## Strengthening our global leadership in treatment of addiction

Q2 2018 Investor Handout



## **Forward Looking Statements**

This presentation contains certain statements that are forward-looking and which should be considered, amongst other statutory provisions, in light of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty 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 2018 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation.

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## **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



## Why Invest in Indivior?

Targeting a global epidemic – addiction and its co-occurrences

- 2 Building on <u>leading Buprenorphine Medication-Assisted Treatment</u>
  (BMAT) position to develop and commercialize novel, breakthrough addiction treatments
- Generating <u>strong profitability and cash flow</u> today with potential upside from new products and continued pipeline success



## Indivior PLC (LON: INDV) Snapshot

### 2017 Operating Highlights

\$1.09 bil. (+3% vs. 2016)

Net revenue

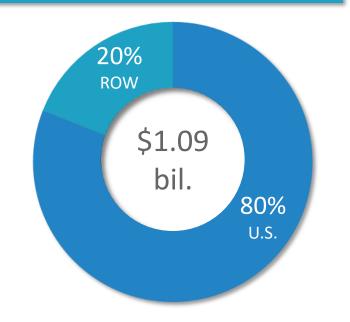
\$403 mil. (37% margin) Adj. operating profit (1)

\$863 mil.

40+
Countries of presence

1,000+
Employees worldwide

## 2017 Sales by Geography (2)





See Indivior Annual Report 2017, pg. 13

## Addiction

The scale of the problem



## Treating Addiction is our Primary Focus

## Addiction affects millions globally

- 29.5 mil. people aged 15 to 64 suffer from drug use disorders or drug dependence (1)
- 3.6 mil. years of life were lost due to premature death caused by drug use in 2010 (2)
- 55% of the lost years were due to premature death caused by opioid dependence (2)
- 124 mil. people globally dependent on alcohol (3)
- 3 mil. deaths caused by harmful alcohol use annually (3)



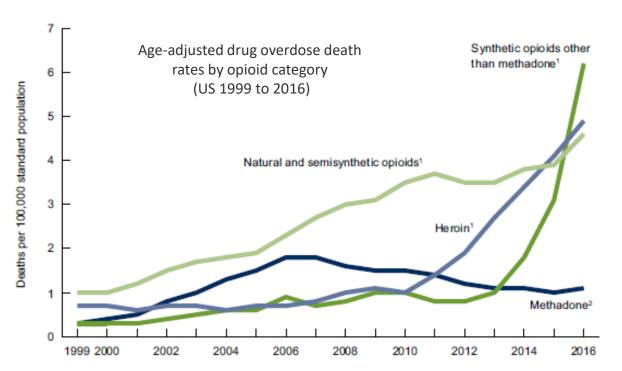


United Nations Office on Drugs and Crime, World Drug Report 2017

<sup>2)</sup> L. Degenhardt and others, Global burden of disease attributable to illicit drug use and dependence: findings from The Global Burden of Disease Study 2010 The Lancet 2013

World Health Organization (WHO) Global Status Report on Alcohol and Health 2014

## Deaths Due to Drug Overdose are Increasing in the US\*



21%

The increase in drug overdose deaths to 63,632 lives in 2016 vs. 52,404 lives in 2015\*\*

**2**x

The rate of increase in deaths from synthetic opioids such as fentanyl from 2015 to 2016\*\*

US Life Expectancy 2016 & 2015
declines largely
due to drug
overdoses, and
follow more than
a decade of
increases\*\*

<sup>\*</sup>Source: Center for Disease Control and Prevention and National Center for Health Statistics,

<sup>&</sup>quot;Drug Overdose Deaths in the United States, 1999-2016" December 2017 (https://www.cdc.gov/nchs/products/databriefs/db294.htm)

<sup>\*\*</sup>Source: https://www.cdc.gov/nchs/data/databriefs/db294\_table.pdf#page=2

<sup>(1 )</sup> Significant increasing trend from 1999 to 2016 with different rates of increase over time,  $p\!<\!0.05$ 

<sup>(2)</sup> Significant increasing trend from 1999 to 2006, then decreasing from 2006 to 2016, p<0.05

## The US Recognizes OUD as a Legitimate Disease

Large Market (1) (2)

• US represents 5% of the world's population, but consumes 80% of world's opioid supply

Conducive Intervention Policy (3)

- Growing awareness of epidemic with increased government focus declared as a nationwide public health emergency
- Medication-assisted treatment (MAT) endorsed by US government
- CARA legislation and CURES Act increased addiction resources

Growing
Treatment
Capacity (4)

- Patient cap raised to 275 from 100; NP and PAs able to prescribe with training
- Record physician certifications in 2017



<sup>(1)</sup> December 9, 2014 Express Scripts report titled, "America's Pain Points," http://lab.express-scripts.com/lab/insights/drug-safety-and-abuse/americas-pain-points

http://path-consult.com/wp-content/uploads/2013/08/April-2017.pdf

<sup>(3)</sup> https://www.hhs.gov/opioids/treatment-and-recovery/#mat

<sup>(4)</sup> CARA legislation expands treatment availability: DEA report of waivered HCPs December 2017

