- ✔ Grow / conserve cash
- ✔ Resolve other litigation



Medium / Long-term aspiration

- ✔ Diversification ex.-US (current products)
- ✔ M&A / BD (addiction and comorbidities)



H1 2020 headlines

Financial Highlights



- Net revenue of \$303m (-33%); net income* of \$14m (-92%)
 - SUBLOCADE® net revenue of \$58m (+107%); PERSERIS® net revenue of \$7m
 - \$908m ending gross cash (net cash of \$671m)
-

2020 Outlook**



- Providing planning assumptions for the remainder of FY 2020 given ongoing COVID-19 uncertainties
-

DOJ Agreement



- \$600m to fully resolve specified matters (\$624m provision recorded)
 - ✓ \$100m immediate payment
 - ✓ \$50m due every January from 2022 to 2027 (\$300m in total)
 - ✓ \$200m due December 2027
- Ability to continue in Government channels
- Effect government compliance requirements (e.g., CIA)
- Subject to judicial approval (October)

* On an Adjusted basis. See slides 25 and 26 for full reconciliation.

** See slide 17 for further FY 2020 Planning Assumption details.









SUBLOCADE®

(buprenorphine extended-release) Injection



ONCE-MONTHLY
Sublocade®
*(buprenorphine extended-release)
injection for subcutaneous use ©
100mg-300mg*

SUBLOCADE® H1 2020 performance context

	Commercial	Foundational	Takeaways
Pre-COVID			<ul style="list-style-type: none">• Comprehensive growth strategy working – new patient enrollments and new HCP initiations accelerating• Organized Health Systems (OHS) contracting and activation on target• Prescription journey KPIs on target
COVID Onset			<ul style="list-style-type: none">• Patient enrollments continuing, but at a lower rate compared to pre-COVID levels (in-line w/ industry analogues⁽¹⁾) due to population movement restrictions• HCPs maintaining current patients; in-person commercial activity greatly restricted due to social distancing measures• OHS contracting and activation on target• Prescription journey KPIs on target
Current			<ul style="list-style-type: none">• Modest renewed patient enrollment growth; field force is actively calling on ~50% of target HCPs, but with lower frequency• Many HCPs still not seeing pharmaceutical representatives in-person• OHS contracting and activation on target• Prescription journey KPIs on target

(1) IQVIA



SUBLOCADE® focus areas

1.

Commercial



- Approx. 80% of U.S. sales force reactivated in the field
- Full conversion of all marketing materials and tactics to digital and virtual; relaunched SUBLOCADE.com
- Return to face-to-face interactions with HCPs aligned with local government guidance and restrictions; all field employees supplied with PPE

2.

Channel



- Organized Health Systems (OHS) access capability strengthened and prioritized
- Criminal Justice System (CJS) capability established
- Infrastructure (specialty pharmacy and distributor network) resilient and capable of handling increased enrollments and refills

3.

Evidence

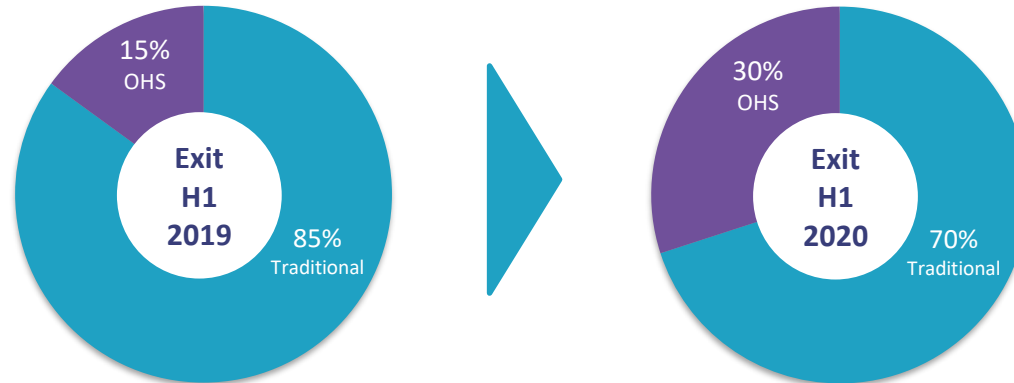


- Peer-reviewed publications and conferences proceeding
- Investigator Sponsored Studies (ISS) and “Real World” evidence generation programs underway
- Robust medical conference and publication plan proceeding



