

Strengthening our global leadership in treatment of addiction

Half Year Results 2016
July 29th 2016



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 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 2016 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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AGENDA

Cary Claiborne

Financial Review

- Profit & Loss Account
- Cash Flow
- Balance Sheet

Revised Guidance for 2016

Javier Rodriguez

Litigation Update

Christian Heidbreder

Pipeline Update

Shaun Thaxter

The future

Question & Answers



Half Year Highlights

Financials Above Plan

- NR \$531m
- Op Profit \$198m
- Net Income \$107m
- EPS 15c
- Cash \$577m
- Net Debt (\$5m)

Operationally Strong

- US market growth in mid to high single digits
- Second consecutive quarter of net revenue growth in USA
- Suboxone® Film share at 61% slightly ahead year to date.
- Resilience underlined by ANDA litigation result

Pipeline Continuing Progress

- Buprenorphine Monthly Depot Phase 3 trial efficacy top-line results due Q3
- Risperidone Monthly Depot – safety extension results due Q4.
- Arbaclofen Placarbil for alcohol use disorder – cap target dose well tolerated but some individual variability in PK levels observed

Guidance for Full Year Raised
NR guidance increased by at least 5%,
Net Income guidance increased by at least 10%



What we said in February...

Basis for Guidance for 2016

- **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**
- **Estimated Tax charge of 25% + \$19m exceptional tax charges**

What we are saying now

Current Assumptions for 2016

At the moment, the market trends continue

- Some slight deterioration in Generic tablet pricing
- No major change in market share for Suboxone Film
- No major increases in rebating levels to retain formulary

But some cautions for H2.

- Existing generic discounts could move further and faster
- Launch of more generics possible
- Additional competitor in Probuphine now on market

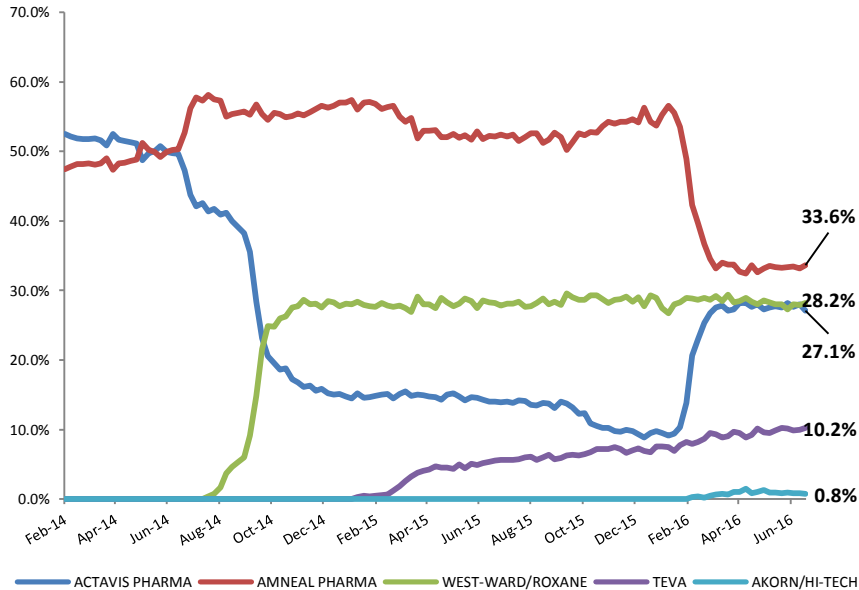
Increased legal expenses associated with litigation/investigations

We will update at Q3 results on 2nd November.



So has anything changed?