## We Continue to Advance Treatment Policy Development in the US

Advancing MAT

#### THE PRESIDENT'S COMMISSION

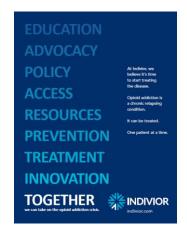
ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS

Eisenhower Executive Office Building | September 27, 2017 #DrugCommission



Expanding access to quality treatment

Removing barriers to treatment





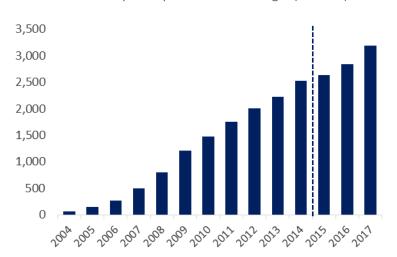




## Core US Market Growth Remains Strong as Treatment Capacity Continues to Grow in Response to Opioid Epidemic

#### Strong, consistent market expansion...

- Total buprenorphine market in mg<sup>(1)</sup> (millions) -

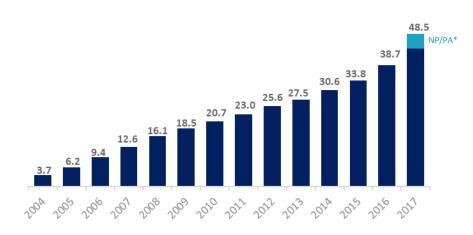


Source: Symphony Health Retail & Non-Retail TRx MG (IDV) ending Dec 2017

Market MG volume in 2015 - 2017 derived from New IDV

#### Driven by growing treatment capacity

- No. of HCP certifications (cumulative certifications in thousands) -

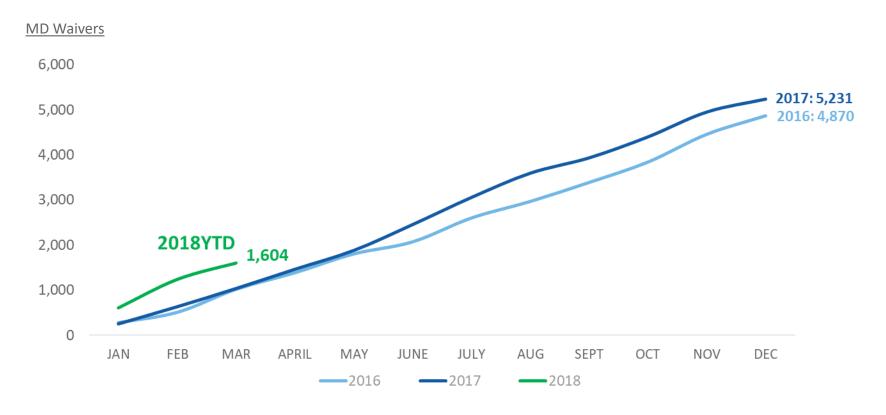


Source: NTIS DEA Certifications; Internal estimates

\* 2017 includes 4,571 newly waivered NP/PAs



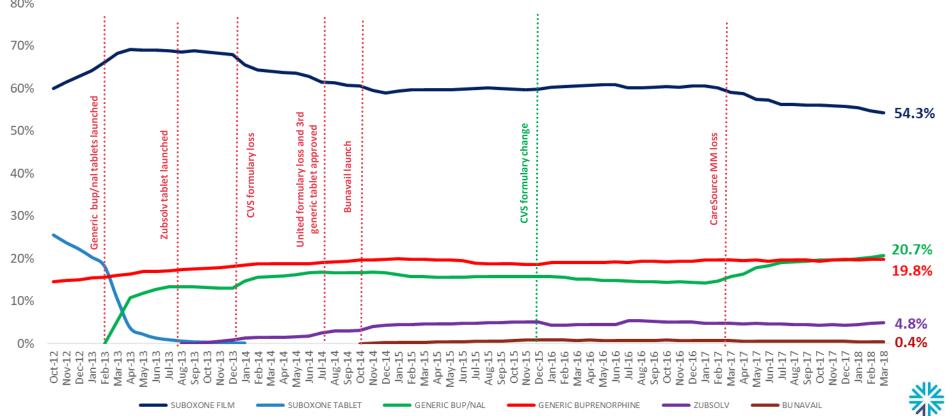
## National Newly Waivered Treating MDs Continue on a Strong Pace So Far in 2018





Source: NTIS DEA Waivers and Veeva

# Competition has Intensified, but US SUBOXONE® Film Share Remains Resilient



<sup>\*</sup>Please Note: Share values may not foot due to rounding.

