# A World Leading Addiction Treatment Company ...with enormous future potential

JP Morgan Conference, San Francisco January 2016



#### **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 will or may 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 our financial guidance for 2015 and our medium- and long-term growth outlook, our operational goals, our 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 Suboxone Tablet, Suboxone Film, Subutex Tablet and any future 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; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of the Suboxone Film patent litigation relating to 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.

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# Indivior PLC is the industry leader in treatment of addiction

# Global Leader in Opioid Addiction Treatment

- Structurally growing market
- Unrivalled experience and reputation

# Several Levers for Future Growth

- Pipeline & business development
- Global expansion

# Sustainable franchise with existing products

• Multi-layered IP protection to 2030

Strong, experienced, stable management team





# **OUR VISION**

That all patients around the world will have unrestricted access to high quality treatment services for the chronic relapsing conditions and co-morbidities of addiction



# Addiction is a growing global epidemic

- 230m people worldwide abusing drugs, 153m dependent on opioids, cannabis, cocaine, other stimulants and alcohol
- Growing global governmental recognition of the issue
- Indivior is the main company working to expand access to treatment for addiction

# Addiction – A Growing Global Epidemic



- 230m people worldwide use illicit drugs
- 122m people worldwide dependent on alcohol (and under-reported)
- 23m people worldwide dependent on opioids (and under-reported)
- 8m people dependent on other substances cocaine, cannabis, methamphetamine
- 39 Deaths per 100,000 population due to alcohol and drug use – implies >2.5m global deaths a year

United Nations Office on Drugs and Crime, World Drug Report 2015 (United Nations publication, Sales No. E.15.XI.6); European Monitoring Centre for Drugs and Drug Addiction (EMCDDA): European Drug Report 2015: Trends and Development, doi:10.2810/084165; ISBN: 978-92-9168-776-3



# And the focus of growing attention



Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use

White House: 21/10/2015





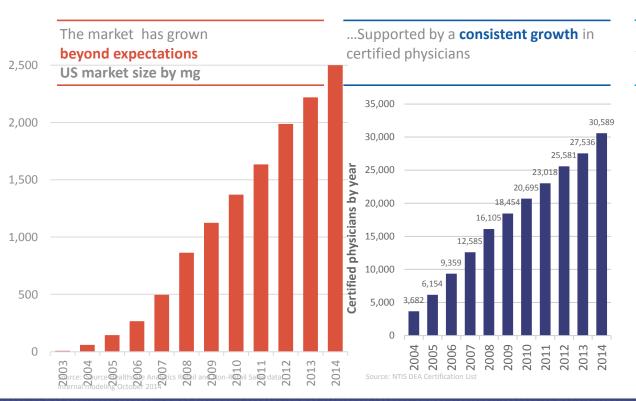
Obama Tells Outdated Opioid Treatment Industry It's Time To Change

Huffington Post 21/10/2015

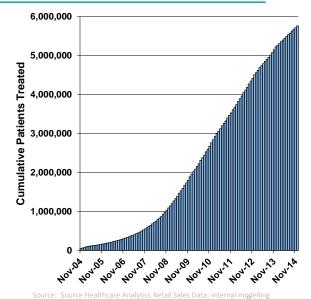
# THE TIMES

Successful middle classes suffering crisis in alcohol abuse

# But when authorities get it right, the market develops rapidly...



**Nearly 6mm patients** have received treatment through Suboxone therapy (tablets & film)...



### Addiction is a growing global epidemic

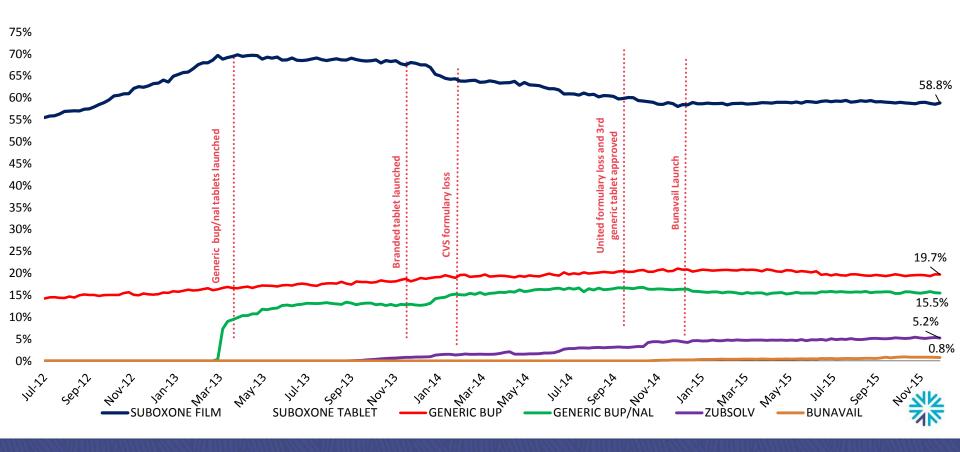
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### A sustainable franchise with existing products in face of growing competition