Generic Bup/Nal Tablet : Market Share

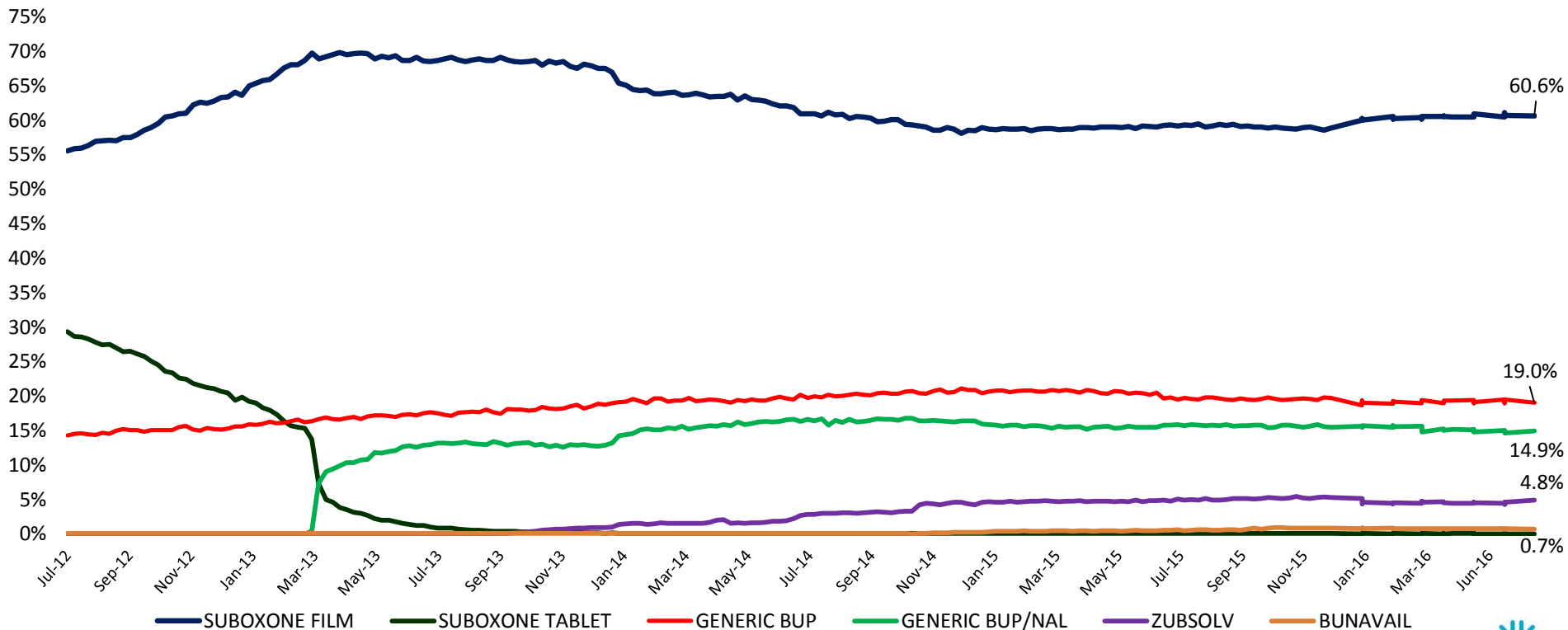


No major shift in discounts since Q1 2016

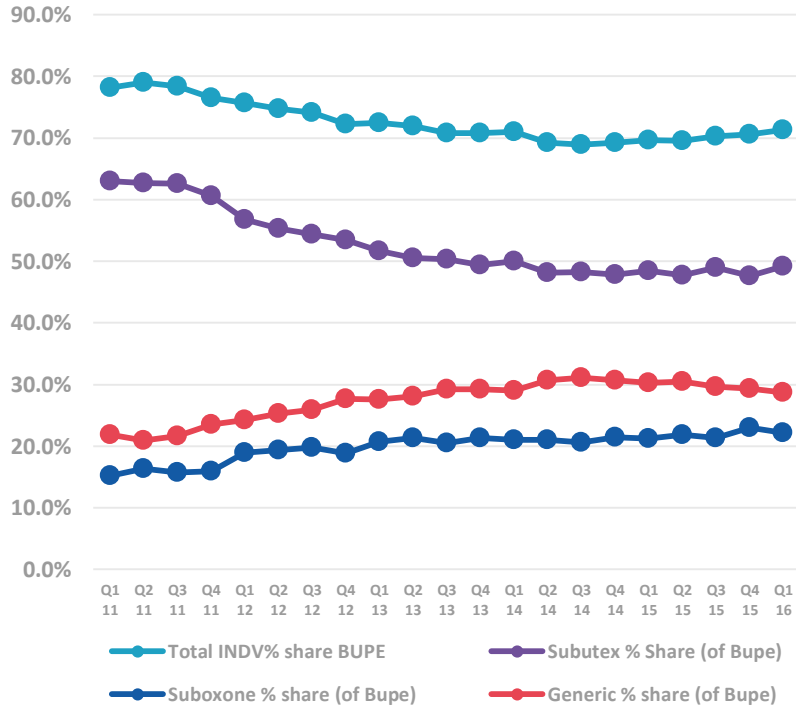
- Teva continue to build up their share of the generic market
- Akorn/Hi-tech making relatively little impact so far
- Other generic company shares have stabilised now.