## Targeting Ex.-US Growth Opportunities







#### **EMEA**

(1.3 mil. high risk opioid users) (1)

- Steady and leading BMAT share performance continues at ~70%<sup>(2)</sup>
- Growth in certain export markets – Scandinavia and Middle East
- Markets remain price constrained due to austerity measures
- Opioid dependence remains a long-term opportunity
- European Drug Report 2017, European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- (2) IMS Data Dec. 2017 (EU 20)

#### Australia

(0.2 mil. opioid dependent) (1)

- Third highest country worldwide for prescription painkiller abuse<sup>(2)</sup>
- Continued steady growth driven by SUBOXONE® Film share gain vs. methadone<sup>(3)</sup>
- New government policies going into effect to identify and help opioid dependent patients
- Targeting to file SUBLOCADE™ new drug application in 2018
- CIA World Factbook, Australia Treatment of patients with opioid dependence, N. Lintzeris
- (2) UNODC, World Drug Report 2014
- (3) Indivior Data on File

#### Canada

(0.2 mil. opioid dependent) (1)

- Rapidly developing BMAT market due to opioid public health crisis<sup>(2)</sup>
- SUBLOCADE™ NDS submitted to Health Canada with "Priority Review" designation<sup>(3)</sup>



Canadian Medical Association Journal – Medically induced opioid addiction Reaching alarming levels. Feb. 21, 2012

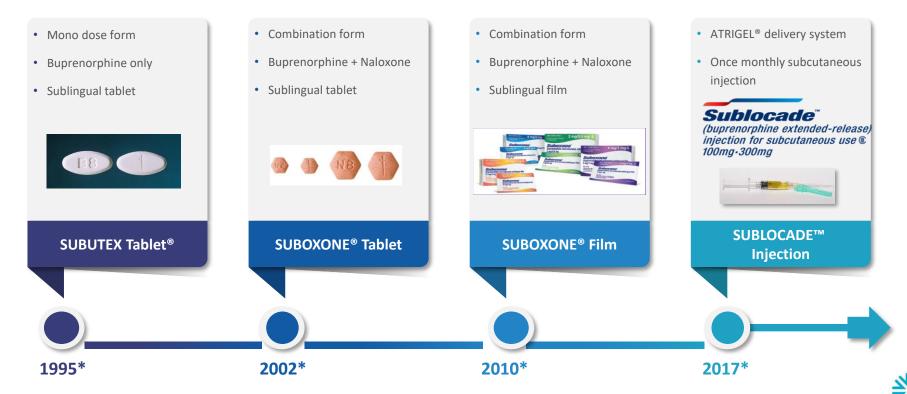
Gov't. of Canada. (2017). Gov't. of Canada Actions on Opioids 2016 and 2017

<sup>(3)</sup> Indivior press release April 20, 2018

Extending Indivior's Leadership Position in US Addiction

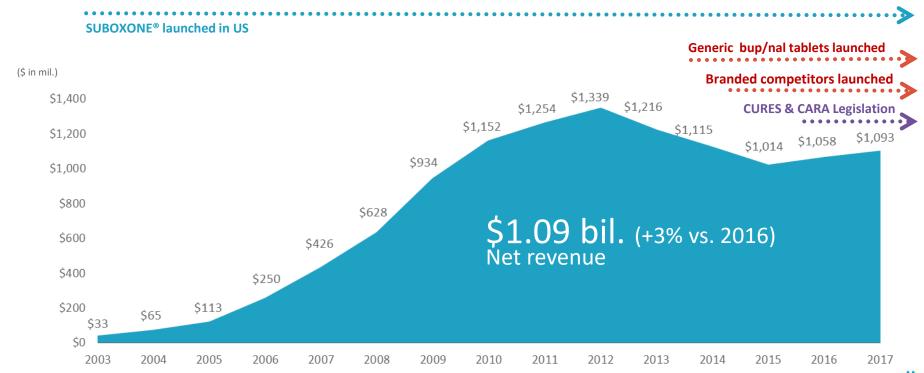


## A BMAT Innovator for Over 20 Years



<sup>\*</sup> Date of approval

# Net Revenue Growth Restored, Supporting SUBLOCADE™ and RBP-7000 Launch Investments



## Well-Positioned to Address the US OUD Epidemic and Generate Long-term Profitable Growth





O Daily Film

- Monthly SC Injection
- Treatments that deliver on unmet patient needs
- Complementary options for physicians and patients
- In concert with psychosocial support



> 2.5<sub>mil.</sub>

patients diagnosed with OUD in the US (1)

< 50%

of diagnosed patients receive any MAT (1)



# SUBLOCADE™ (buprenorphine extended release) Injection— A Novel Treatment for Moderate to Severe Opioid Use Disorder (OUD)

**What:** The first once-monthly

buprenorphine extended

release injection system

**US Status:** Available in US March 1,

2018

**ROW Status:** NDS filed w/ Health

Canada on April 19

2018\*





## SUBLOCADE™ Injection: A New Treatment of Moderate to Severe OUD

**SUBLOCADE™** is a scientific innovation that represents a new treatment option to help patients attain more illicit opioid-free weeks during their treatment program

