# Strengthening our global leadership in treatment of addiction

Half Year Results 2018
July 25<sup>th</sup> 2018



# **Shaun Thaxter**

**Chief Executive Officer** 



# 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.

Various factors may cause differences between Indivior's expectations and actual results, including: 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; 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; 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.



# **AGENDA**

**Shaun Thaxter** H1 2018 Performance Overview

SUBLOCADE™ Update

Javier Rodriguez Legal Update

Mark Crossley H1 2018 Financial Review

**FY 2018 Cost Actions** 

**Shaun Thaxter** Conclusion

**Question & Answers** 



H1 2018 Overview & FY 2018 Guidance



# Indivior Half Year 2018 Overview

% Δ vs.

#### H1 2018 Performance

		H1 17 (actual FX)
Net Revenue (NR)	\$524m	-5%
Op. Profit *	\$183m	-32%
Net Income *	\$147m	-13%
EPS (fully-diluted) *	20 cents	-13%
Cash	\$951m	+\$159m
Net cash	\$469m	+\$201m

FY 2018 guidance to be issued no later than Q3 18 results on Nov. 1st

## **Operational Overview**

Double-digit US market growth; continues to be driven by Medicaid

H1 2018 Suboxone® Film average share was 54%; Q2 18 exit share was 52%

NR: market growth more than offset by market share decline, adverse mix and further rebating vs. generic tablet price

SUBLOCADE™ NR \$2m; patient and physician feedback positive; payor coverage ahead of plan; strong progress toward improving prescription journey

Profit reflects lower NR and planned higher investment in SUBLOCADE™ and RBP7000

PI granted against DRL; DRL requesting expedited appeal

Advanced discussions with DOJ continuing, litigating all other cases

## **Pipeline Progress**

SUBLOCADE™ new drug submissions made in Canada and Australia

SUBLOCADE™ HEOR 1-year endpoint is expected in December; key LEGO studies ongoing or in active planning

RBP-7000 PDUFA date of July 28th

Arbaclofen Placarbil and early stage assets progress.



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

# SUBLOCADE™ Update



# SUBLOCADE™ Fundamentals are Strong, Prescription Journey and HCP Trial Improving

# **Strengths**

- Patient experience and satisfaction (1)
- Payor coverage (quantity and quality)
- Number of prescription journey initiations per physician
- Ease and efficiency of refill process
- Adherence to treatment
- Safety profile of reported events consistent with transmucosal buprenorphine and Phase 3 study outcomes
- FDA review of promotional materials now received (albeit delayed by four months)

# Challenges

- Duration of prescription journey
- Prescription journey success rate
- HCP trial (below initial expectations)
- Absolute number of prescription journey initiations
- Patient support materials becoming available from August onwards



# SUBLOCADE™ Prescription Initiation to Injection (Prescription Journey) is New and More Complex

# SUBOXONE® Film (Retail)

# Two highly automated & standardized touch points

- Physician initiates prescription direct to pharmacy via computer
- Pharmacy computer completes prescription journey enabling the patient to collect medication

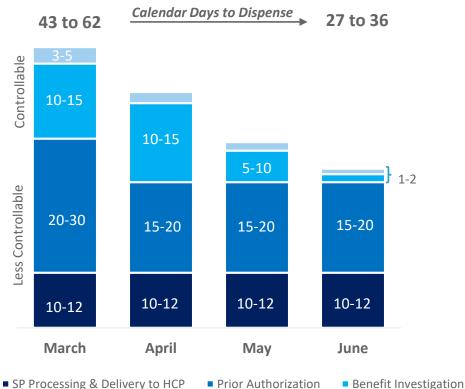
# SUBLOCADE™ Injection (SP) Specialty Pharmacy

# Over 30 touch points in a paper-driven manually administered process

- Patient and HCP office staff complete intake form together
- HUB/SP administrators conduct manual benefit investigation to identify prior authorization requirement and to confirm patient's eligibility
- SP receives prescription and confirms patient eligibility with payor
- SP collects payment from patient
- SP coordinates delivery of SUBLOCADE to HCP



# 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
- HUB capacity
- Payor coverage (quantity & quality)
- SP coordination between patient and HCP office



