

Indivior PLC

Q1 2019 Results

May 2, 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.



Q1 2019 snapshot

Financial Performance

Q1 19 vs. Q1 18 (adjusted basis⁽¹⁾)

Net Rev.:	\$238m	-6%
Op. Profit:	\$102m	+3%
Net Inc.:	\$89m	+14%
Cash:	\$1,054m	(\$924m at FY18)
Net Cash:	\$812m	(\$681m at FY18)

FY 19 Guidance⁽²⁾

- Net Revenue: \$525m to \$575m
- SUBLOCADE™ NR of \$50m to \$70m
- OPEX of \$440m to \$460m
- Net (loss) / income: (\$40m) to \$10m

(1) See Appendix for reconciliation

(2) See slide 8 for more detail

Operational Highlights

Double-digit market growth in U.S. market continues to be mainly driven by Government channels

Q1 19 NR: +ive U.S. NR from continued market growth, slower than expected decline in SUBOXONE® (buprenorphine/naloxone) Film share, strong AGx launch and SUBLOCADE™ (buprenorphine extended-release) Injection were more than offset by the decline in ROW NR

Q1 19 SUBLOCADE™: NR of \$11m; dispense yield consistently above 50%; KPIs continue to improve

Q1 19 Op. Profit: +ive reflecting OPEX savings from significant streamlining actions to cost base

Q1 19 Cash Balance: \$1,054m, +\$130m vs FY18 reflects strong Q1 operating cash conversion and conservative capital allocation

Pipeline & Study Progress

PERSERIS™ (risperidone) for extended release injectable suspension launched week of February 18th

Reviews of SUBLOCADE™ new drug submissions made in Australia and key European markets are ongoing

SUBLOCADE™ 12 mos. HEOR study findings being released through robust conference and publication plan; 24 mos. HEOR study (the RECOVER Study) final report on-track for Dec. 19

SUBOXONE® Film Market Authorization Application submitted in Europe



DOJ matter

- A U.S. federal criminal grand jury investigation of Indivior was initiated in December 2013, and includes marketing and promotion practices, pediatric safety claims, and overprescribing of medication by certain physicians.
- The U.S. Attorney's Office for the Western District of Virginia served a number of subpoenas relating to SUBOXONE® Film, SUBOXONE® Tablet, SUBUTEX® Tablet, buprenorphine and our competitors, among other issues. The Group responded to the subpoenas and otherwise cooperated fully with the Department and prosecutors.
- The Group was in advanced discussions with the Department of Justice (DOJ) about a possible resolution to its investigation until recently.
- In December 2018, the company first learned from U.S. Health and Human Services/Office of Inspector General (HHS/OIG) that the proposed resolution could likely result, in HHS/OIG's view, in exclusion. This represented a change in HHS/OIG's interpretation of its exclusion authority. This change, and HHS/OIG's view that the proposed plea by Indivior could result in exclusion from US federal healthcare programs, was confirmed by HHS/OIG during a meeting in January. These programs are material to the Group's revenue.
- The Group continued in dialogue with DOJ and HHS/OIG and, at the time of the FY 2018 results, believed that a resolution was still possible.
- In early April, it became clear that an alternative resolution with DOJ and HHS/OIG would be necessary. DOJ then did not give the Group sufficient time to negotiate any alternative resolution that would work under the new HHS/OIG interpretation.
- On April 9th, Indivior Inc. and Indivior PLC were indicted by a grand jury in the Western District of Virginia. DOJ is seeking the forfeiture of all assets derived from the commission of the alleged offenses, including but not limited to \$3 billion. The Group's external counsel has advised it has strong defenses to the government's charges with which the Group will vigorously defend itself. However, an adverse outcome at trial could also result in the Group's exclusion from participating in U.S. Federal Health Care Programs.
- Because the Group remains open to resolving the matter, it maintains a \$438m provision substantially related to that purpose. Should the matter go to trial, the Group has been advised by counsel that in their view the provision is materially in excess of the fine, forfeiture, and/or restitution that would likely be incurred in an adverse outcome at trial.



SUBLOCADE™ Update

Unique SUBLOCADE™ patients injected increasing month over month; Dispense yield now in line with analogs