Sustained Medication Delivery

- Sustained plasma levels of buprenorphine that translate into high  $\mu$ -opioid receptor occupancy to block the subjective and objective effects of illicit opioid drugs
- Shown superior to placebo in achieving more illicit opioid-free weeks (p<0.0001)
- Achieved *complete blockade* of drug-liking effects for a full month in most patients

**Treatment Compliance** 

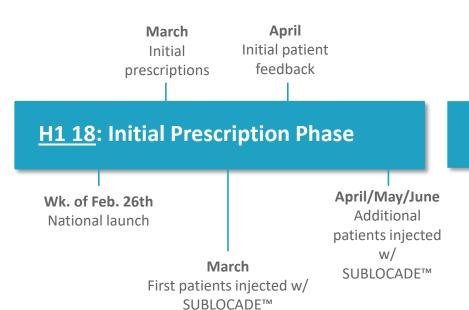
- Once-monthly SUBLOCADE™ removes the need for patients to remember to take their medication every day
- Monthly decisions (12/year) rather than daily decisions (365/year)

Known Safety Profile

- Adverse event profile comparable to SL buprenorphine, except for injection site reactions which were common but generally transient, mild or moderate in severity, and not treatment-limiting
- SUBLOCADE is distributed through a restricted distribution system, which is intended to prevent direct dispensing to the patient



## SUBLOCADE™ Uptake Weighted to H2 2018



**H2 18**: Expected SUBLOCADE™ Uptake

#### SUBLOCADE™ Disclosure:

- Net Revenue
- Key Prescribing & Adoption Metrics



## Working Alongside Payers to Provide Patient Access & Support

#### **Payer Coverage**

- Consulting with Payer Groups
  - ✓ Aligned on burden of disease
  - ✓ Firm understanding of unmet needs
- Targeting robust formulary coverage in 2018
- Medical benefit
- Complements overall patient treatment program, including psychosocial support

#### **Patient Access**

 As low as \$5 for eligible patients with co-pay card



### **Patient Support Hub**



inSUPPORT<sup>™</sup> is Indivior's patient support platform providing services to help facilitate unrestricted access to



treatment



PROVIDER LOCATOR FIELD REIMBURSEMENT SERVICES (FRS)







## SUBLOCADE™ US Launch Update Q1 2018 (as of May 2<sup>nd</sup>)

### Encouraging in the first two months of availability:

- Initial patient and physician feedback is positive
- Achieved coverage that equates to 25% of total covered US lives
- Centers for Medicare & Medicaid Services have issued unique Q-codes for both SUBLOCADE™ dosages (100 mg & 300 mg)
- De-bottlenecking underway at inSupport patient hub with added resources
- Net revenue disclosure to begin with H1 2018 results



## **RBP-7000**

Targeting unmet needs in schizophrenia



## RBP-7000 for Schizophrenia

## **Unmet Patient Needs**

**23**<sub>mil.</sub>

People worldwide affected by schizophrenia (1)

**76**%

of patients initiated on long-acting injectables have concurrent oral supplementation (2)

## RBP-7000 Treatment

What: Investigational Once monthly

Risperidone in ATRIGEL®

Where: US

Status: NDA Accepted

PDUFA Date = July 28, 2018



## **RBP-7000 Objectives**

- 1 Rapid onset
- 2 Extended treatment duration
- 3 Manageable tolerability
- 4 No oral co-medication
- 5 Measurable quality of life benefits



## RBP-7000: Indivior's Next Commercial Growth Opportunity

### Why It's Attractive:

- First commercial expansion outside addiction
- Demonstrates agility and diversification aligned with growth strategy
- US antipsychotic LAI market growth is attractive:
  - √ 20%+ growth over last 5 years (1)
  - ✓ LAI share of total US antipsychotic market has grown from 4.1% in 2010 to 12.7% in 2015 (1)
  - ✓ Schizophrenia is understood by payers as a disease area requiring vigilant management

### **Leverages Existing Capabilities:**

- Underserved/stigmatized patient population
- Known unmet patient needs related to PK
- Specialty product
- Known molecule
- Consistent pharmacokinetic profile
- ATRIGEL<sup>®</sup> technology

