### **Indivior PLC**

Jefferies 2019 Global Healthcare Conference June 4, 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 matter; 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.



# Why Indivior?

 Focused on complex and expanding disease areas – No. 1 in buprenorphine medication-assisted treatment (BMAT) for opioid use disorder (OUD) and diversifying into schizophrenia

2. Launched novel, long-lived IP depot technologies in the U.S. for the treatment of OUD (SUBLOCADE™ (buprenorphine extended-release)) and schizophrenia (PERSERIS™ (risperidone))

3 Successfully executing transition to renewed growth while continuing to fortify the business

# FY 2018 snapshot: market-related challenges impacted growth and profitability...but financial strength improved<sup>(1)</sup>

- 8%

\$1.005 bil. Net Revenue - 18%

\$332 mil. Adj. Op. Profit \* + 1%

\$272 mil. Adj. Net Income \*

\$327 mil.

Cash Flow From Operations

\$924 mil.

Cash and Cash Equivalents (+\$61 mil. vs. 2017) \$681 mil.

Net Cash (+\$305 mil. vs. 2017)



<sup>(1)</sup> All figures from Indivior 2018 Annual Report, pgs. 2, 96 and 98

<sup>\*</sup> Excluding exceptional costs

# We are managing well-known business risks effectively

Key Risk	Our Response
Growth	✓ Launched novel depot technologies – SUBLOCADE™ and PERSERIS™ – targeting attractive markets and disease areas
Generic entry	<ul> <li>✓ Launched authorized generic buprenorphine/naloxone film through Sandoz Inc.</li> <li>✓ Continue to assert intellectual property against ANDA filers</li> </ul>
Profitability & cash flow	➤ ✓ Streamlined organization (~\$100 million reduction versus FY 18 OPEX)
Financial flexibility	<ul> <li>✓ Prepaid \$235m of term loans in FY 2018 (\$242 mil. remains outstanding)</li> <li>✓ Growing significant cash balance</li> </ul>

### **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.



# COMMITTED TO OUR VISION & STRATEGY



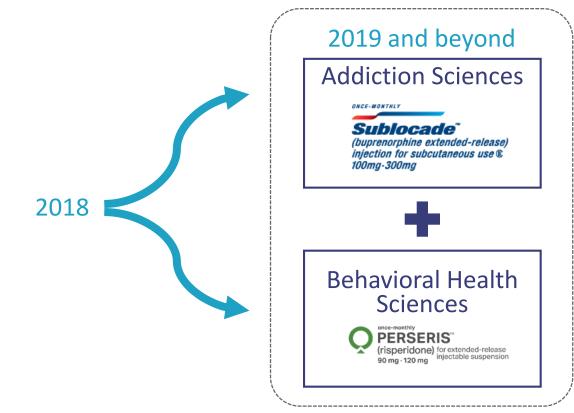


# **OUR VISION**

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



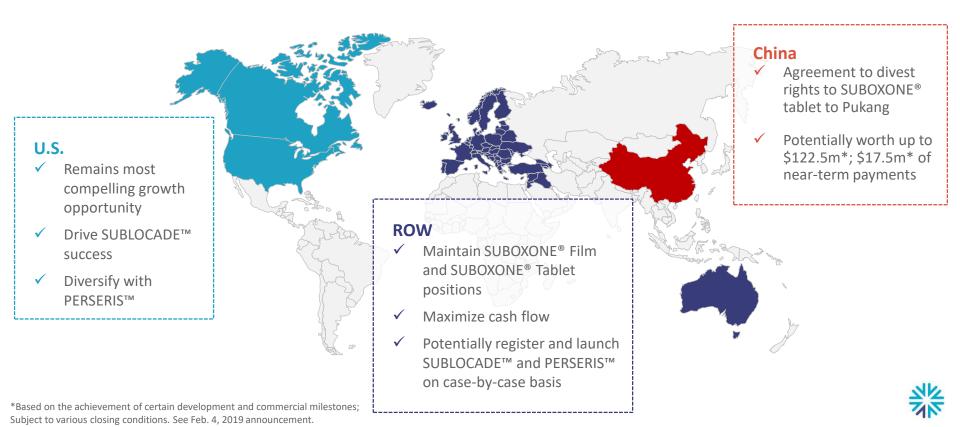
# Our growth platform targeting addiction and schizophrenia



Adding Behavioral Health to established leadership position in OUD provides diversification and additional revenue growth as well as a broader scope for long-term business development



# Targeting growth in the highest value markets



# Driving long-term value with innovative depot technologies in the U.S.

# **Innovative Depot Technologies**



(buprenorphine extended-release) injection for subcutaneous use ® 100ma-300ma



for extended-release injectable suspension 90 mg · 120 mg











Ex-U.S. (selective)

### Later:



Business development



Early stage assets

# Indivior **Future State**



Renewed profitable growth post transition phase



More balanced mix (product/geographic)