Competition is intensifying, but Film share has been resilient



Europe



European share performance continues to be extremely resilient

Market growth – austerity measures a drag

- Price gaps versus generics are a challenge in some markets

Opioid Painkiller Dependence market remains an opportunity long-term

- Challenges remain to accessing the opportunity
- Trials continuing but too early to report any results



Cary Claiborne

Chief Financial Officer



P&L

Half Year Ended 30 th June: Unaudited	2015 Reported	2015 Adjusted	2016 Reported	% change	2016 Adjusted	% change
\$m						
Net Revenues	517	517	531	+3	531	+3
Cost of Sales	(48)	(48)	(43)		(43)	
Exceptional items	-	-	(10)			
Gross Profit	469	469	478	+2	488	+4
<i>Gross Margin</i>	91%	91%	90%		92%	
Selling, Distribution and Administration Expenses	(180)	(180)	(217)	+21	(217)	+21
Research & Development Expenses	(54)	(54)	(59)	+9	(59)	+9
Exceptional items	(5)		(4)			
Profit on Ordinary Activities before interest & taxation	230	235	198	-14	212	-10
<i>Operating Margin</i>	44%	45%	37%		40%	
EBITDA	242	247	210	-13	224	-9
Net interest	(31)	(31)	(26)	-16	(26)	-16
Taxation	(55)	(54)	(51)	+18	(51)	-9
- Exceptional tax item within taxation line above			(14)			
<i>Effective Tax Rate</i>	28%	26%	38%		27%	
Net Income	144	148	107	-26	135	-9



Q1 & Q2 Trend – Adjusted (excludes exceptionals)

(%Δ at constant exchange: *numbers may not aggregate due to rounding)

\$m	Q1*	% Δ	Q2*	% Δ	HY	% Δ
Net Revenue	258	+4	274	+3	531	+3
Gross Profit (% margin)	237	(92%)	251	(92%)	488	(92%)
SD&A	(105)		(112)		(217)	
R&D	(31)		(28)		(59)	
Exceptional Costs	-					
Operating Profit	101	-12	111	-11	212	-11
<i>Operating Margin</i>	39%		41%		40%	
Finance Expense	(15)		(11)		(26)	
Tax (% rate)	(31)	(36%)	(20)	(20%)	(51)	(27%)
Net Income	55	-35	80	+18	135	-9



Net Revenue – By Region

Net Revenue

\$m	Half Year 2015	Half Year 2016	% Change	% change Const FX
USA	412	433	+5%	+5%
Rest of World	105	98	-7%	-4%
Total	517	531	+3%	+3%

Commentary

USA

- Market growth mid-to-high single digits
- Share gain from 60% to 61%
- Price increase offset by annualising of rebate increases from last year.

Rest of World

- European government driven austerity measures still impacting price.



Operating Expenses

Operating Costs H1 2016

	2015	2016	% ch
SD&A	180	217	+21
R&D	54	59	+9
Exceptional item	5	4	-
<i>Depreciation & Amortisation (included in SD&A)</i>	12	12	-

- SD&A increase driven by ongoing legal costs plus annualised standalone PLC costs (FY \$55m).
- R&D increase with 2 products in Phase 3, but (with projects terminated) full year will not see R&D increase at this % rate.
- Exceptional items cover one off legal & advisory costs for strategic initiatives put in place to prepare against possibility of negative outcome in ANDA litigation

Margins

H1	2015 Adjusted	2016 Adjusted	2016 Reported
Gross margin	91%	92%	90%
Operating margin	44%	40%	37%

- Gross Margin adjusted slightly higher due to sterling weakening against USD and ending of manufacturing royalties paid to Monosol Rx.
- Exceptional items of \$10m for strategic initiatives related to potential negative ANDA ruling included in Cost of Sales.
- Operating margin 4% points down
- Exceptional cost reduced reported margin by further 3%