Focused on continued acceleration of Organized Health Systems (OHS) penetration

SUBLOCADE® US NR by Source: H1 2019 vs. H1 2020



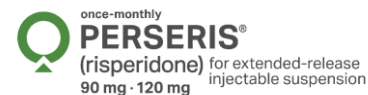
- Targeting 500+ OHS opportunities across IDNs*, Federal Systems and Criminal Justice Systems
 - ~25K waived HCPs
 - ~1MM patients
- Continuing to increase commercial resources / efforts toward OHS channel
- OHS expected to reach >50% of SUBLOCADE® US NR in FY 2021

* Integrated Delivery Networks



PERSERIS®

(risperidone) for extended-release injectable suspension



PERSERIS® priorities

- Confident engagement with HCPs – re-engaging face-to-face where possible and focusing on where HCPs are on the adoption continuum
- Continue to cultivate deep understanding of local eco-systems to execute with excellence – understand where and how prescribing decisions are made and strategically allocate resources to increase uptake
- Leverage Organized Health Systems (OHS) capabilities and infrastructure to enable targeted contracting in key OHS to expand access
- Robust medical conference and publication plan proceeding



Ex-US progress

ROW

- ✓ **SUBLOCADE®** listed in Australia and Canada; approved in Sweden and Finland; select EU regulatory review ongoing
- ✓ **SUBOXONE® Film** approved for marketing in EU (listing process underway) and Canada
- ✓ **PERSERIS®** out-licensed to HLS Therapeutics in Canada



Ryan Preblich

Interim Chief Financial Officer



Profit & Loss Account*

	Q2			H1		
	2020 Adjusted	2019 Adjusted	% change	2020 Adjusted	2019 Adjusted	% change
(\$ in mil.)						
Net Revenues	150	215	-30%	303	454	-33%
Cost of Sales	(19)	(27)		(35)	(64)	
Gross Profit	131	188	-30%	268	390	-31%
<i>Gross Margin (%)</i>	87%	87%		88%	86%	
Selling, General and Administration Expenses	(99)	(86)		(223)	(174)	
Research & Development Expenses	(8)	(13)		(19)	(25)	
Operating Profit	24	89	-73%	26	191	-86%
<i>Operating Margin (%)</i>	16%	41%		9%	42%	
EBITDA	30	95	-68%	41	204	-80%
Net interest	(5)	1		(6)	3	
Taxation	(2)	(14)		(6)	(29)	
<i>Effective Tax Rate (%)</i>	10%	16%		27%	15%	
Net Income	17	76	-78%	14	165	-92%

* Please see Appendix for full reconciliation for periods indicated.



Cash & borrowing position

(\$ in mil.)	H1 2020	FY 2019
Cash & Cash Equivalents	\$908	\$1,060
Current Borrowings	(4)	(4)
Long-term Borrowings	(232)	(233)
Loan issuance costs	(1)	(2)
Net cash	\$671	\$821

- Net cash of \$671m at H1 2020
- Retaining cash on balance sheet:
 - ✓ Ability to continue resourcing depot technology growth initiatives
 - ✓ Provide for legal settlement
- Escrowed \$100m of DOJ agreement payment



FY 2020 planning assumptions

The impact of the COVID-19 pandemic on Indivior's operations remains highly uncertain. The extent of any adverse impact on the Group's operations will depend on the unforeseeable duration, extent and severity of the pandemic, notably in the U.S., Indivior's largest market. The Group is, however, sharing the following planning assumptions for the remainder of 2020, which are based on the Group's current expectations:

- US BMAT market: continued low teens volume growth.
- SUBLOCADE®: modest growth in new patient enrollments compared with Q2 exit levels.
- SUBOXONE Film®: significant reduction in net revenue H2 2020 compared with H1 2020 as a result of share loss reaching historical industry analogues⁽¹⁾ and negative channel mix.
- Rest of World: sustained competitive pressures, mainly in Western Europe.
- Operating expenses: combined SG&A and R&D expenses in H2 2020 to be slightly below H1 2020 level, despite expected increases in compliance and R&D expenses.
- Tax rate: mid-to-high teens.