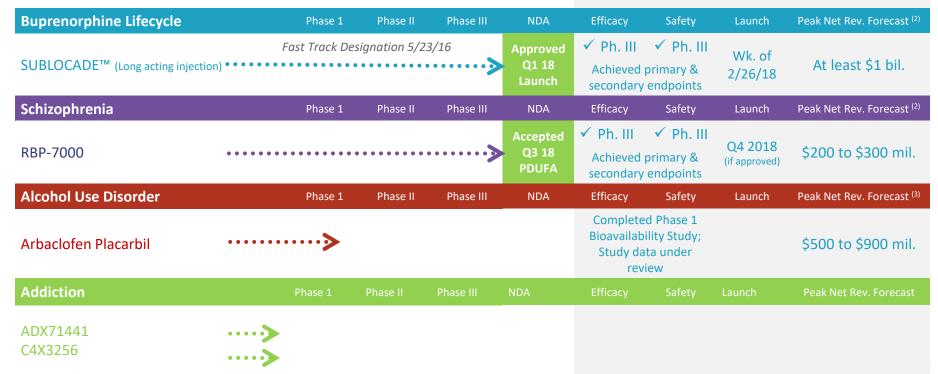


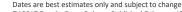
## **R&D Focus**



## Key Pipeline Assets Have Sales Potential of >\$2 billion Stage of Development

#### Status<sup>(1)</sup>





FY 2017 Results Press Release Published February 15th, 2018, Pg. 184



Investor Day presentation, November 21st 2014

## Health Economics & Outcomes Research (HEOR) Studies





#### **STEP #1**

#### SUBLOCADE™ (RB-US-13-0001) Pivotal Trial Analysis

Quality of Life

Treatment satisfaction

Resource Use

Employment Status & Health Insurance

#### **STEP #2**

#### SUBLOCADE™ (RB-US-13-0003) Long-Term Safety Trial Analysis

Quality of Life

Treatment satisfaction
Impact of opioid use

disorder on daily living

#### **STEP #3**

## SUBLOCADE™ Targeted HEOR Trial Analysis of 0001/0003

Comparison of outcomes in 0001/0003 by:
Retention; Opioid use, withdrawal, cravings

#### **STEP #4**

#### **RECOVER® Study**

Characterize the periods of abstinence over a 12-month observational window, such as # days abstinent, time to relapse, # relapses, and time to return to abstinence after relapse

Economic impact of compliance such as adherence & persistence to MAT

December 2018





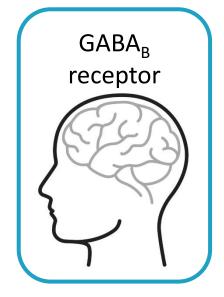


Study	Objective	Start	End
Buprenorphine Abuse, Misuse, Diversion (AMD) Epidemiology	Deep understanding of root causes of abuse, diversion & misuse	Q4-2017	Q3-2019
SUBLOCADE™ VAS craving	Explore how craving VAS and other craving measurement tools might be used as valid clinical endpoint in addiction medicine trials	Q4-2017	Q4-2018
SUBLOCADE™ Emergency Room	Assess efficacy and safety of SUBLOCADE™ in preventing repeat overdose in OUD patients	Q3-2018	Q4-2020
Global Real-World RECOVER® Study	Understand determinants of recovery of patients initiating treatment with SUBLOCADE™ in a naturalistic real-world setting	Q1-2018	Q1-2021





- Announcement: January 3, 2018
- Strategic Alliance launch meeting: Geneva, March 1, 2018
- Clinical Development of lead molecule ADX71441
  - Regulatory affairs hand-over
  - CMC strategy (Drug Substance & Drug Product)
  - IND readiness: Completion of preclinical studies & additional pre-IND toxicology requirements
  - Phase I plans, NIDA grant (\$5.3M)
- Collaboration Research Agreement
  - Medicinal Chemistry & Biology Strategies for the identification of backup/follow up molecules

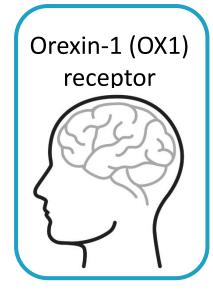


GABAb positive allosteric modulators ("PAMs") have demonstrated preclinical efficacy and tolerability in animal models for alcohol use disorder (AUD) and cocaine use disorder (CUD) (1)(2)



## Alliance with **C4X Discovery** for C4X3256

- Announcement: March 29, 2018
- Most advanced Selective Orexin-1 (OX1) Program available
  - Novel mechanism supported by sound preclinical science
  - Exclusive license to all OX1 modulators from C4X Discovery
  - Potential research collaboration plan for the discovery of backup/follow up OX1 modulators
- Strategic alliance launch meeting: London, May 11, 2018



Selective blockade of the OX1 system has been shown preclinically to decrease drug-seeking behavior related to psychomotor stimulants <sup>(1)</sup>, opiates <sup>(2)</sup> and alcohol <sup>(3)</sup>, and to prevent relapse or re-instatement of drug-seeking behavior during abstinence



<sup>(1)</sup> Hutcheson et al. Behav Pharmacol. 2011 Apr;22(2):173-81.

<sup>(2)</sup> Baimel et al. Br J Pharmacol. 2015 Jan; 172(2):334-48

<sup>(3)</sup> Moorman et al. Psychopharmacology (Berl). 2018 Mar 6.