Tax Rate

Guidance for rate of 25% in 2016

Plus one-off exceptional tax charge of \$14m

- \$5m in Q1

- \$14m in Q2 less \$5m tax impact on exceptional costs in Cost of Sales and SD&A

Reflects mix of profits between UK and USA

Working progressively towards that guidance

Q1 rate 36%

Plus \$5m exceptional

Q2 rate 20%

Plus Net \$9m exceptional

Half Year rate 27%

Continue to guide towards full year rate of 25%

plus exceptional tax charges



Cash flows

Six months ended 30th June Unaudited

\$m

Cash Flows from Operating Activities

	2015	2016
Operating Profit	230	198
Reversal of non-cash items	(4)	7
Depreciation and amortisation	12	12
Changes in assets and liabilities	82	13
Cash generated from Operations	320	230
Taxes and interest paid	(100)	(47)
Net Cash inflow from Operating Activities	220	183

Cash Flows from Investing Activities

Capex	(8)	(13)
Purchase of intangible assets	(4)	-
Net Cash outflow from Investing Activities	(12)	(13)

Free Cash Flow	208	170
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Net proceeds from financing activities	(16)	(60)
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Cash Flows from Financing Activities

Net transfers to owners		
Net Cash from Financing Activities	(16)	(60)
Net (decrease)/increase in cash and cash equivalents	192	110
Cash and cash equivalents at beginning of year	331	467
Cash and cash equivalents at end of year	523	577



Cash Conversion

Six months ended 30th June:

\$m

Cash Flows from Operating Activities

	2015	2016
Operating Profit	230	198
Reversal of other non-cash items	(4)	7
Depreciation and amortisation	12	12
Changes in assets and liabilities	82	13
Cash generated from Operations	320	230
Loan expenses and taxes paid	(100)	(47)
Net cash inflow from operating activities	220	183
Net Cash Flow as % of Operating Profit	96%	92%

Cash conversion continued strong

Net working capital release of cash not as strong as First Half last year which benefited from timing of payments.



Balance Sheet

\$m	2015 Full Year	Unaudited 2016 Half Year
Intangible Assets	62	49
Other non-current Assets	154	153
Total Non-Current Assets	216	202
Cash and Cash Equivalents	467	577
Other current assets	254	294
Total Current Assets	721	871
Total Assets	937	1,073
Short-term Borrowings	(34)	(47)
Other Current Liabilities	(569)	(649)
Total Current Liabilities	(603)	(696)
Borrowings (non-current)	(571)	(504)
Provisions for liabilities and charges	(42)	(40)
Total Non-Current Liabilities	(613)	(544)
Total Liabilities	(1,216)	(1,240)
Net Liabilities	(279)	(167)
Total Equity	(279)	(167)



Cash & Borrowing Position at Half Year

	Full Year 2015	Half Year 2016
Cash & Cash Equivalents	467	577
Current Borrowings	(34)	(47)
Long-term Borrowings	(571)	(504)
Other	(36)	(31)
Net Debt	(174)	(5)

- Second interim dividend totalling \$68m for 2015 payable in July

Net Debt of **\$5m** at half year, improvement of \$169m in the period due to strong cash in-flow.*

After repurchase of additional \$46m of debt in the period in open market at discount.

Retaining cash on balance sheet at present

- Flexibility on business development
- Flexibility on corporate debt/cash structure

* Note 6 in the H1 2016 Financial Results shows net debt including debt issuance costs.



Guidance for 2016

	Previous Guidance	Delta	New Guidance
Net Revenue	\$945m - \$975m	\$25m - \$55m	\$1,000m-\$1,030m
Net Income (adjusted)	\$155m - \$180m	\$20m-\$25m	\$180m-\$200m

Guidance is based on

- **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
- **Excluding Exceptional Items (\$14m year to date)**
- **At constant exchange rates (to estimated 2015 averages)**
- **Estimated tax charge of 25% plus exceptional tax charges**



