Strengthening our global leadership in treatment of addiction

Jefferies 2017 London Healthcare Conference November 15th, 2017



Forward Looking Statements

This announcement 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 2017 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 investigative and antitrust litigation matters; the 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.



Why Indivior?

Targeting a global epidemic – addiction and its co-morbidities

Building on <u>leading Buprenorphine Medication-Assisted Treatment</u>
(BMAT) position to develop and commercialize novel, break-through addiction treatments



Generating <u>strong profitability and cash flow</u> today with potential upside from pipeline success



Indivior PLC (LON: INDV) Snapshot

2016 Operating Highlights ⁽¹⁾

\$1.05 bil. (+4% vs. 2015) Net revenue

\$387 mil. (37% margin) Adj. operating profit ⁽³⁾

\$692 mil. Cash balance

40

Countries of presence

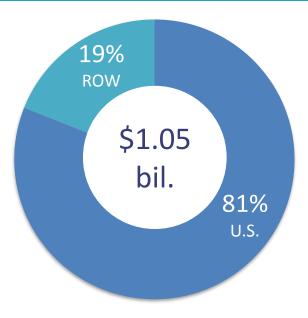
965 Employees worldwide

Indivior 2016 Annual Report – inside cover, pgs. 4, 36

(2) FY 2016 press release, pg. 19

(3) Adjusted basis, excluding the impact of exceptional SD&A items of \$2 million in Q4 and \$238 million in the full year

2016 Sales by Geography⁽²⁾





Addiction

The scale of the problem



NDIVIOR

OUR VISION

For all **patients** around the **world to have access** to **quality treatment** for the chronic relapsing **condition and co-occurring disorders of addiction**



Treating Addiction is our Primary Focus

Addiction affects millions globally

- 29 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⁾



⁽¹⁾ United Nations Office on Drugs and Crime, World Drug Report 2016

²⁾ 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

⁽³⁾ World Health Organization (WHO) Global Status Report on Alcohol and Health 2014

Opioid Use Disorder is an Epidemic in the U.S.

THE EQUIVALENT OF A PASSENGER PLANE CRASHING EVERY DAY WITH NO SURVIVORS



AMERICANS die every day from an opioid overdose (that includes prescription opioids and heroin). 4 PEOPLE IN THE US DIE OF OPIOID OVERDOSE EVERY HOUR OF EVERY DAY

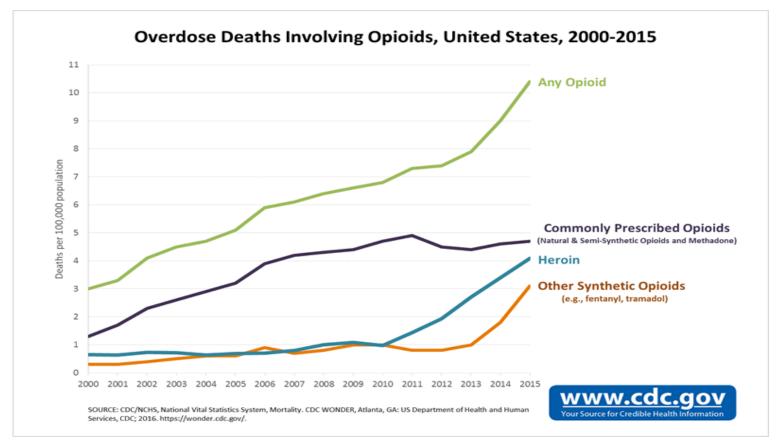


Stories like the shocking Ohio overdose one last September are becoming all too common



⁽¹⁾ CDC: https://www.cdc.gov/drugoverdose/media/index.html
⁽²⁾ Picture Sources: <u>http://www.civilaviation.eu/Embraer/EMB-170</u>
⁽³⁾ globalnews.ca/news/2932561/shocking-photos-of-ohio-overdose-victims-problematic-say-addiction-experts

The U.S. Opioid Epidemic has Accelerated





The U.S. Represents a Tremendous Growth Opportunity

•	80% of world's
	200 million no
	•

- s opioid users
- 300 million pain prescriptions written in 2015 worth \$24 billion

Conducive Policy ⁽³⁾

- Medication-assisted treatment (MAT) endorsed by U.S. government
- CARA legislation and CURES Act increased addiction resources

Growing Capability ⁽⁴⁾

- Patient cap raised to 275; NP and PAs able to prescribe with training
- Record physician certifications in 2016 ۲