Scalable organization



Long-dated IP assets



# Positive fundamentals underpin our strategy

- Recognized leader in global addiction treatment
- > Core U.S. OUD treatment market volume continues to grow at double-digit rates<sup>(1)</sup>
- > Favorable U.S. legislation for OUD treatment additional funding; permanent treatment capacity expansions; favorable to long-acting injectable (LAI) market development
- Expand to behavioral health almost half of patients with schizophrenia have a co-morbid substance use disorder<sup>(2)</sup>
- Scalable operating structure and tightened strategic focus to maximize cash through transition phase
- > Patient-inspired culture; high level of organizational agility and resilience supported by continued investment in capabilities and compliance



### SUBLOCADE™ focus

- Only once-monthly buprenorphine subcutaneous injection in U.S.
- > Sustained plasma concentrations of buprenorphine for a month
- Blocks the subjective effects of opioids









# 2019 SUBLOCADE™ priorities

Payor access quality – simpler coverage & expand to IDNs\*

Continued progress in improving dispense yield %

Improve commercial effectiveness

Increase HCP / patient awareness & request



Simplify the treatment journey



Increase HCP trial and adoption



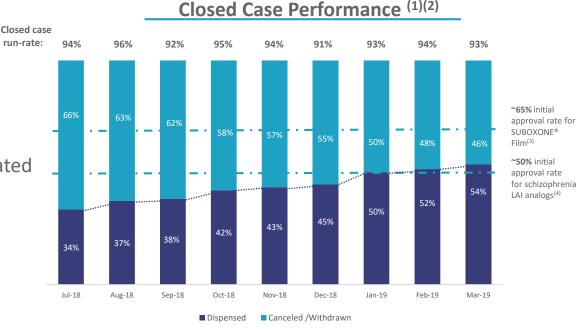
# Unique SUBLOCADE™ patients injected increasing month over month; Dispense yield now in line with analogs

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)



- (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® data
- (4) Amundsen Consulting Analysis



# SUBLOCADE™ KPIs – HCP data & patient treatment persistence

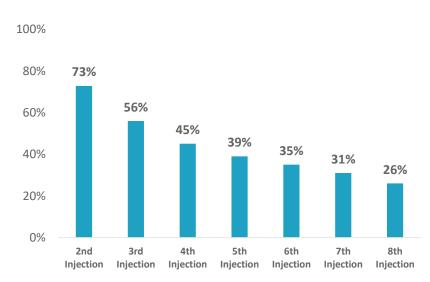
**2,930** HCPs initiated prescription journeys

1.745 HCPs administered SUBLOCADE™

415

HCPs administered > 5 patients

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





# PERSERIS™ is an attractive long term growth opportunity

PERSERIS is an important new option in the LAI market

- Growing branded market
  - 22% CAGR and projected to continue to grow to >\$3 billion net sales<sup>(1)</sup> as more patients migrate to LAIs and new entrants lead to greater adoption
- > PERSERIS' expands HCP armamentarium and no loading dose or oral supplementation is recommended during treatment initiation
- > Commercial approach is to map to the existing dynamics of the market where possible and effectively engage HCPs with simple, clear value proposition
- > Potential opportunities for lifecycle development in US, and ex-US launches
  - Announced Canada exclusivity with HLP





Q1 19 PROGRESS



# Our focus and execution are driving results

# Focus Areas

# Q1 19 progress

Transition to growth products



- ✓ U.S. BMAT market continues to grow at low double-digit rates
- ✓ SUBOXONE® Film erosion less than observed analogues<sup>(1)</sup> (so far)
- ✓ SUBLOCADE™ NR of \$11m, improving KPIs
- ✓ PERSERIS™ performing to expectations

Auth. Gx film



- ✓ High-quality launch executed by Sandoz Inc.
- ✓ Achieved leading position among all generic film producers with a current No. 1 share

Financial strength



- ✓ \$1.054b of cash (+\$130m vs. FY 18); Net cash of \$812m (+\$131m vs. FY 18)
- ✓ On-track to achieve FY 2019 savings target
- ✓ Continue to maintain conservative allocation stance given uncertainties



## FY 2019 guidance

### FY 2019 Guidance (\$ in mil.)



\$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 analogues<sup>(1)</sup> (80% to 90% within 12 mos.); authorized generic film product erosion in-line with analogues
  - ✓ 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<sup>(2)</sup>
- Ongoing investments to drive the progression of SUBLOCADE™ and PERSERIS™
- Before F/X and exceptional costs



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

<sup>(2)</sup> See page 20 in Q1 2019 press release dated May 2, 2019 – Litigation/Investigative Matters

# Why Indivior?

- Most experienced and recognized leader in BMAT for opioid use disorder (OUD)
- Diversifying into co-occurrences of OUD via Behavioral Health (schizophrenia)
- > Proven innovator of differentiated depot technologies that address treatment gaps
- > Continued momentum in growing SUBLOCADE™ access and adoption
- > Fortress balance sheet provides resilience against known risks
- > Continuing to invest in people, capabilities and compliance



# **Appendix**



### 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.

<u>Unintentional Pediatric Exposure:</u> 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 <a href="https://www.suboxone.com">www.suboxone.com</a>.



### 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 ELDERY 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 (≥ 5% and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions (≥ 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.

