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

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**Chief Executive Officer** 



#### **Forward-Looking Statements**

This presentation contains forward-looking statements. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. 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 three 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.

Any forward-looking statements that we make in this presentation speak only as of the date of this presentation. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this presentation.





# **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



## Suboxone Disclaimer

#### **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 physicians qualified under the Drug Addiction Treatment Act.

IMPORTANT SAFETY INFORMATION.

PLEASE READ THE FULL SAFETY INFORMATION IN THE HARD COPY OR ON THE WEBSITE LISTED BELOW.

For more information about SUBOXONE Sublingual Film or SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet (CIII), please see <u>full Prescribing Information</u> and <u>Medication Guide</u> <u>at www.SuboxoneFilmREMS.com</u>.



## Indivior PLC – Five Value Drivers

#### 1. Addiction is a growing epidemic worldwide

- Over 145m people worldwide are addicted to opioids, alcohol, cocaine, methamphetamine, cannabis
- Structurally growing market
- Increasing recognition that every \$1 spent on treatment saves \$12 in healthcare and societal costs



# Addiction – A Growing Global Epidemic



- 230m people worldwide use illicit drugs <sup>1</sup>
- 122m people worldwide dependent on alcohol (and under-reported)<sup>2</sup>
- More than 25m people worldwide dependent on illicit drugs (and underreported)<sup>3</sup>
- 23m people worldwide dependent on opioids (and under-reported)<sup>3</sup>
- 39 Deaths per 100,000 population due to alcohol and drug use – implies >2.5m global deaths a year <sup>4</sup>



## Government & Payors have a clear economic opportunity

For every



spent on a patient in treatment

Society saves up to



in funding the costs of healthcare and other societal costs\*



# But market development is at different stages around the world

#### Drug Policy & Regulatory Environment

	<b>01</b> Illegal	<b>02</b> Harm Reduction	<b>03</b> Recognised Disease	<b>04</b> Legitimised Disease
USA & Australia	a •••••••••		••••••	····›>
EU	••••••	>>>		
RoW	• • • • • • • • • • •	••>		



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

The market in the USA has grown beyond expectations US market size by mg

2,500

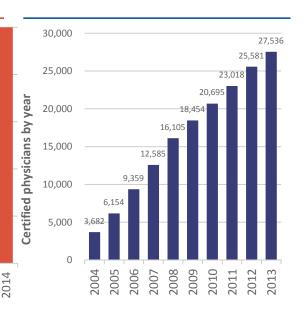
2,000

1.500

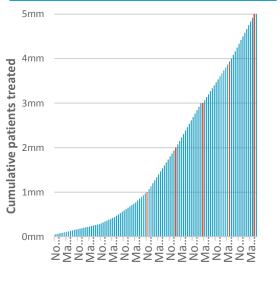
1.000

500

...Supported by a consistent growth in certified physicians



5mm+ patients have received treatment through Suboxone therapy (tablets & film)...





2007

2008 2009 2010

2006 2005



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#### 2.Indivior is Global Leader in Addiction Treatment

- Unrivalled experience and reputation
- At least 12 years ahead of competition

## Indivior: Global Leader in Addiction

Year to Dec 31st	2014 \$m	2015 Guidance
Net Revenue	1,115	850-880
Operating Profit <sup>1</sup>	586	
Net Income <sup>1</sup>	403	135-155
EPS (cents per share) <sup>1</sup>	58	

- Operate in over 40 countries globally.
- Suboxone is the leading buprenorphine-based treatment globally
- Indivior was primary developer of market for buprenorphine-based treatment in US since 2003 launch of Suboxone
- Helped to initiate training of >3,000 physicians
- Helped to bring >5m patients into treatment
- Only company with significant direct clinical liaison team working on addiction treatment in US or Europe.



<sup>&</sup>lt;sup>1</sup> excluding \$24m exceptional items related to the demerger

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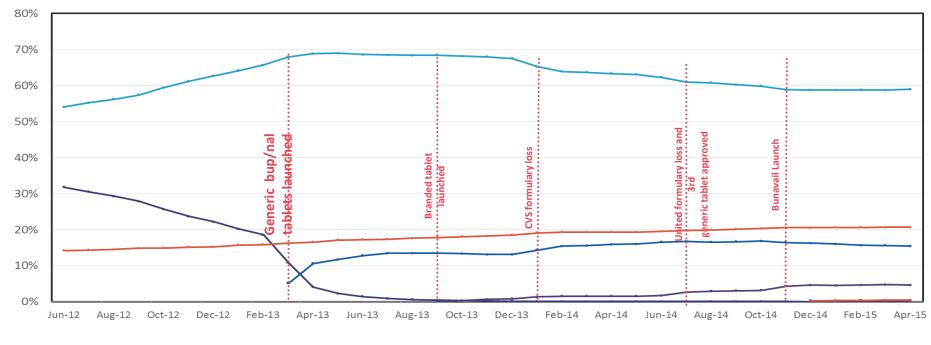
#### 3. Sustainable franchise with existing products

- Suboxone Film resilient in face of growing competition from generic tablet and other brands
- Multi-layered IP protection to 2030



## Competition is intensifying, but Suboxone Film share has been resilient





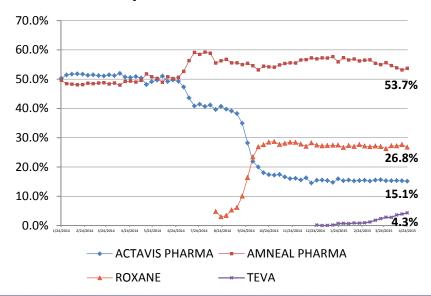




## **Update on Competition**

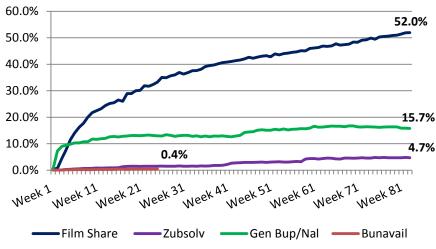
Now 4 Generic Tablet competitors on the market