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





H1 Results 2020 – R&D Update

Christian Heidbreder, Chief Scientific Officer



H1-2020 R&D Update

- **SUBLOCADE® in the US: PMRs & PMCs**
 - *Clinical PMCs*: all approved by FDA
 - *Nonclinical PMRs*: under FDA review.
 - *Clinical PMR rapid induction (403 + 404 extension studies)*: completed with final CSR of 403 study
 - *Clinical PMR high-dose users (401)*: under feasibility assessment; delayed due to COVID-19
- **SUBLOCADE® in the US: Safety, LEGOS, other Post-Marketing Studies**
 - *Safety PK/UDS study*: completed with final CSR
 - *Fentanyl study*: completed with PK/PD report near completion.
 - *VOTIVE and RECOVER-LT*: impacted by COVID-19, contingency plans in place
 - *HEOR US Payor Database Analysis*: 6-month longitudinal analysis report expected Q4-2020
- **SUBUTEX® Prolonged-Release Solution for Injection ex-US**
 - Approved in Israel, Sweden, and Finland
 - Dealing with advanced RTQs in Denmark, Germany, UK, Italy
 - Anticipated delays in France/DCP and Norway due to COVID-19
 - Review ongoing in New Zealand
- **SUBOXONE® ex-US**
 - Approvals in Israel, Canada and Europe (27 EU member states + United Kingdom, Norway, Iceland and Liechtenstein)
 - Anticipated approvals in NZ and MENAT in Q4-2021/Q1-2022
- **PERSERIS® US & Canada**
 - *US Clinical PMC*: completed with final CSR expected in November 2020. Designed to support labeling for both the 180 mg (2 x 90 mg) dosage strength and alternative injection sites. Submission expected Q4-2020 with anticipated approval Q3-2021
 - *Canada*: NOC date November 16, 2020
- **Early Stage Assets**
 - *INDV-2000 (OX1)*: SAD study delayed by 3 months due to COVID-19. First dose in Man on track for August 2020. All other activities either achieved or on track. NIDA Annual Performance Report for NIH Grant completed
 - *INDV-1000 (GABA_B PAM)*: Commitment to Late Lead Optimization (LLO) at the end of July 2020
- **Peer-Reviewed Publications**
 - *Peer-reviewed publications*: 6 published; 9 submitted and under review
 - *Conferences*: major contributions (N=11) to ASAM and CPDD both held virtually. Next Conferences: US Psych (Sep) and ACoP (Oct)



Conclusion

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



Q2 Profit & Loss Account Reconciliation

	Q2 2020			Q2 2019		
	2020 Actual	Adjustments	2020 Adjusted	2019 Actual	Adjustments	2019 Adjusted
(\$ in mil.)						
Net Revenues	150		150	215		215
Cost of Sales	(18)	1 ¹	(19)	(27)		(27)
Gross Profit	132		131	188		188
Selling, General and Administration Expenses	(99)		(99)	(87)	(1) ¹	(86)
Research & Development Expenses	(8)		(8)	(13)		(13)
Operating Profit	25		24	88		89
Net interest	(5)		(5)	1		1
Taxation	(2)		(2)	(14)		(14)
Net Income	18		17	75		76

(1) Exceptional item related to favorable inventory provision

(1) Exceptional item related to restructuring costs



H1 Profit & Loss Account Reconciliation

	H1 2020			H1 2019		
	2020 Actual	Adjustments	2020 Adjusted	2019 Actual	Adjustments	2019 Adjusted
(\$ in mil.)						
Net Revenues	303		303	454		454
Cost of Sales	(41)	(6) ¹	(35)	(64)		(64)
Gross Profit	262		268	390		390
Selling, General and Administration Expenses	(408)	(185) ²	(223)	(202)	(28) ¹	(174)
Research & Development Expenses	(19)		(19)	(25)		(25)
Operating (Loss) / Profit	(165)		26	163		191
Net interest	(6)		(6)	3		3
Taxation	26	32 ³	(6)	(25)	4 ²	(29)
Net (Loss) / Income	(145)		14	141		165

(1) H1 2020 adjusted cost of sales excludes \$6m related to the adverse impact of COVID-19 on inventory

(2) H1 2020 adjusted results exclude \$183m increase of legal provision related to the DOJ matter and \$2m primarily of lease disposal cost

(3) H1 2020 adjusted taxation exclude the effects of exceptional items

(1) H1 2019 adjusted results exclude \$20m of exceptional restructuring costs and \$8m of exceptional legal expenses for ongoing IP-related litigation

(2) H1 2019 adjusted taxation exclude the effects of exceptional items