Javier Rodriguez

Chief Legal Officer



ANDA Litigation

- The ruling after trial against **Actavis** and **Par** in the lawsuit involving the Orange Book-listed patents for Suboxone® Film issued on June 3rd, 2016. Ruling found the asserted claims of the '514 patent valid and infringed; the asserted claims of the '150 patent valid but not infringed; and the asserted claims of the '832 patent invalid, but found that certain claims would be infringed if they were valid.
- Based on the ruling as to the '514 patent, **Actavis** and **Par** are currently enjoined from launching a generic product. Par has appealed and Actavis is expected to appeal this ruling. The generics have also moved to reopen the judgment based on a more stringent claim construction in the Teva case, which is expected to deactivate the appeals until the District Court rules on the motions to reopen the judgement..
- Trial against **Teva**, **Actavis** and **Par** in the lawsuits involving the recently granted process patent (US Patent No. 8,900,497) scheduled for November 2016.
- Trial against **Teva** in the lawsuit involving the Orange Book-listed patents for Suboxone® Film scheduled for November 2016, with Teva's 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17th, 2017. Indivior believes Teva's 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17th, 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 the '497 process patent for Suboxone® Film scheduled for April 2017, with Alvogen's 30-month stay of FDA approval expiring October 29th, 2017.
- Trial against **Mylan** and **Sandoz** in the lawsuit involving the Orange Book-listed patents for Suboxone® Film is scheduled for September 25th, 2017, with Mylan's stay expiring March 24, 2018 and Sandoz's stay expiring April 2, 2018. There is also a second, stayed lawsuit between the Company and Mylan in the Northern District of West Virginia
- Indivior received a Paragraph IV notification from **Teva**, dated February 8, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of Buprenorphine/naloxone sublingual film. The Indivior Group and Teva agreed that infringement by Teva's 16 mg/4 mg dosage strength will be governed by the infringement ruling on the accused 8 mg/2 mg dosage strength in its ANDA currently scheduled for trial in November 2016.
- The USPTO declined to institute **Teva's** petitions for inter partes review of the three Orange Book-listed patents on procedural grounds.
- **Dr. Reddy's** has filed an inter partes review petition on each of the three Orange Book Patents. These petitions are substantively similar to those filed by Teva.



FTC Investigation

The Judge overseeing the legal privilege dispute in the FTC investigation has appointed a Special Master (an independent external lawyer) to investigate the claims of legal privilege and provide a recommendation to the Court on how the documents at issue should be treated. An initial report and recommendation relating to the first tranche of privileged documents reviewed by the Special Master was finalized in April 2016. The Court will determine whether to adopt the Special Master's recommendations in whole or in part, at which point the parties will work with the Special Master to implement procedures for the Special Master to review the remaining documents at issue. Ultimately the Court's determinations regarding the privilege status of the documents at issue may be subject to appeal in the United States Court of Appeals by either party.

Class Action Antitrust Litigation

- Fact discovery is continuing in the Class Action litigation.
- In August 2015, the Company was informed that a contingent of additional states has initiated a coordinated investigation into the same conduct that is the subject of the FTC investigation and the Class Action litigation. The existing investigation of these same issues by the State of New York has now been incorporated within this multi-state investigation. On July 1, 2016, Indivior Inc. was notified that 22 states and the District of Columbia intend to file a complaint in the Eastern District of Pennsylvania alleging violations of state and federal antitrust and consumer protection laws relating to the same conduct. The notice indicated that additional states may decide to join in any action, and more recently the Company has learned that additional states do intend to join.
- Amneal Pharmaceuticals LLC, a manufacturer of generic buprenorphine / naloxone tablets, has joined the class action litigation as an additional plaintiff. Amneal's complaint contains antitrust allegations similar in nature to those set out in the class action complaints, and Amneal has also alleged violations of the Lanham Act



Department of Justice Investigation

A federal criminal grand jury investigation of Indivior initiated in December 2013 is continuing, and includes marketing and promotion practices, pediatric safety claims, and overprescribing of medication by certain physicians. The U.S. Attorney's Office for the Western District of Virginia has served a number of subpoenas relating to SUBOXONE Film, SUBOXONE Tablet, SUBUTEX Tablet, buprenorphine and our competitors, among other issues. We are in the process of responding by producing documents and other information in connection with this ongoing investigation. It is not possible at this time to predict with any certainty or to quantify the potential impact of this investigation on us. We are cooperating fully with the relevant agencies and prosecutors and will continue to do so.