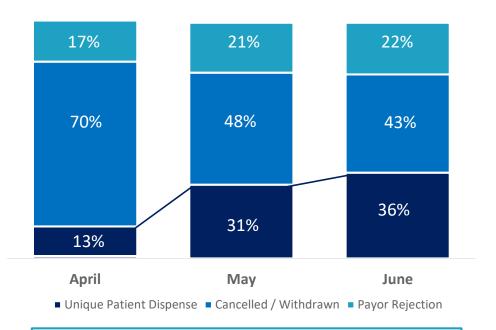
# Specialty has Low Success Rates for First Prescription - Dispense Conversion Rate<sup>(1)</sup> Improving

# Cumulative to H1 2018 (1)

**6,400+** Unique patient prescription initiations

**1,000+** Unique patient injections

**56%** Payor coverage (currently 67%)



36% of closed cases were dispensed to in June



# SUBLOCADE™ KPIs<sup>(1)</sup> – HCP Data & Patient Treatment Adherence

**79%** 

Prompted awareness

1,300+

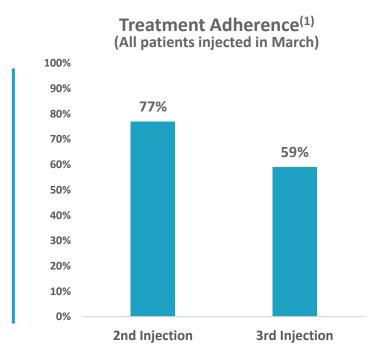
HCPs initiated prescription journeys

384

HCPs administered SUBLOCADE™

30

HCPs administered ≥ 5 patients





# What Patients and HCPs are Saying (1)

# **Patients**

- Pre-treatment anxiety
- Frustration with the process and time from prescription to injection
- Injection site pain

## But for those who have started:

 Overall satisfaction with treatment<sup>(1)</sup>

# **HCPs**

- Positive feedback from HCPs who have administered SUBLOCADE™ to patients
- Reports of safety cases consistent with transmucosal buprenorphine and Phase 3 study outcomes
- Frustration with the process and time of prescription journey
- Varying rates at which storage and processes being set up by practices
- Reticence to initiate additional patients until experience of first prescriptions is smoothed



# SUBLOCADE™ Next Steps

- Sustained focus to maintain the momentum on reducing the prescription journey duration and improving success rates
- Increase rate of HCP trial and initiation of new prescription journeys

Remain confident in annual peak net revenue goal of \$1 billion+



# Javier Rodriguez

**Chief Legal Officer** 



# **Major Litigation**

The Group carries a provision for investigative and antitrust litigation matters of \$438m. Substantially all of the provision relates to the US Department of Justice investigation. The Group is in advanced discussions with the Department of Justice about a possible resolution to its investigations, although it cannot predict with any certainty whether, when, or at what cost it will reach an ultimate resolution.

The Group reduced other elements of the provision that relate to other litigation matters reflecting the Groups' belief that it has strong defences in the antitrust and other litigations and is actively litigating these matters. Indivior cannot predict with any certainty the costs or timing of the ultimate resolution of the antitrust and other litigation matters.

The final aggregate cost of these matters may be materially higher from the amount provided.

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

FTC Investigation & Antitrust Litigation (1)

ANDA Litigation (1)



See H1 2018 Results Announcement published 7/25/18 "Litigation Update" and "Risk Factors" for complete description.

# **ANDA Litigation Update**

### **DRL Preliminary Injunction**

- On June 14<sup>th</sup>, DRL received approval for all 4 strengths of its generic buprenorphine/naloxone film product and launched its product "at risk"
- On June 15<sup>th</sup> and July 13<sup>th</sup>, respectively, Indivior obtained a temporary restraining order (TRO) and a Preliminary Injunction (PI), which prohibits DRL from using, selling, offering to sell or importing its generic product in the U.S.
- As security against the PI, Indivior has posted a surety bond for \$72 million as ordered by the District Court
- DRL has appealed the PI and has filed emergency motions seeking to expedite appeal and stay the PI pending the appeal