- Suboxone Film is demonstrating resilience in US market with 59% share
- Valid & Enforceable patents extending up to 2030.



# Competition is intensifying, but Film share has been resilient



### **ANDA Litigation Update**

- Trial in the lawsuits against Actavis and Par involving the Orange Book-listed patents for Suboxone® Film November and December 2015. A decision in these lawsuits will follow post-trial briefing and is expected prior to any potential generic launch. Actavis' 30 month stay of FDA approval expires February 28th, 2016. Par's 30 month stay of FDA approval expires on September 25th, 2016.
- Trial against Actavis and Par in the lawsuits involving the two recently granted process patents (US Patent No. 8,906,277 and US Patent No. 8,900,497) scheduled for November 2016.

- Trial against Teva in the lawsuit involving the Orange Booklisted patents and process patents for Suboxone® Film scheduled for November 2016, with Teva's 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17<sup>th</sup>, 2017. Indivior believes Teva's 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17<sup>th</sup>, 2017, however, Teva disputes the applicability of the stay to this ANDA.
- Trial against Alvogen in the lawsuit involving the Orange Book-listed patents and process patents for Suboxone® Film scheduled for April 2017, with Alvogen's 30-month stay of FDA approval expiring October 28<sup>th</sup>, 2017.
- Indivior received Paragraph IV notifications from Mylan and Sandoz on September 24<sup>th</sup>, 2015 and October 2<sup>nd</sup>, 2015, respectively. Indivior has filed patent infringement lawsuits against both ANDA-filers within 45-days of having received the Paragraph IV notifications, triggering the automatic stay of FDA approval of the ANDAs pursuant to the Hatch Waxman statute, with Mylan's stay expiring March 24th, 2018 and Sandoz's stay expiring April 2, 2018.

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- Lifecycle management of Buprenorphine and extension into alcohol, cocaine and early stage developments on other addictions



# AN INNOVATIVE PIPELINE DESIGNED TO IMPROVE PATIENT OUTCOMES

Stages of development and earliest approval dates\*

	Stage of Development			Estimated Approval Dates						
	Phase I	Phase II	Phase III	NDA	2015	2016	2017	2018	2019	2020
Buprenorphine Lifecycle										
Suboxone® Tablet	• • • • • •	• • • • •	• • • • • •	····>				China 🗸		
Suboxone® Film	• • • • • •	• • • • • •	• • • • • •	••••>				Can? EU?	China 🗹	
Buprenorphine Monthly Depot	• • • • • •	• • • • • •	•••>				US 🗸			EU 🗸
Oral Swallowable Capsule	• • • • • •	>							<b>✓</b>	
Overdose Rescue Products										
Cocaine Esterase	• • • • • •	·>							<b>✓</b> US	
Alcohol Use Disorders										
Arbaclofen Placarbil	• • • • • •	•>							US/I	EU 🗸
Adjacency - Schizophrenia										
Risperidone Monthly Depot	• • • • • •	• • • • • •	····>				<b>√</b> US	S		



<sup>\*</sup> Dates are best estimates only and could be subject to change

# Highlights of R&D delivery in 2015

## Continuing progress with our innovative pipeline

- Label expansion for Suboxone Film (Buccal Indication) and new patents approved
- China FDA approved clinical trial application for Suboxone Film Nov 2015
- French ATU for Nasal Naloxone approved Nov 2015
- Compelling Phase 3 efficacy data (end points met) on Risperidone Monthly Depot, safety extension in progress
- Monthly buprenorphine depot progressing well through phase 3
- 1 new Phase 2 trial started (Arbaclofen Placarbil)
- 1 new Phase 1 trial initiated (RBP 6300)
- 6 peer reviewed publications plus two publications in press