Strong Franchise

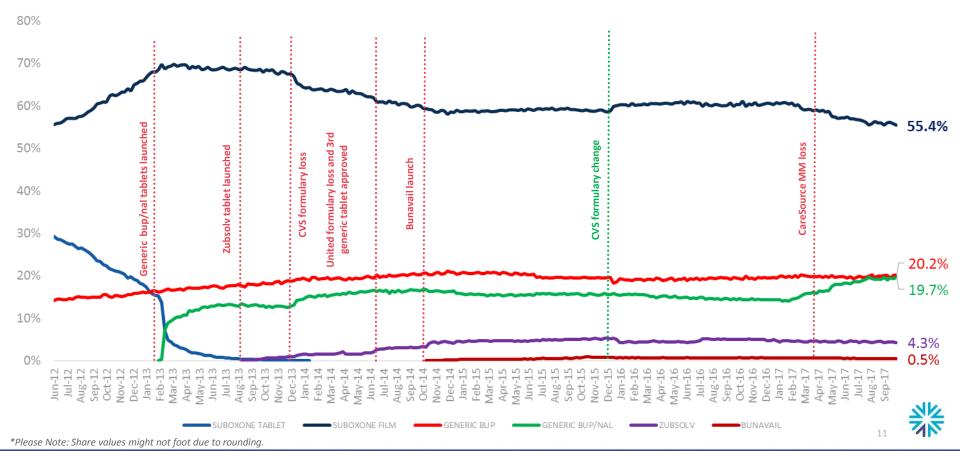
- 200+ Clinical Liaisons
- Nationwide coverage •





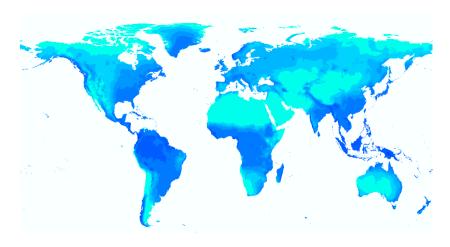
- (2) http://path-consult.com/wp-content/uploads/2013/08/April-2017.pdf
- http://www.npr.org/sections/health-shots/2017/05/16/528614422/prices-remarks-on-opioid-treatment-were-unscientific-and-damaging-experts-say (3)
- (4) CARA legislation expands treatment availability: DEA report of waivered HCPs December 2016

US SUBOXONE[®] Film Share has been Resilient



Source: Symphony Health, Retail PHAST Weekly Prescription Data ending September 29th

Ex-US Markets in Earlier Stage of Development



EU (>1 mil. problem opioid users) differs from US as opioiddependence mainly heroin addiction ⁽¹⁾

- Policy focused more on harm reduction for society than on patient recovery
- ✓ Methadone clinics, strict supervision prevail
- ✓ Volume growing slowly, value in decline due to austerity pressures
- ✓ Scope to grow by building recognition of painkiller dependence (estimated up to 0.45 mil. patients)

ROW (~23 mil. people with drug use disorders) opioid drug use almost exclusively heroin addiction ⁽¹⁾

- Under-developed or adversarial policy regimes (penal sentences for possession) in many countries
- ✓ China is the largest potential market (~7 mil. opioid dependent including 1.4 mil. registered drug users)
- ✓ Australia is a well developed market based on US model

Scope for growth in ex-US markets in the medium to long-term

(1) 2015 World Drug Report. European Drug Report 2015 (EMCDDA): China Narcotics Control Report, 205-2014, NNCC Office Drug use and dependence from World Drug Report refers to opiates, cocaine, cannabis, amphetamines, and psychoactive substances -Indivior PLC annual report 2015 p.13. Full details of sources on p.137



The Pipeline



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

Stage of Development

Status⁽¹⁾

Buprenorphine Lifecycle	Phase 1	Phase II	Phase III	NDA	Efficacy	Safety	Launch	Peak Net Rev. Forecast ⁽²⁾
RBP-6000	Fast Track De	signation 5/2	3/16	Submitted	🗸 Ph. III	🗸 Ph. III 🖌 Ph. III	Q1 2018	≥\$1 bil.
	•••••	•••••		(Priority Review) Achieve		primary & / endpoints		
Schizophrenia	Phase 1	Phase II	Phase III	NDA	Efficacy	Safety	Launch	Peak Net Rev. Forecast ⁽²⁾
					🖌 Ph. III	🖌 Ph. III		
RBP-7000	• • • • • • • • • • • • • • • • • •	•••••	·····>	Submitted		primary & endpoints	Q4 2018	\$200 to \$300 mil.
Alcohol Use Disorders	Phase 1	Phase II	Phase III	NDA	Efficacy	Safety	Launch	Peak Net Rev. Forecast ⁽²⁾
Arbaclofen Placarbil	·····>				Bioavailat Study da	ed Phase 1 bility Study; ata under view		\$500 to \$900 mil.