**Legal Update** 



## **Major Litigation**

The Group maintained its provision for investigative and antitrust litigation matters to \$438m. Because these matters are in various stages, Indivior cannot predict with any certainty the ultimate resolutions, costs or timing of the resolutions of any of the matters. The final aggregate amount may be materially different from this provision. The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. The Group cannot predict with any certainty whether it will reach an ultimate resolution with the Department of Justice or any or all of the parties to the other matters below under State Subpoenas and FTC Investigation and Antitrust Litigation.

DOJ & State Subpoenas (1) / Risk Factor (2)

FTC Investigation & Antitrust Litigation (1)

ANDA Litigation & Inter Partes Review (1)



<sup>1)</sup> See Q1 2018 Results Announcement published 5/2/18 "Litigation Update" for complete description

<sup>2)</sup> See 2017 Annual Report "Risk Factors" for a complete description, Pgs. 50 to 56

## **ANDA Litigation Update**

- 1. Nothing has changed in the marketplace
- 2. The FDA have not approved a generic version of our Film
- 3. ANDA filers must weigh the potential of significant damages if launching "at-risk"
- 4. We are vigorously defending our IP: pursuing litigation for infringement of three new Orange-Book listed patents ('454 '221 '305)
- 5. We settled the ANDA litigation with Mylan and Par
- 6. We are prepared to bring an "Authorized Generic" to market



### **DELIVERING ON OUR PRIORITIES**



### 2018 Q1 Overview

# First Quarter Performance In-line with Expectations (actuals on an adjusted basis vs. Q1 2017)

Net Revenue \$255m Op. Profit\* \$99m 23% Net Income\* \$78m Cash \$895m +\$166m Net Cash \$407m

- Net revenue reflects a continuation of US market dynamics for SUBOXONE® Film (solid market growth and price improvement more than offset by generic tablet competition and unfavorable channel mix) and trade destocking.
- Operating profit primarily reflects lower net revenue and the planned increase in investments for the launch of SUBLOCADE™ and the anticipated launch of RBP-7000.
- Net income primarily reflects a decline in operating income offset by lower financing costs and a reduced overall effective tax rate.

### **Operating Highlights**

- US BMAT market growth remained solid
- SUBOXONE® Film share averaged 55% proving resilience
- SUBLOCADE™ launched in US; initial market reception encouraging
- Formation of New Behavioral Health unit to grow RBP-7000 on track
- Asserted 3 new Orange-book listed patents against remaining ANDA filers
- Financial flexibility continues to improve

#### **Pipeline Realization**

- SUBLOCADE™ New Drug Submission made to Health Canada; Priority Review granted
- RBP-7000 on track for Q4 2018 launch; PDUFA date of July 28, 2018
- Arbaclofen Placarbil Preparing for Type C meeting with FDA on next steps with a focus on AUD-induced liver disease with cirrhosis
- Created Joint Research Comm. with ADDEX to drive development of lead compound ADX71441
- Completed agreement with C4X Discovery gaining exclusive global access to lead compound C4X3256



<sup>\*</sup>Excludes \$17m gain related to out-licensing of Nasal Naloxone IP

### Guidance for 2018 – Reconfirmed May 2nd

(\$ in mil.)	Guidance	% change v. FY 17 (at mid-point)		
Net Revenue	\$1,130m -\$1,170m	+5%		
Net Income	\$290m - \$320m	+13%		

#### **Top-line:**

- No material change in US market conditions
  - ✓ No 'at-risk' generic film entry in 2018
- Intensifying competitive pressures in ROW
  - ✓ Increasing competition and austerity in EU, partially offset by growth in Australasia
- Initial net revenue expectations for SUBLOCADE
  - ✓ As previously communicated, sales are expected to be modest in the early stages of launch

#### **Expenses:**

- Launch investments for SUBLOCADE and RBP-7000
- Lower finance expense
- Estimated high-teens tax rate
- Before exceptional items and at constant FX



### Indivior PLC – Priorities for 2018

### **Build on our Leadership Position in Global Addiction Treatment**

# 1.SUBOXONE® Film Resilience

 Preserve leading position in USA against 10 generic and 2 branded competitors

# 2. Ensure Successful Launch for Pipeline Products

- SUBLOCADE™ monthly buprenorphine longacting injection (approved)
- RBP-7000 monthly long-acting risperidone (Q3 18 PDUFA)

# 3. Expand Global Treatment

- Expand treatment access in USA
- Prepare for SUBLOCADE™ launch in Europe, Australia and Canada

# 4. Focus on Capital Allocation

- Continue to manage risks
- Prepare for possible BD/M&A



### Summary

We face the future with confidence

We are making progress in managing the risks to the business

We look forward to continuing our progress to create shareholder value



### **Appendix**



### Income Statement: Q1 18 vs. Q1 17

Q1 2018

Q1 2017

	Q1 2018 Actual	Adjustments	Q1 2018 Adjusted	Δ Y-o-Y (adjusted)	Q1 2017 Actual
(\$ in mil. at Actual FX )					
Net Revenues	255		255	-4%	265
Cost of Sales	(24)		(24)		(19)
Gross Profit	231		231		246
Gross Margin (%)	91%		91%		93%
Selling, Distribution and Administration Expenses	(99)	+17 (1)	(116)		(93)
Research & Development Expenses	(16)		(16)		(25)
Profit on Ordinary Activities before interest & taxation	116		99	-23%	128
Operating Margin (%)	45%		39%	-	48%
EBITDA	119		102	-22%	130
Net interest	(5)		(5)		(11)
Taxation	(18)	(2) (2)	(16)		(37)
Effective Tax Rate (%)	16%		17%		(32%)
Net Income	93		78	-3%	80