BDSI Litigation

Briefing is complete in Indivior's appeal of the Patent Trial and Appeal Board's (PTAB) decision in the *Inter Partes Review* of claims 15-19 of Indivior's US Patent No. 8,475,832 (the '832 Patent) for Suboxone® Sublingual Film. The Court of Appeals for the Federal Circuit has not yet set a date for oral argument. Oral argument is set for August 3, 2016.



Christian Heidbreder

Chief Scientific Officer

The Pipeline

update

SUBOXONE® Tablet

Canada: Additional Dosage Strengths

- *Meeting with Health Canada (HC):* Confirmation that bioequivalence criteria were met for the proposed 12mg/3 mg and 16 mg/4 mg dosage strengths.
- NDS submission plans ongoing.

China: NDA preparation & submission

- *Efficacy Study (RB-CN-10-0013):* Completed with Clinical Study Report signed in June 2016.
- *Planned NDA submission:* Q4-2016.



OPIOID USE DISORDER: RBP-6000 (PHASE III)

Clinical

- *Phase III Efficacy & Safety trial (RB-US-13-0001)*: Database locked July 13th, 2016. On track to deliver topline results before end of Q3-2016.
- *Phase III Long-Term Safety trial (RB-US-13-0003)*: Last Patient First Visit April 2016. On track to deliver database lock in Q1-2017.

Regulatory

- *Fast Track Designation*: Granted May 23rd, 2016.
- *Planned NDA submission (pending outcome of pre-NDA meeting)*: Q2-2017.



RESCUE MEDICATION FOR DRUG OVERDOSE/INTOXICATION

Intranasal Naloxone for Opioid Overdose

- *Temporary Authorization for Use (ATU):* Approved by French ANSM on Nov 5th, 2015. Live July 26th, 2016.



ansm
Agence nationale de sécurité du médicament
et des produits de santé

RBP-8000: Cocaine Esterase for Cocaine Intoxication (Phase II)

- *Breakthrough Therapy Designation:* Granted October 17th, 2014.
- *Second Type B meeting with the FDA:* Mar 16th, 2016.
- Clinical development plans under review.



ALCOHOL USE DISORDER: ARBACLOFEN PLACARBIL (PHASE IIA)

- **Phase IIA trial (RB-US-14-0001):**
 - ✓ Arbaclofen Placarbil found to be safe & well tolerated to doses up to 240mg (cap) in controlled abstinence setting.
 - ✓ High inter-individual PK variability with increased doses.
- New formulation development and additional clinical studies will be required to mediate safety risk prior to further outpatient studies in AUD patients.
- Clinical development plans under review.



SCHIZOPHRENIA: RBP-7000 (PHASE III)



J. Clin. Psychopharmacology 36(2):130-140. <http://dx.doi.org/10.1097/JCP.0000000000000479>

- **Phase III efficacy trial (RB-US-09-0010):** Efficacy, safety, and tolerability of RBP-7000 (90, 120 mg) compared to placebo in subjects with acute exacerbation of schizophrenia over an 8-week period.
- Efficacy evaluated as a change from baseline to EOS in Positive and Negative Syndrome Scale (PANSS) total score (*primary endpoint*) and Clinical Global Impression – Severity (CGI-S) score (*secondary endpoint*).
- RBP-7000 significantly reduced PANSS total scores and significantly improved CGI-S scores. Both RBP-7000 dosages were well tolerated.



Schizophr. Res. 174(1-3): 126-131. <http://dx.doi.org/10.1016/j.schres.2016.03.020>

- **Phase III efficacy trial (RB-US-09-0010):** Health-Related Quality of Life (HRQoL) data derived from pivotal Phase III trial.
- Significantly greater improvements in HRQoL and overall well-being were demonstrated in patients randomized to RBP-7000 vs. placebo.
- Patient satisfaction improved significantly and patient preference for their medicine favored RBP-7000 90 mg and 120 mg vs. Placebo.



SCHIZOPHRENIA: RBP-7000 (PHASE III)

Clinical

- *Long Term Safety trial (RB-US-13-0005):* On track with Last Patient Last Visit expected in August 2016.

