

Strengthening our global leadership in treatment of addiction

Jefferies 2017 Global Healthcare Conference
June 6th, 2017



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 2017 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation.

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Why Indivior?

- 1 Targeting a global epidemic – addiction and its co-morbidities
- 2 Building on leading Buprenorphine Medication-Assisted Treatment (BMAT) position to develop and commercialize novel, break-through addiction treatments
- 3 Generating strong profitability and cash flow today with future 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

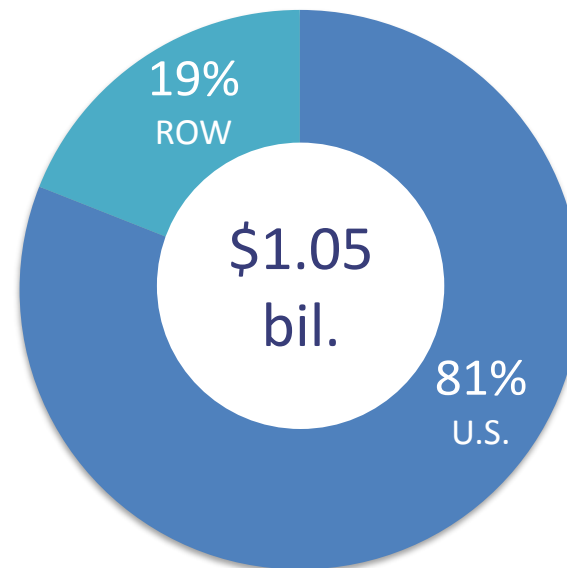
40

Countries of presence

965

Employees worldwide

2016 Sales by Geography ⁽²⁾



(1) 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



Addiction

The scale of the problem



OUR VISION

For all **patients** around the **world** to have **access** to **quality treatment** for the chronic relapsing **condition** and **co-morbidities** 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.



91 ⁽¹⁾
AMERICANS

die every day from
an **opioid overdose**
(that includes prescription
opioids and heroin).

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



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: <http://www.civilaviation.eu/Embraer/EMB-170>

⁽³⁾ globalnews.ca/news/2932561/shocking-photos-of-ohio-overdose-victims-problematic-say-addiction-experts



The U.S. Represents a Tremendous Growth Opportunity

Largest Market ⁽¹⁾

- 80% of world's opioid users
- 300 million pain prescriptions written in 2015 worth \$24 billion

Conducive Policy ⁽²⁾

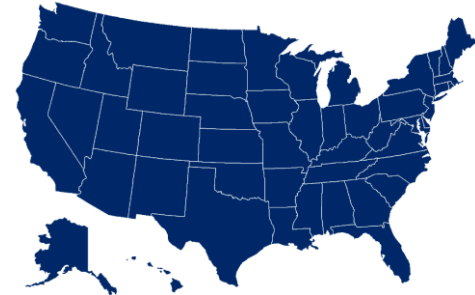
- Medication-assisted treatment (MAT) endorsed by U.S. government
- CARA legislation and CURES Act increased addiction resources

Growing Capability ⁽³⁾

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

Strong Franchise

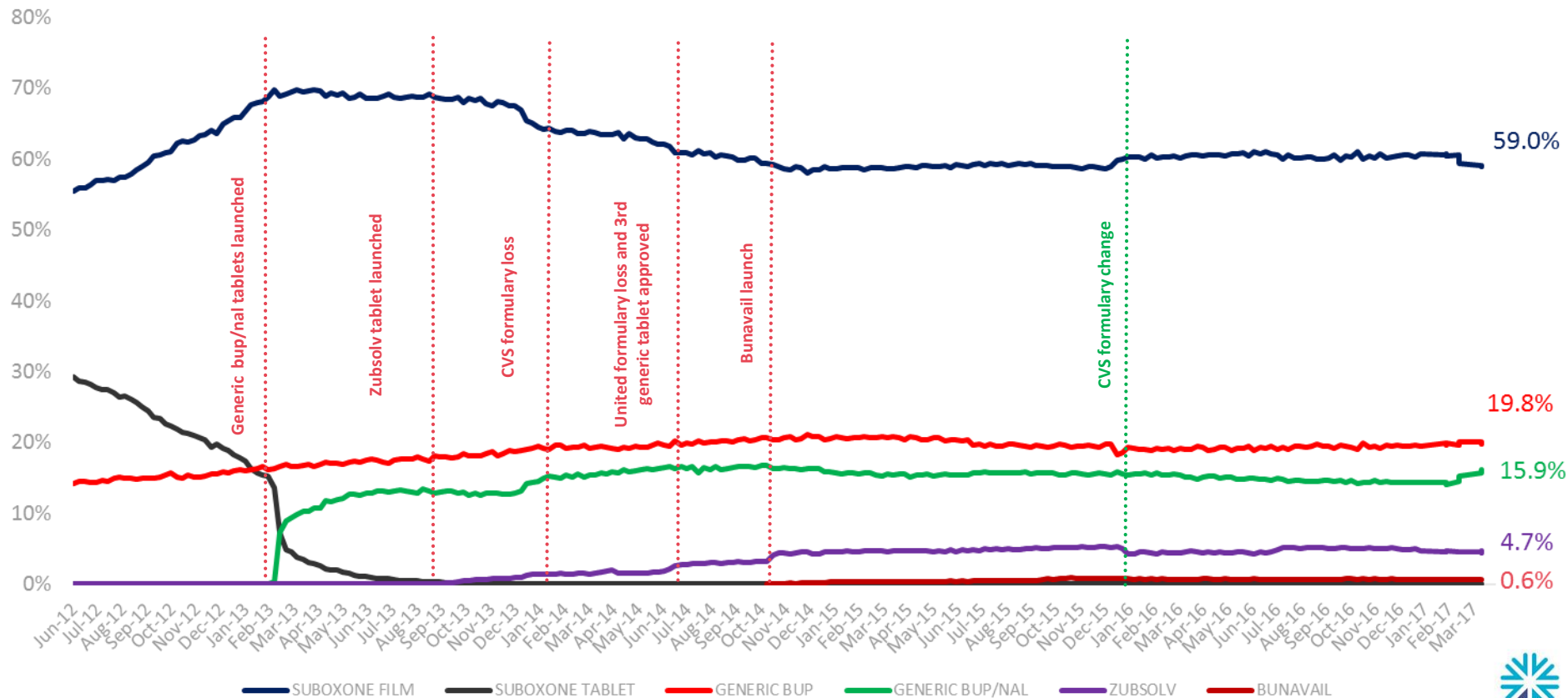
- 200+ Clinical Liaisons
- Nationwide coverage



