## Strengthening our global leadership in treatment of addiction

Year-to-Date / Q3 2018 Results
November 1st



## Forward Looking Statements

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## Indivior Year-to-Date 2018 Overview

% Δ vs.

### **YTD 2018 Performance**

		(actual FX)
Net Revenue (NR)	\$768m	-7%
Op. Profit*	\$254m	-24%
Net Income*	\$205m	-5%
EPS (fully-diluted)*	28 cents	-7%
Cash	\$901m	+\$95m
Net cash	\$569m	+\$247m

On track to achieve revised FY 2018 guidance\*\*:

- Net revenue btw. \$990m-\$1,020m
- Adj. net income btw. \$230m-\$255m

## **YTD Operational Overview**

Double-digit US market growth; continues to be primarily driven by government channel

YTD 2018 SUBOXONE® Film average share was 54%; Q3 18 exit share was 52%

<u>Total NR</u>: U.S. market growth more than offset by market share decline, adverse mix and further rebating vs. generic tablet price

SUBLOCADE™ NR: \$5m YTD; patient and physician feedback positive; payor formulary access continues to expand; progress toward improving prescription journey; enhanced sales and marketing efforts underway

Adj. Op. Profit reflects lower NR and planned higher investments for SUBLOCADE™ and PERSERIS™, partly offset by lower R&D, legal and cost savings initiative

PI against DRL remains; expedited Federal appeal heard Oct. 4<sup>th</sup>; ruling pending

Advanced discussions with DOJ ongoing; litigating all other cases

## **Pipeline Progress**

PERSERIS™ (risperidone) approved by FDA July 27<sup>th</sup>; initial quantities available in Q4 18; full promotional launch contingent on PI appeal decision. Post Marketing Commitment studies on track.

SUBLOCADE™ new drug submissions made in Canada, Australia; Europe planned for Q4 2018

SUBLOCADE™ RECOVER Study 1-year endpoint is expected in December; key LEGO studies initiated and on track. All Post Marketing Requirement and Commitment studies on track

SUBOXONE® Film submission in Israel; Canada and Europe on track Q1-2019.

Arbaclofen Placarbil clinical trial supplies being manufactured to support studies

Early stage asset – ADDEX and C4X – development on track

(1) Lifecycle Evidence Generation & Optimization studies

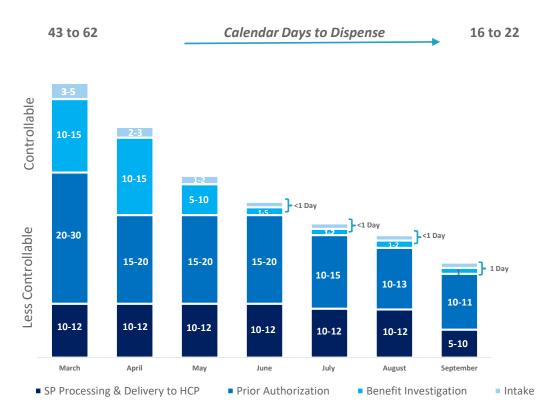
<sup>\*</sup>On an adjusted basis, excluding the impact of exceptional items in the comparable periods.

<sup>\*\*</sup> Revised FY 2018 guidance assumes no material change in U.S. market conditions and excludes exceptional items and assumes constant FX.

# SUBLOCADE™ Update



## First SUBLOCADE™ Prescription Journey Timeline – Journey Process Reduction



#### **Drivers of Journey Time Reduction**

- Education of HCP office staff by Field Reimbursement (FRS) team
- Accuracy of patient application
- Payor coverage (quantity & quality)
- SP coordination between patient and HCP office
- Increasing process experience leading to growing HCP/Payor/SP confidence in the system



# The Number of Unique Patients Injected Increasing Month Over Month; Dispense Conversion Rate Remains a Key Challenge.



82%

Payor coverage

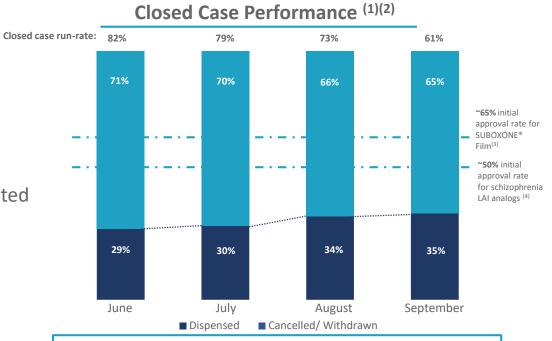
10,750+

Unique prescriptions initiated

2,500+

Unique patients injected

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



**35%** of closed cases were dispensed to in September vs. **29%** in June

<sup>(1)</sup> Proprietary Indivior SUBLOCADE™ data – September figure will change based on data refresh

<sup>(2)</sup> 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

<sup>(3)</sup> Proprietary Indivior SUBOXONE® data

<sup>(4)</sup> Amundsen Consulting Analysis

## SUBLOCADE™ KPIs – HCP Data & Patient Treatment Adherence

**1,870+** HCPs initiated prescription journeys

**824** HCPs administered SUBLOCADE™

108 HCPs administered  $\geq$  5 patients

## 

**3rd Injection** 

2nd Injection

**Treatment Adherence** 



4th Injection

## 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 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 weap 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™**

#### INDICATION

PERSERIS<sup>TM</sup> (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 ( $\geq$  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 <a href="https://www.perseris.com">https://www.perseris.com</a>.