Regulatory

- *Pre-NDA Meeting with FDA:* August 2016.
- *Planned NDA submission (pending outcome of pre-NDA meeting):* Q4-2017.



NEW R&D CENTRE OF EXCELLENCE (HULL, UK)



New cross-functional R&D facility that will support Indivior's Vision and Mission

Building is expected to be water tight by early October 2016, and anticipated to be handed over to Indivior within Q2-2017, ahead of schedule, to allow exit of RB TSA by end of Q4-2017



INDIVIOR R&D DAY - DECEMBER 2016

- New York – venue to be announced
- Invitations to be sent out in September/October
- We aim to live webcast for those who cannot travel to New York.



Shaun Thaxter

Chief Executive Officer



The Future

Indivior PLC – Priorities for 2016

Resolve ANDA litigation and secure long-term certainty for Company



1. Suboxone Film Resilience

Preserve leadership position in USA against 5 generic and 3 branded competitors

2. Develop the pipeline

- Transformational lifecycle products for Buprenorphine
- Treatments for other addictions and addiction rescue

3. Finance ready for BD / M&A

- Expand business
- diversify business risk

through targeted business development

US Listing process under way

4. Expand Global treatment

- New treatment areas of addiction and related morbidities
- Expand treatment access in USA
- Opioid painkiller dependence in Europe
- File NDA in China



Cost Saving Initiative 2016

2014-2016 Building fit-for-purpose as PLC

First priority was to get it right

- separation from RB
- standalone PLC functions
- appropriate compliance and regulatory infrastructure for a company selling a schedule III drug
- SAP implementation,
- taking control of supply / Fine Chemical Plant

2016 forward: Optimizing the Organisation

Now optimising what we have

- We have initiated a project in H2 2016
- We are benchmarking costs against appropriate comparators
- We are looking at optimizing our structure

We will report more in due course



Market Growth assisted by government focus & legislation

Patient Cap

Patient Cap raised to 275

- but with ability for states to enact lower cap
- Only if physician has additional credentialing status or has a qualified practice.
- Only a small minority of doctors today at or even close to the 100 patient cap – probably comfortably under 10% of waived doctors
- Of these, many will choose not to go through the extra burden or will not see enough additional demand in their areas

Nurse Practitioners / Assistants

Nurse Practitioners & Physician Assistants to be allowed to prescribe

- Up to 30 patients in year one, up to 100 patients thereafter
- After at least 24 hours of professional training
- Under supervision in some states or in conjunction with qualified physician
- 12 months before the education/training is created and we start to see the first nurses / assistants waived.

Directly Administered Drugs

- Secretary given power to exclude directly administered drugs in the physicians' office from the cap.

**Net, we see this as increasing market growth by a low single digit percentage.
Incremental growth but not a game changer.**



Agenda for 2016 – 2

Date	Activity	Event
Q3		
Q3	Arbaclofen Placarbil for Alcohol use disorder	Final CSR phase 2A study (RB-US-14-0001)
July 29	Half Year Results	Presentation in London
Sept 12	Morgan Stanley Conference	Presentation in New York
Q3	RBP 7000 Risperidone Depot	Pre-NDA meeting
Q3	RBP 6000 Buprenorphine Depot	Topline results of Phase 3 efficacy clinical trial
Q4		
Q4	RBP 6000 Buprenorphine Depot	Safety Trial (RB-US-13-0003) last patient out
Q4	RBP 7000 Risperidone Depot	Phase 3 safety trial (RB-US-13-0005) final CSR
Q4	Suboxone Tablet China	NDA filing
Nov 2	Q3 Results	Conference Call
Nov	Trial v Actavis / Par / Teva	Process Patent litigation
Nov	ANDA Trial v Teva	Teva ANDA litigation (Orange Book-Listed Patents)
Nov	Jefferies Conference	Meetings in London
Dec	R&D Day	Presentations in New York, Live Webcast

Summary

We face the
future with
renewed
confidence

We are making
progress in
managing the
risks to the
business

We look forward
to continuing our
progress



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

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

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 doctor can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE 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 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 doctor 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 doctor if you are pregnant or plan to become pregnant. If you are pregnant or become pregnant while taking SUBOXONE Film, alert your doctor immediately and you should report it using the contact information provided below.*

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 doctor 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 doctor 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 negative 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!

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