#### Q1 2018 Notes:

- (1) Excludes \$17 mil. gain from the out-licensing of the intranasal naloxone opioid overdose patents.
- (2) Impact of exceptional item within tax



### Income Statement: FY2017 vs. FY2016

	F12017			F12010			
	2017 Actual	Adjustments	2017 Adjusted	Δ Y-o-Y (adjusted)	2016 Actual	Adjustments	2016 Adjusted
(\$ in mil. at Actual FX)				-			
Net Revenues	1,093		1,093	+3%	1,058		1,058
Cost of Sales	(104)		(104)		(107)	(11) (1)	(96)
Gross Profit	989		989	+3%	951		962
Gross Margin (%)	90%		90%		90%		91%
Selling, Distribution and Administration Expenses	(707)	(210) (1)	(497)		(683)	(227) (2) (3)	(456)
Research & Development Expenses	(89)		(89)		(119)		(119)
Profit on Ordinary Activities before interest & taxation	193		403	+4%	149		387
Operating Margin (%)	18%		37%		14%		37%
EBITDA	206		416	+4%	163		401
Net interest	(56)	(14) <sup>(2)</sup>	(42)		(51)		(51)
Taxation	(79)	12 (3)	(91)		(63)	19 <sup>(4)</sup>	(82)
Effective Tax Rate (%)	58%		25%		64%		25%
Net Income	58		270	+6%	35		254

EV2017

#### FY2017 Notes:

(1) Excludes \$185 mil. provision for investigative and antitrust matters and the release of a legacy provision and \$25 mil. related to the settlement of Amneal antitrust matter

(2)Excludes \$14 mil. of exception costs related to the replacement of the Term Loan facilities

(3) Excludes \$12 mil. benefit related to exceptional pre-tax and taxation items.

#### FY2016 Notes:

(1) Excludes \$11 mil. write off of manufacturing costs related to potential negative ANDA outcome.

EV2016

- (2) Excludes \$7 mil. exceptional items related to costs for ANDA strategic planning.
- (3) Excludes \$220 mil. provision for investigative and antitrust matters.
- (4) Excludes \$19 mil. benefit related to exceptional pre-tax and taxation items.



### Indivior Share Price Since the Initial Listing (as of 5/4/18)





## Capital Markets Agenda 2018\*

Date	Event		
Feb. 15 <sup>th</sup>	FY 2017 Results (London Presentation)		
Feb 27 <sup>th</sup> & 28 <sup>th</sup>	CSFB One-on-one Conference (London)		
March 12 <sup>th</sup> to 14 <sup>th</sup>	Stifel-sponsored NDR (US)		
March 19 <sup>th</sup>	Bank of America Merrill Lynch "Bus Tour" (London)		
May 2 <sup>nd</sup>	Q1 2018 Results (Conference Call)		
May 8 <sup>th</sup> & 9 <sup>th</sup>	Deutsche Bank US Healthcare Conference & Morgan Stanley NDR		
June 5 <sup>th</sup> & 6 <sup>th</sup>	Jefferies US Healthcare Conference (New York City)		
July 25 <sup>th</sup>	H1 2018 Results (London)		
September 12 <sup>th</sup> & 13 <sup>th</sup>	Morgan Stanley Healthcare Conference (New York City)		
November 1 <sup>st</sup>	mber 1 <sup>st</sup> Q3 2018 Results (Conference Call)		
December 5 <sup>th</sup> (TBC)	Indivior-hosted R&D / Capital Markets Mtg. (New York City)		



<sup>\*</sup> Subject to updates and changes

### Planned Science & Medical Conferences / Events 2018\*

- **5th Annual Western Canada Addiction Forum (WCAF)**: May 4-5, Kelowna, BC, Canada
- American Psychiatry Association (APA): May 5-9, New York, NY
- American College of Preventive Medicine (ACPM): May 23-26, Chicago, IL
- 12e Congrès International d'Addictologie de l'Albatros: June 6-8, Paris, France
- College on Problems of Drug Dependence (CPDD): June 9-14, San Diego, CA
- Nordic Congress of Psychiatry (NCP): June 13-16, Reykjavik, Iceland
- The Royal College of Psychiatrists (RCP) International Congress: June 24-27, Birmingham, England
- American Association of Nurse Practitioners (AANP): June 26-July 1, Denver, CO
- **Deutscher Suchtkongress**: September 17-19, Hamburg, Germany
- American College of Emergency Physicians (ACEP): October 1-4, San Diego, CA
- American Academy of Family Physicians (AAFP FMX): October 9-13, New Orleans, LA
- American Psychiatric Nurses Association (APNA): October 24-27, Columbus, OH
- Canadian Society of Addiction Medicine (CSAM): October 25-27, Vancouver, BC, Canada
- American College of Neuropsychopharmacology (ACNP): December 3-7, Hollywood, FL
- American Academy of Addiction Psychiatry (AAAP): December 6-9, Bonita Springs, FL
- Third Indivior-hosted R&D / Capital Markets Day: New York, NY, December 5th (TBC)