# PROGRESS ON PIPELINE IN 2015 – Key Projects

Product	Stage	Status	
RBP-6000: BUPRENORPHINE ONCE MONTHLY IN ATRIGEL®	Phase 3 (US)	<ul> <li>On track with pivotal efficacy trial (RB-US-13-0001): First patient randomized February 20<sup>th</sup>, 2015</li> <li>Current status – On track with last patient in Nov. 2015</li> <li>Phase 3 Safety extension study (RB-US-13-0003) screening and enrollment ongoing.</li> <li>US Patent No.8,975,270 granted with expiry in 2031, the second Orange Book-listable patent upon FDA approval of NDA</li> </ul>	
RBP-6300: BUPRENORPHINE HEMIADIPATE IN ADF*	Phase 1	<ul> <li>First Patient In pivotal PK study in Man (RB-EU-14-0001) Sep 2015</li> </ul>	
Arbaclofen placarbil	Phase 2A (US)	<ul> <li>Pre-IND meeting with FDA January 29<sup>th</sup>, 2015</li> <li>IND submission June 26<sup>th</sup>, 2015</li> <li>First Patient screened In Phase IIA study (RB-US-14-0001) September. 2015</li> </ul>	

# New Product Development: Psychiatric co-morbidities

#### Product

#### Status

#### RBP-7000: Risperidone once monthly in Atrigel®



- Phase 3 pivotal efficacy study (RB-US-09-0010): Completed; Preliminary data from pivotal Phase III Efficacy study were published on May 5th, 2015
- Phase 3 long-term safety study (RB-US-13-0005): Enrolment ongoing
- Granted Patents: Orange Book-listable upon FDA approval of NDA
  - 1) US Patent No. 9,190,197 (expiry 2028)
  - 2) US Patent No. 9,186,413 (expiry 2028)

#### <u>Preliminary data from pivotal Phase III Efficacy study.</u>

Both doses met the primary endpoint with statistically and clinically significant reductions in the symptoms of acute schizophrenia over an 8-week treatment period using the change from baseline to end of treatment in the total Positive and Negative Syndrome Scale (PANSS) scores. RBP-7000 also met the key secondary endpoint with significant improvements in the Clinical Global Impression-Severity of Illness (CGI-S) scale compared with placebo over the 8-week treatment period. These results further emphasise the compatibility of our Atrigel® drug delivery platform with a range of pharmaceutical compounds for their safe, sustained release over targeted time period through an easy biodegradable and biocompatible process.

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### External routes to Growth

## **Expand Global Treatment Access**

# Expand treatment in USA = Grow the Market

- More physicians trained and waivered
- Increased awareness of treatment
- Reduced barriers to treatment access

### Opioid painkiller dependence in Europe

- 500K plus patient population unrecognised
- Growing awareness of condition

#### Clinical trials for Suboxone in China

# **Inorganic Growth Strategy**

### **Business Development in Addiction**

- More than 70 compounds in addiction tracked
- Will bring assets in house at opportune time

### Adjacencies where our model works

- Focus on disease space where we add value
  - Intensive market development
  - Behavioural modification focus
  - Sticking to our knitting

Transformative M&A not on radar



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# Financial Guidance for 2016

	2015 Indivior Guidance	2016 Indivior Guidance
Net Revenue \$m	990-1010	945-975
Operating Margin %		>30%
Net Income \$m*	215-225	155-180

<sup>\*</sup>Excluding Exceptionals

- No material change in current market conditions;
  - ✓ no deterioration in generic tablet pricing;
  - ✓ limited impact of branded competition
  - ✓ no generic film entry in 2016.
  - ✓ modest loss of US share due to formulary changes & managed Medicaid accounts lost in 2015

- Reinvestment of >\$35m of the gross profit above original assumptions in driving innovations:-
  - ✓ Buprenorphine Monthly Depot

At constant exchange rates (to estimated 2015 averages)



# Full Agenda for 2016 will be published on February 18th

Date Activity		Event			
<u>Q1</u>					
Jan 10-14	JP Morgan Conference	Presenting Weds Jan 13th			
Feb 18	FY 2015 Results	Presentation in London			
<u>Q2</u>					
May 3	Q1 Results	Conference Call			
May 4-5	Deutsche Bank Conference	Presentation (Boston)			
May 11	AGM	London			
June 7-10	Jefferies Conference New York	Presentation in New York			
<u>H2</u>					
July 29	Half Year Results	Presentation in London			
Sept 12	Morgan Stanley Conference	Presentation in New York			
Nov 2	Q3 Results	Conference Call			

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