### **BUP/NAL SHARE BY MFR**



#### Branded competitors not making much impact

#### **Launch MG Share**





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#### 4. Several Levers for Future Growth

- Pipeline of innovative products to improve patient and physician outcomes
- Business development and M&A
- Global expansion



# An innovative pipeline to improve patient/physician 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 film	• • • • •	• • • • • •	USA LAU	INCHED >		Can V		China 🗸		
Buprenorphine Monthly Depot	• • • • • •	• • • • • •	·>				<b>✓</b>	EU 🗸		
Oral swallowable tablet	• • • • • •	>						<b>✓</b>		
Overdose Rescue Products										
Nasal Naloxone	• • • • • •	• • • • • •	•••••			<b>✓</b>				
Cocaine Overdose	• • • • • •	•>							<b>V</b>	
Alcohol Use Disorders										
Arbaclofen Placarbil	• • • • • •	•>								<b>✓</b>
Adjacency - Schizophrenia										
Risperidone	• • • • • •	• • • • • •	····>				<b>✓</b>			

# Pipeline Update – all key targets achieved since November

- RBP-6000 monthly depot buprenorphine
  - Phase 3: RB-US-13-0001: first patient randomized in Q1 2015
- Intranasal naloxone for the treatment of opioid overdose
  - Fast Track Designation granted Q3 2014
  - Pre-NDA meeting with FDA Q4 2014
  - NDA submission May 2015
- RBP-8000, a cocaine esterase for the treatment of cocaine intoxication
  - Breakthrough Therapy Designation granted by the FDA in Q4 2014
  - Type B meeting with the FDA May 2015
- Arbaclofen placarbil a novel transported prodrug of R-baclofen

Pre-IND meeting with FDA occurred Q1 2015: IND submitted by end June 2015

- Risperidone Monthly Depot
  - compelling Phase III results announced 5/5/2015: long term safety study currently ongoing



# Business Development / M&A

# Business Development in Addiction

>70 compounds in addiction identified and tracked

Will bring assets in-house at most opportune time

Strong track record delivering such deals at low initial capital cost

- Atrigel Technology 2008
- Cocaine Esterase 2008
- Anti-Op (Nasal Naloxone) 2014
- Arbaclofen Placarbil 2014

# Adjacencies where Our model works

Focus on disease spaces where we can add value

- Intensive market development model
- Behavioural modification focus
- Sticking to our knitting

### **Transformative M&A**

Not on our radar for the foreseeable future

- Build a track record
- Secure more favourable funding platform



# **Global Expansion**



### **Expand Global Access to Treatment**

- 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 today unrecognised
  - Greater awareness of condition.
- Clinical trials for Suboxone tablet in China
- Work on widening access to treatment in more markets



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# 5. Strong, experienced, stable management team

- Excellent track record
- 60 Years of Cumulative Experience



# Strong, Experienced Management Team























Cumulatively 60 years experience at Indivior

The core of the team that built up Indivior's US business 2003-12

Also a powerful Board with more than 200 years of collective experience in Pharma

## Summary

## The leading global company in the growing epidemic of addiction

- 230m people worldwide abusing drugs, 122m dependent on alcohol
- Indivior has the leading portfolio of existing and future treatments
- Indivior is the only company working to expand access to treatment

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

- Suboxone Film is demonstrating resilience in US market
- Confident that it will fund the business model pipeline, business development and M&A

### Consistent progress in developing the levers of future growth

- Pipeline of innovative products to improve patient and physician outcomes
- Business Development and M&A to widen business coverage

A management with the experience and capabilities necessary to deliver the future



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Treatment should be initiated under the direction of physicians qualified under the Drug Addiction Treatment Act.

#### **IMPORTANT SAFETY INFORMATION**

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

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

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

SUBOXONE Sublingual 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 Sublingual Film.

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

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

Your doctor may monitor liver function before and during treatment.

SUBOXONE Sublingual Film is not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. However, SUBOXONE Sublingual 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 Sublingual Film out of the sight and reach of children. Accidental or deliberate ingestion of SUBOXONE Sublingual Film by a child can cause severe breathing problems and death.

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

Injecting SUBOXONE may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

Before taking SUBOXONE Sublingual Film, tell your doctor if you are pregnant or plan to become pregnant. If you are pregnant or become pregnant while taking SUBOXONE Sublingual Film, alert your doctor immediately and you should report it using the contact information provided below.\*

Neonatal withdrawal has been reported following the use of buprenorphine by the mother during pregnancy.

Before taking SUBOXONE Sublingual Film, talk to your doctor if you are breastfeeding or plan to breastfeed your baby. SUBOXONE can pass into your breast milk. You and your doctor should consider the development and health benefits of breastfeeding along with your clinical need for SUBOXONE Sublingual Film and should also consider any potential adverse effects on the breastfed 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 Sublingual Film affects you. Buprenorphine in SUBOXONE Sublingual Film can cause drowsiness and slow reaction times during dose-adjustment periods.

Common side effects of SUBOXONE Sublingual 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 Sublingual Film. Please see <u>full Prescribing Information</u> for a complete list.

\*To report negative side effects associated with taking SUBOXONE Sublingual Film, please call 1-877-782-6966. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

For more information about SUBOXONE Sublingual Film or SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet (CIII), please see <u>full Prescribing</u> Information and Medication Guide at <u>www.SuboxoneFilmREMS.com</u>.