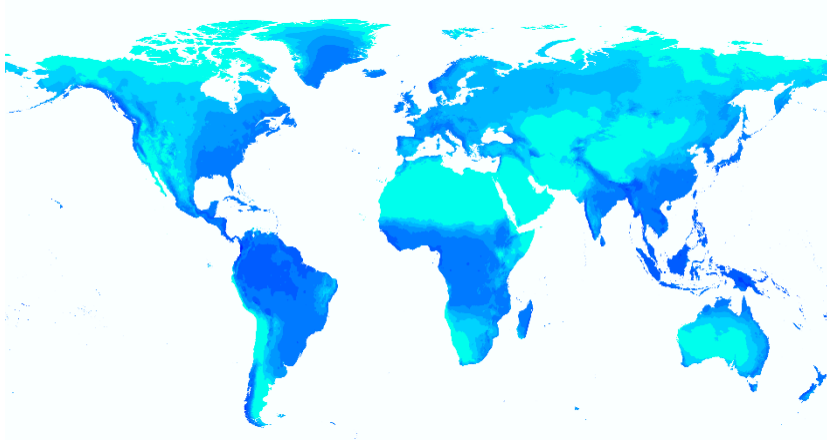
(1) December 9, 2014 Express Scripts report; <http://path-consult.com/wp-content/uploads/2013/08/April-2017.pdf>
(2) <http://www.npr.org/sections/health-shots/2017/05/16/528614422/prices-remarks-on-opioid-treatment-were-unscientific-and-damaging-experts-say>
(3) CARA legislation expands treatment availability; DEA report of waived HCPs December 2016



Film Share Remains Resilient



Ex-US Markets in Earlier Stage of Development



EU (>1 mil. problem opioid users) differs from US as opioid-dependence 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 (~7 mil. opioid dependent including 1.4 mil. registered drug users) the largest potential market – a strategic target for Indivior
- ✓ Australia a well developed market 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⁾			
	Phase 1	Phase II	Phase III	NDA	Efficacy	Safety	Launch	Peak Net Rev. Forecast ⁽²⁾
Buprenorphine Lifecycle								
RBP-6000	<i>Fast Track Designation 5/23/16</i>			Submitted	✓ Ph. III Achieved primary & secondary endpoints	✓ Ph. III	Q1 2018	≥\$1 bil.
Schizophrenia								
RBP-7000				Q4 2017 ⁽¹⁾	✓ Ph. III Achieved primary & secondary endpoints	✓ Ph. III	Q4 2018	\$200 to \$300 mil.
Alcohol Use Disorders								
Arbaclofen Placarbil	Completed Phase 1 Bioavailability Study							\$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 Opioid Use Disorder

Unmet Patient Needs

>2.5 mil.

patients diagnosed
with OUD in the US ⁽¹⁾

<50%

of diagnosed
patients receive
any MAT ⁽¹⁾



RBP-6000 Treatment

What: Once monthly buprenorphine depot injection in the Atrigel[®] delivery system

Where: U.S., initially

When:⁽²⁾ NDA submitted, priority review requested, Q417 approval estimated

(1) [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](#)

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



Objective: Address What We Believe the Current Unmet Medical Needs are in BMAT

- 1 Sustained plasma levels of buprenorphine that translate into high μ -opioid receptor occupancy to suppress withdrawal symptoms and block the subjective and objective effects of opioid agonists
- 2 Once-monthly buprenorphine delivery that is consistent across the entire 1-month period
- 3 Make abuse and diversion difficult
- 4 Enhance compliance/adherence to treatment
- 5 Monthly decisions (12/year) rather than daily decisions (365/year)



Key Phase 3 Asset: RBP-7000 for Schizophrenia

Unmet Patient Needs

23 mil.