#### IMPORTANT SAFETY INFORMATION

#### Indication

SUBOXONE\* (buprenorphine and naloxone) Sublingual Film (CIII) is a prescription medicine indicated for treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. Treatment should be initiated under the direction of healthcare providers qualified under the Drug Addiction Treatment Act.

#### Important Safety Information

Do not take SUBOXONE® Film if you are allergic to buprenorphine or naloxone as serious negative effects, including anaphylactic shock, have been reported.

SUBOXONE® Film can be abused in a manner similar to other opioids, legal or illicit.

SUBOXONE® Film contains buprenorphine, an opioid that can cause physical dependence with chronic use. Physical dependence is not the same as addiction. Your healthcare provider can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE Film suddenly without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

SUBOXONE® Film can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other medications that act on the nervous system (ie, sedatives, tranquilizers, or alcohol). It is extremely dangerous to take nonprescribed benzodiazepines or other medications that act on the nervous system while taking SUBOXONE® Film.

You should not drink alcohol while taking SUBOXONE Film, as this can lead to loss of consciousness or even death.

Death has been reported in those who are not opioid dependent.

Your healthcare provider may monitor liver function before and during treatment.

SUBOXONE® Film is not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. However, SUBOXONE® Film may be used with caution for maintenance treatment in patients with moderate hepatic impairment who have initiated treatment on a buprenorphine product without naloxone.

Keep SUBOXONE® Film out of the sight and reach of children. Accidental or deliberate ingestion of SUBOXONE® Film by a child can cause severe breathing problems and death.

Do not take SUBOXONE® Film before the effects of other opioids (eg, heroin, hydrocodone, methadone, morphine, oxycodone) have subsided as you may experience withdrawal symptoms.

Injecting the SUBOXONE® Film product may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and crayings,

Before taking SUBOXONE® Film, tell your healthcare provider if you are pregnant or plan to become pregnant. If you are pregnant, tell your healthcare provider as withdrawal signs and symptoms should be monitored closely and the dose adjusted as necessary. If you are pregnant or become pregnant while taking SUBOXONE® Film, alert your healthcare provider immediately and you should report it using the contact information provided below. \*

Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor.

Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy, whether that use is medically-authorized or illicit. Unlike opioid withdrawal syndrome in adults, NOWS may be life-threatening if not recognized and treated in the neonate. Healthcare professionals should observe newborns for signs of NOWS and manage accordingly.

Before taking SUBOXONE® Film, talk to your healthcare provider if you are breastfeeding or plan to breastfeed your baby. The active ingredients of SUBOXONE Film can pass into your breast milk. You and your healthcare provider should consider the development and health benefits of breastfeeding along with your clinical need for SUBOXONE® Film and should also consider any potential adverse effects on the breastfeed child from the drug or from the underlying maternal condition.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBOXONE Film affects you. Buprenorphine in SUBOXONE® Film can cause drowsiness and slow reaction times during dose-adjustment periods.

Common side effects of SUBOXONE® Film include nausea, vomiting, drug withdrawal syndrome, headache, sweating, numb mouth, constipation, painful tongue, redness of the mouth, intoxication (feeling lightheaded or drunk), disturbance in attention, irregular heartbeat, decrease in sleep, blurred vision, back pain, fainting, dizziness, and sleepiness.

This is not a complete list of potential adverse events associated with SUBOXONE Film. Please see full Prescribing Information for a complete list.

\*To report pregnancy or side effects associated with taking SUBOXONE® Film, please call 1-877-782-6966. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about SUBOXONE Film, SUBOXONE® (buprenorphine and naloxone) Sublingual Tablets (CIII), or SUBUTEX® (buprenorphine) Sublingual Tablets (CIII), please see the respective full Prescribing Information and Medication Guide at www.suboxoneREMS.com



#### INDICATION AND USAGE

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 a dose adjustment period for a minimum of seven days.

SUBLOCADE should be used as part of a complete treatment program 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.

#### IMPORTANT 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.

<u>Treatment of Emergent Acute Pain:</u> 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.

The full prescribing information, including BOXED WARNING, for SUBLOCADE™ can be found at: http://www.indivior.com/wp-content/uploads/2018/01/2018 01 12-CLEAN-USPI-SUBLOCADE.pdf