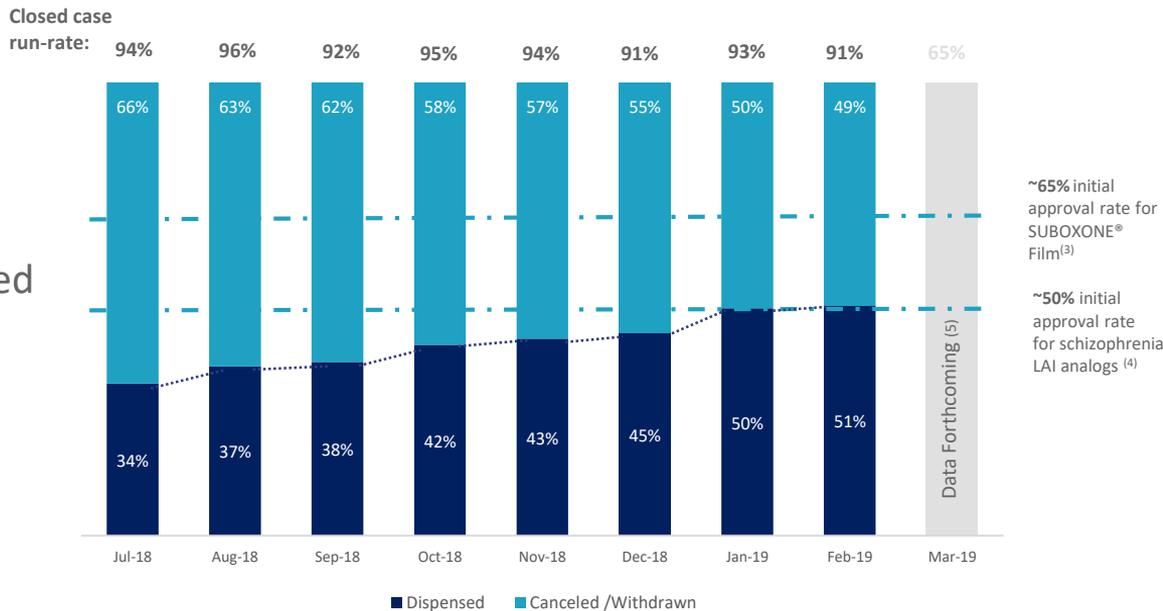
Cumulative Launch to 3/31/19 ⁽¹⁾

22,415 Unique prescriptions initiated

7,495 Unique patients injected

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

Closed Case Performance ⁽¹⁾⁽²⁾



(1) Proprietary Indivior SUBLOCADE™ data – Feb & March dispensing rate will change based on data refresh

(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® data

(4) Amundsen Consulting Analysis

(5) Data is measured 45 days after month close



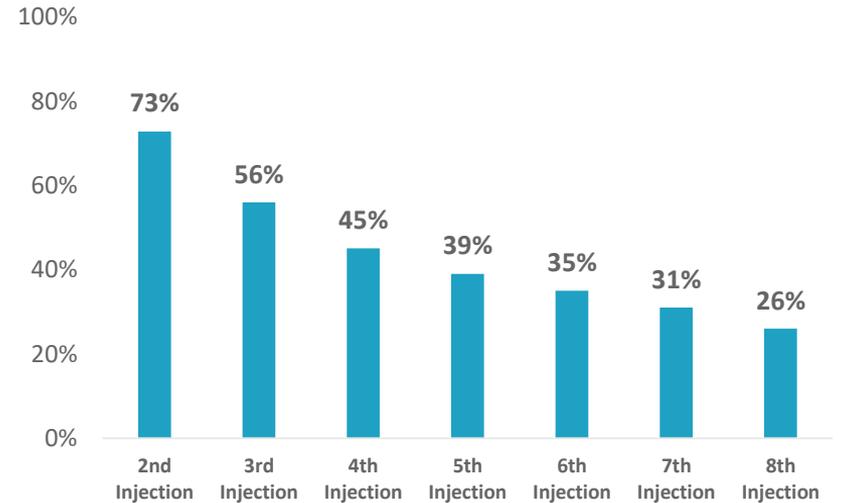
SUBLOCADE™ KPIs – HCP data & patient treatment adherence

2,930 HCPs initiated prescription journeys

1,745 HCPs administered SUBLOCADE™

415 HCPs administered ≥ 5 patients

Repeat Injections
(All patients with initial injection during March '18 to Jan '19)



FY 2019 guidance introduced

FY 2019 Guidance (\$ in mil.)

>	Net Revenue	\$525m - \$575m
>	Net (loss) / income	(\$40m) - \$10m

Top-line:

- **U.S. Buprenorphine/ Naloxone Film market conditions**
 - ✓ Continued double-digit underlying BMAT market growth
 - ✓ Reversion of U.S. SUBOXONE® Film share erosion in-line with industry analogs⁽¹⁾ (80% to 90% within 12 mos.); authorized generic film product erosion in-line with analogs
 - ✓ Authorized generic contribution in the tens of \$-million
 - ✓ No change in underlying payor or HCP receptivity to Indivior products
- **Intensifying competitive pressures in legacy W. European markets and Canada, partially offset by continued modest growth in Australia**
- **Net revenue expectations for SUBLOCADE™ & PERSERIS™**
 - ✓ Maintain SUBLOCADE NR range of \$50m 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™
- 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 20 in Q1 2019 press release dated May 2, 2019 – Litigation/Investigative Matters



Appendix



Income statement reconciliation: Q1 2019 vs. Q1 2018

	Q1 2019			Δ Y-o-Y (adjusted basis)	Q1 2018		
	Q1 2019 Actual	Adjustments	Q1 2019 Adjusted		Q1 2018 Actual	Adjustments	Q1 2018 Adjusted
(\$ in mil. at Actual FX)							
Net Revenues	238		238	-6%	255		255
Cost of Sales	(37)		(37)		(24)		(24)
Gross Profit	201		201	-13%	231		231
<i>Gross Margin (%)</i>	85%		85%	<i>-600 bps</i>	91%		91%
Selling, General and Administration Expenses	(114)	(27) ⁽¹⁾	(87)		(99)	17 ⁽¹⁾	(116)
Research & Development Expenses	(12)		(12)		(16)		(16)
Profit on Ordinary Activities before interest & taxation	75		102	+3%	116		99
<i>Operating Margin (%)</i>	32%		43%	<i>+400 bps</i>	45%		39%
Net interest (expense) / income	2		2		(5)		(5)
Taxation	(11)	2 ⁽²⁾	(15)		(18)	(2) ⁽²⁾	(16)
<i>Effective Tax Rate (%)</i>	<i>(14%)</i>		<i>(14%)</i>		<i>(16%)</i>		<i>(17%)</i>
Net Income	66		89	+14%	93		78

Q1 2019 Notes:

(1) Excludes \$27m of exceptional items – \$19m costs related to restructuring; \$8m cost related to potential legal redress related to intellectual property cases

(2) Excludes \$3m benefit related to exceptional pre-tax items

Q1 2018 Notes:

(1) Excludes \$17m gain related to the out-licensing of intranasal naloxone opioid overdose patents

(2) Excludes (\$2) mil. of related to taxable gains related to out-licensing of the intranasal naloxone opioid overdose patents



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>.