People worldwide affected by schizophrenia ⁽¹⁾

76%

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



RBP-7000 Treatment

What: Once monthly Risperidone in Atrigel[®]

Where: U.S.

When:⁽³⁾ Targeting Q417 NDA; anticipate Q418 approval

(1) 2016 Indivior Annual Report, page 19

(2) <https://www.ncbi.nlm.nih.gov/pubmed/26075492>

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



Objective: Address What We Believe the Current Unmet Needs are in Long Acting Antipsychotics

We believe that the following characteristics are potential differentiating attributes for future LAIs treating psychosis⁽¹⁾:

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

⁽¹⁾ Based on prescribing Information for RISPERDAL® CONSTA®, INVEGA SUSTENNA®, and ARISTADA®, Section 2 Dosage and Administration

LITIGATION UPDATE

Major Litigation

The Group carries a provision of \$218m for the investigative and antitrust litigation matters noted below. 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 we will reach 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 reserve.

DOJ & State Subpoenas ⁽¹⁾

FTC Investigation & Antitrust Litigation ⁽¹⁾

ANDA Litigation & Inter Partes Review ^{(1) (2)}

- (1) See Q1 2017 Results Announcement Published May 3th, 2017, pgs. 5 to 7 for a description of Litigation developments through the indicated date.
- (2) In relation to the petition by Mylan seeking an Inter Partes Review (IPR) of the Orange Book patent No. 8,603,514 for Suboxone® Film, the U.S. Patent Trial and Appeal Board (PTAB) on May 12th, 2017, determined that Mylan demonstrated a “reasonable likelihood” that certain claims of patent No. 8,603,514 are invalid for obviousness and therefore instituted an IPR proceeding. The PTAB scheduled a hearing for January 10th, 2018. It is expected that the final decision regarding the validity of the challenged claims should be issued no later than May 12th, 2018.



PRIORITIES FOR 2017

Guidance for 2017

	2017 Guidance	vs.	2016
Net Revenue	\$1,050 to \$1,080 mil.		\$1,058 mil.
Net Income (adjusted)	\$200 to \$220 mil.		\$254 mil.

Assumptions

- **No material change in current market conditions**
 - ✓ No major deterioration in generic tablet pricing
 - ✓ limited impact of branded competition
 - ✓ no generic film entry in 2017
 - ✓ modest loss of US share due to new competition & some managed Medicaid accounts lost in 2016/2017
- ✓ At constant exchange
- ✓ Excluding exceptional items
- **Investment of \$40 to \$60 mil. in driving long-term organic growth**
 - ✓ Preparing for the launch of RBP-6000 Monthly Depot of buprenorphine on its approval
 - ✓ Expanding access to treatment in US market following regulatory/legislative changes in 2016
 - ✓ Preparing for the launch of RBP-7000 Monthly Depot of risperidone on its approval



Q1 2017 Highlights

Financial Highlights ⁽¹⁾

	Reported	
(In \$m, except EPS)	<u>2017</u>	<u>Y/Y</u>
		(Δ%)
Net Revenue	265	3%
Operating Profit	128	26%
Net Income	80	61%
Diluted EPS (c)	11	59%
Cash	729	34%
Net Cash /(Debt)	182	<-150%

Operational Highlights ⁽¹⁾

- Support for medication-assisted treatment (MAT) continues to grow
- US market growth low double digits
- List pricing was up, but was offset by tactical rebates
- Suboxone[®] Film share remains resilient
- Newly certified prescribing physicians continue to grow

- Confirmed FY 2017 Guidance -



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 filing NDAs in 2017

- 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

US Listing process suspended temporarily but work continues



Agenda for 2017

Date	Activity	Event
<u>Q2 ending June 30th</u>		
June 29th	RBP-6000 Conference Call	RBP-6000 Phase III efficacy, safety & HEOR data
<u>Q3 ending September 30th</u>		
July 27 th	Half Year 2017 Financial Results	Presentation in London (webcast live)
Sept	Morgan Stanley Healthcare Conference	Presentation in New York City (webcast live)
Sept 25th - 27th	ANDA trial for Alvogen and Mylan	Trial on patent infringement of certain SUBOXONE® Film patents
<u>Q4 ending December 31st</u>		
October	ACoP Conference	RBP-6000 Phase III Exposure/Response Data
Nov 2nd	Q3 2017 results	Conference Call
Nov	Jefferies Healthcare Conference	Presentation in London (webcast live)
Q4	RBP-7000	NDA submission
Q4	PDUFA date for RBP-6000	Assuming “Priority Review” is granted by FDA



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 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 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.

Strengthening our global leadership in treatment of addiction