(1) Dates are best estimates only and subject to change

(2) Q4 FY 2017 Results Press Release Published February 22nd, 2017, Pg. 184; Investor Day presentation, November 21st 2014

Key Phase 3 Asset: RBP-6000 for Adults with Moderateto-Severe Opioid Use Disorder

Unmet Patient Needs

 $>2.5_{mil}$ <50%

of diagnosed

any MAT⁽¹⁾

patients receive



What: Investigational once-monthly buprenorphine depot injection in the ATRIGEL[®] delivery system Where: U.S., initially Recommended for approval Status: by FDA Advisory Committees; PDUFA target date of Nov. 30th



Volkow ND, Frieden TR, Hyde PS, Cha SS. 2014. Medication-assisted therapies-tackling the opioid-overdose epidemic. N Engl J Med 370(22): 2063-2066. doi: 10.1056/NEJMp1402780 SAMHSA, Results from the 2014 National Survey on Drug Use and Health Rockville MD: Substance Abuse and Mental Health Services Administration

patients diagnosed

with OUD in the US⁽¹⁾

<u>Objective</u>: Address What We Believe the Current Unmet Medical Needs are in BMAT

- Sustained plasma levels of buprenorphine that translate into high μ-opioid receptor occupancy to suppress withdrawal symptoms <u>and</u> block the subjective and objective effects of opioid agonists in most patients
- 2 Once-monthly buprenorphine delivery that is consistent across the <u>entire</u> 1-month period



Enhanced compliance/adherence to treatment



Monthly decisions (12/year) rather than daily decisions (365/year)



Key Phase 3 Asset: RBP-7000 for Schizophrenia

Unmet Patient Needs



People worldwide affected by schizophrenia ⁽¹⁾



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

RBP-7000 Treatment

<u>What</u>: Once monthly Risperidone in ATRIGEL[®]

Where: U.S.

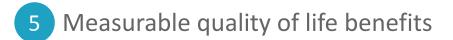
Status: NDA submitted Sept. 28th



<u>Objective</u>: Address What We Believe the Current Unmet Needs are in Long Acting Antipsychotics



- 2 Extended treatment duration
- 3 Manageable tolerability
- 4 No oral co-medication





LITIGATION UPDATE



Major Litigation

The Group carries a provision of \$217m for the investigative and antitrust litigation matters noted below. The provision was reduced by \$25m compared to period ending Q2 2017, reflecting payment of previously reserved settlement amount to Amneal Pharmaceuticals LLC (Amneal). Other than reducing by the Amneal settlement amount, the Group has not changed the previously recorded provision, as the other litigation and investigations are ongoing. 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 other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this provision.

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

FTC Investigation & Antitrust Litigation ⁽¹⁾

ANDA Litigation & Inter Partes Review ⁽¹⁾

(1) See Half Year 2017 Results Announcement published July 27th, 2017, pgs. 5 to 7 "Litigation Update" for complete description

(2) See Half Year 2017 Results Announcement published July 27th, 2017, pgs. 7 to 9 "Risk Factors" for a complete description



The Facts: ANDA Litigation

- 1 Nothing has changed in the marketplace
- 2 ANDA filers must weigh the potential significant damages if launching "at-risk"
- 3 <u>We are vigorously defending our IP</u>: pursuing litigation for infringement of new '454 Orange Book listed patent issued in June 2017
- 4 Settled litigation with Mylan; settlement currently under review by FTC, as required
- 5 Mylan terminated '514 and '497 IPR challenges; PTAB subsequently denied Dr. Reddy and Par's petitions to join the Mylan IPR since it was terminated



PRIORITIES FOR 2017



Reconfirmed Guidance for 2017

(\$ in mil.)

Net Revenue	\$1,090m - \$1,120m)m	
Net Income (adjusted)	\$265m - \$285m		

Guidance is based on no material change in market conditions:

Top-line

- Strong US market conditions in H1 2017 continue in H2 2017:
 - ✓ Continued low double-digit volume growth
 - Modest loss of US share due to formulary changes and managed Medicaid accounts
 - ✓ No deterioration in generic tablet pricing and limited impact of branded competition
 - ✓ No generic film entry in 2017

Expenses

- Lower R&D:
 - Arbaclofen Placarbil reformulation studies partially phase into 2018
- Pre-launch Investments Maintained:
 - ✓ \$40m to \$60m
- Estimated FY tax rate of 24% (ex.-exceptionals)
- Before exceptional items and at constant FX



Year to Date 2017 Highlights

Financial	Highlights ⁽¹⁾
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		Y/Y
(In \$mil., except EPS)	<u>2017</u>	<u>(Δ%)</u>
Net Revenue	\$828	+4%
Operating Profit	\$333	+6%
Net Income	\$216	+5%
EPS (fully-diluted)	30 cents	+7%
Net Cash (vs. FY2016)	\$322	+146%

Operational Highlights ⁽¹⁾

- US market growth continues at low double digits
- Maintaining leadership in core SUBOXONE[®] Film market
- Key pipeline launch initiatives on-track
- Vigorously asserting and expanding intellectual property
- Financial position remains strong



Priorities for 2017

Resolve legal risks and secure long-term certainty for Company

1.SUBOXONE[®] Film Resilience

 Preserve leadership position in USA against 7 generic and 3 branded competitors 2. Ensure Successful launch for Pipeline products upon approval

- RBP-6000 Monthly Depot Buprenorphine
- RBP-7000 Monthly Depot Risperidone

3. Expand Global treatment

- Expand treatment access in USA
- Opioid painkiller dependence in Europe
- NDA filed in China Dec. 2016

4. Prepare for possible BD / M&A

- Pay down debt and strengthen balance sheet
- Manage down other risks



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



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 cravings.

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

THANK YOU.