## We continue to vigorously defend our SUBOXONE® Film intellectual property

- Have opposed appeal and motions to expedite appeal/stay PI
- Will continue to pursue appeal of '514 patent non-infringement ruling and District Court litigation asserting '454, '221, and '305 patents

Other ANDA filers must weigh the potential of significant damages of "at-risk" launch



# **Key ANDA Litigation Milestones**

<u>Event</u>	Estimated Date
Federal Circuit Court ruling in DRL PI appeal (expedited basis)	Q4 2018
Federal Circuit Court ruling in appeal of '514 patent non-infringement ruling	Q2 2019
Federal Circuit Court ruling in DRL PI appeal (non-expedited basis)	Q2/Q3 2019
District Court ruling in '305 patent litigation	Q2/Q3 2020
Federal Circuit Court ruling in appeal of '305 patent litigation	Q2/Q3 2021
Generic early entry license date per terms of Par settlement agreement	January 1, 2023, or earlier under certain circumstances



# **Mark Crossley**

**Chief Financial Officer** 



# Profit & Loss Account\*

		Q_L				
	2018 Adjusted	2017 Adjusted	% change	2018 Adjusted	2017 Adjusted	% change
(\$ in mil.)						
Net Revenues	268	288	-7%	524	553	-5%
Cost of Sales	(35)	(25)		(59)	(45)	
Gross Profit	233	263	-11%	465	508	-8%
Gross Margin (%)	87%	91%		89%	92%	
Selling, General and Administration Expenses	(131)	(102)		(248)	(195)	
Research & Development Expenses	(18)	(19)		(34)	(44)	
Operating Profit	84	142	-41%	183	269	-32%
Operating Margin (%)	31%	49%		35%	49%	
EBITDA	87	144	-39%	191	273	-30%
Net interest	(6)	(14)		(11)	(25)	
Taxation	(8)	(39)		(25)	(75)	
Effective Tax Rate (%)	10%	30%		15%	31%	
Net Income	70	89	-21%	147	169	-13%

**Q2** 

**H1** 



<sup>\*</sup> Please see Appendix for full reconciliation for periods indicated.

# Net Revenue – By Region

#### Net Revenue

(\$ in mil.)	Half Year 2018	Half Year 2017	% Change	% Change Const. FX
USA	411	452	-9%	N.A.
Rest of World	113	101	12%	2%
Total	524	553	-5%	-7%

## Commentary

#### **USA**

- Market growth continues in low double digits, mainly driven by Medicaid channel growth from increased government funding
- Suboxone® Film share was resilient in H1 2018 (54% avg. share); however recent negative share impact of DRL market entry before the temporary restraining order (TRO) being granted still being assessed
- Jan. 2018 price increase more than offset by tactical rebating to maintain formulary access and unfavourable mix impact from Medicaid channel growth

#### **Rest of World**

 Increase primarily driven by continued growth in Australasia and Canada



# **Operating Costs & Margins**

## Operating Costs H1 2018

(\$ in mil.)	H1 18	H1 17	% ch
SG&A (adjusted)	(248)	(195)	27%
R&D	(34)	(44)	-23%
Exceptional items		(25)	
Depreciation & Amortization (included in SD&A)	(7)	(4)	

- SG&A increase reflects expected annualization of FY 2017
   SUBLOCADE™ launch and support investments, as well as the establishment of the new Behavioural Health unit to launch RBP-7000 (if approved); Legal expenses related to intellectual property (IP) defence were also higher
- R&D decrease reflects expected lower clinical activity as Phase III trials on key pipeline assets have been completed and capitalization of RBP-7000 development costs in Q2 2018
- Higher D&A reflects real property addition (Hull, UK R&D facility)

# Margins H1 2018

	H1 18 Reported	H1 17 Reported	H1 18 Adjusted	H1 17 Adjusted
Gross margin	89%	92%		
Operating margin	38%	44%	35%	49%

- Gross margin decline versus year-ago period reflects lower net revenue and DRL US market entry contingency planning
- YOY operating margin decrease reflects deleveraging of net revenue in conjunction with expected annualization of SUBLOCADE™ launch and support investments, as well as the establishment of the new Behavioural Health unit to launch RBP-7000 (if approved); IP-related legal expenses were also higher
- Exceptional items in the year-ago period reduced reported operating margin by ~450 bps (\$25m related to Amneal settlement)



# Targeting At Least \$25m of Pre-tax Savings in FY 2018

- Actions already initiated with savings expected to be fully captured in FY 2018
- SUBLOCADE™ launch remains fully funded
- Maintaining strong compliance across the organization
- Savings concentrated in non-critical SG&A
  - <u>Targeted areas include</u>:
    - ✓ Global support functions
    - ✓ Consulting / external services

If DRL is granted an expedited briefing we will revisit our contingency plan



# Cash & Borrowing Position at Half Year

(\$ in mil.)	Half Year 2018	Full Year 2017
Cash & Cash Equivalents	\$951	\$863
Current Borrowings	(5)	(5)
Long-term Borrowings Other	(472) (5)	(477) (5)
Net cash	\$469	\$376

- Net cash of \$469m at half year, improvement of \$93m in the period
- Continue to retain cash on balance sheet at present:
  - ✓ Flexibility until resolution of legal matters
  - ✓ Flexibility to revisit capital structure
  - √ Flexibility on business development



# Summary



# 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
- Continue to vigorously defend intellectual property rights

# 2. Ensure Successful US Launch for Pipeline Products

- SUBLOCADE™ monthly buprenorphine extended release injection
- RBP-7000 monthly longacting risperidone extended release injection (July 28<sup>th</sup> PDUFA) (if approved)

# 3. Expand Global Treatment

- Expand treatment access in USA
- Prepare for SUBLOCADE™ launch in Canada and Australia (if approved)
- Preparing European submission for RBP-6000

# 4. Focus on Capital Allocation

Continue to manage risks



# **Appendix**



# Q2 Profit & Loss Account Reconciliation

Q2 2018

Q2 2017

	2018 Actual	Adjustments 2018 Adjusted	2017 Actual	Adjustments	2017 Adjusted
(\$ in mil.)					
Net Revenues	268	268	288		288
Cost of Sales	(35)	(35)	(25)		(25)
Gross Profit	233	233	263		263
Gross Margin (%)	87%	87%	91%		91%
Selling, General and Administration Expenses	(131)	(131)	(127)	25 (1)	(102)
Research & Development Expenses	(18)	(18)	(19)		(19)
Operating Profit	84	84	117	25	142
Operating Margin (%)	31%	31%	41%		49%
EBITDA	87	87	119		144
Net interest	(6)	(6)	(14)		(14)
Taxation	(8)	(8)	(30)	(9) <sup>(1)</sup>	(39)
Effective Tax Rate (%)	10%	10%	38%		30%
Net Income	70	70	73	16	89

<sup>(1)</sup> Q2 2017 adjusted results exclude the effects of exceptional items related to the Amneal settlement.



# **H1 Profit & Loss Account Reconciliation**

		111 2010					
	2018 Actual	Adjustments	2018 Adjusted	2017 Actual	Adjustments	2017 Adjusted	
(\$ in mil.)							
Net Revenues	524		524	553		553	
Cost of Sales	(59)		(59)	(45)		(45)	
Gross Profit	465		465	508		508	
Gross Margin (%)	89%		89%	92%		92%	
Selling, General and Administration Expenses	(231)	(17) (1)	(248)	(220)	25 (2)	(195)	
Research & Development Expenses	(34)		(34)	(44)		(44)	
Operating Profit	200		183	244		269	
Operating Margin (%)	38%		35%	44%		49%	
EBITDA	208		191	248		273	
Net interest	(11)		(11)	(25)		(25)	
Taxation	(27)	2 (1)	(25)	(66)	(9) <sup>(2)</sup>	(75)	
Effective Tax Rate (%)	14%		15%	30%		31%	
Net Income	162	15	147	153	16	169	

H1 2018

H1 2017



<sup>(1)</sup> H1 2018 adjusted results exclude the effects of exceptional items related to out-licensing of the intranasal naloxone opioid overdose patents.

<sup>(2)</sup> H1 2017 adjusted results exclude the effects of exceptional items related to the Amneal settlement in Q2 2017.

# 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 benzo diazepines 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.



# Strengthening our global leadership in Addiction Treatment

