The leader in global addiction treatments

Full Year Results 2017
February 15th 2018

Shaun Thaxter

Chief Executive Officer

INDIVIOR

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 2018 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 ongoing investigative and antitrust litigation matters; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to 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.

AGENDA

Shaun Thaxter	Opening Remarks
Mark Crossley	Financial Review
Javier Rodriguez	Litigation Update
Christian Heidbreder	R&D Update
Shaun Thaxter	Priorities for 2018
Q & A	

INDIVIOR

OUR VISION

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

FY 2017 Key Takeaway: Indivior Executed on its Strategic Priorities

- ✓ **SUBOXONE® Film Resilience** – Maintained leading share (avg. 57%) among daily BMAT options in US

- ✓ **Pipeline Progress** – SUBLOCADE™ approved by FDA and RBP-7000 NDA accepted by FDA

- ✓ **Expanded Treatment Access** – Record treatment providers in the US, strong growth in Australia and Canada; maintained BMAT share in Europe

- ✓ **Created Greater Certainty** – Record cash balance, replaced borrowings, continue to assert strong IP position

FY 2017 Snapshot & FY 2018 Guidance

FY 17 Performance In-line with Raised Expectations
(on an adjusted basis vs. FY 2016)

Net Revenue	$1,093m	↑ +3%
Op. Profit	$403m	↑ +4%
Net Income	$270m	↑ +6%
Cash	$863m	↑ +$171m
Net Cash	$376m	↑ +$245m

FY 17 Operating Highlights

- US market growth accelerated
- SUBOXONE® Film share averaged 57% demonstrating resilience
- Invested in creating a strong SUBLOCADE™ launch platform
- Establishing new Behavioral Health unit for RBP-7000
- Opened new R&D complex in the UK; updated US R&D complex
- Improved financial flexibility

Pipeline Realization

- SUBLOCADE™ on track for launch and availability week of Feb. 26, 2018
- RBP-7000 PDUFA date of July 28, 2018; preparing for launch in Q4
- Entered strategic collaboration with Addex Therapeutics
- Arbaclofen Placarbil – new formulation completed; Type C meeting with FDA on next steps

FY 2018 Guidance:
- Net Revenue : $1,130m to $1,170m (+5% at mid-point vs. FY 2017)
- Net Income: $290m to $320m (+13% at mid-point vs. FY 2017)

Litigation Provision

The Group increased its provision for investigative and antitrust litigation matters to $438m. Because these matters are in various stages, Indivior cannot predict with any certainty the ultimate resolutions, costs, or timing of the ultimate resolution of any of the matters. The final aggregate settlement amount may be materially different from this provision. 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 parties to the other matters referred to under the Litigation Update on Page 6 of the Full 2017 announcement dated February 15, 2018.

SUBLOCADE™ (buprenorphine extended-release) Injection– A New Treatment for Moderate-to-Severe Opioid Use Disorder (OUD)

What: The first once-monthly buprenorphine long-acting injection

When: Launching and available week of Feb. 26th

Where: US, initially; preparing ROW market filings

Dosages: 100mg and 300mg

Coverage: Targeting strong payer support levels

Distribution: Specialty pharmacy and specialty distributor

Expected SUBLOCADE™ Uptake Weighted to H2 2018

March
Initial prescriptions

May
Initial patient feedback

HI 18: Initial Prescription Phase

H2 18: Expected SUBLOCADE Uptake

Key Prescribing & Adoption Metrics

Wk. of Feb. 26th
National launch

April
First patients injected w/ SUBLOCADE™

June
Additional patients injected w/ SUBLOCADE™

PROVIDER LOCATOR

COPAY ASSISTANCE

inSupport

FIELD REIMBURSEMENT SERVICES (FRS)

HUB SERVICES

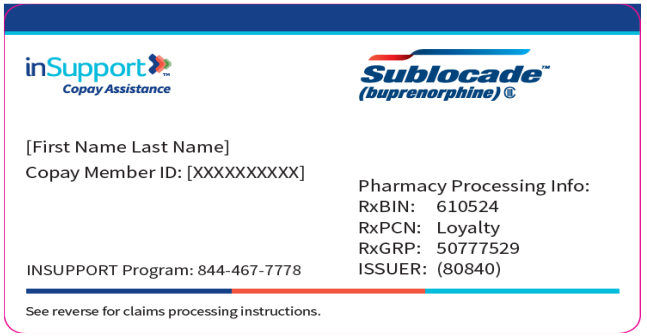
Working Alongside Payers to Provide Access to Treatment

Payer Coverage

- Consulting with Payer Groups
  - ✓ Aligned on burden of disease
  - ✓ Firm understanding of unmet needs
- Targeting robust formulary coverage in 2018
- Primarily a medical benefit
- Complements overall patient treatment program, including psychosocial support

Patient Access

- $5 Copay Program for eligible patients



Mark Crossley

Chief Financial Officer

INDIVIOR

Income Statement*

($ in mil.)	FY 2017 Adjusted	FY 2016 Adjusted	FY % change	Q4 2017 Adjusted	Q4 2016 Adjusted	Q4 % change
Net Revenues	**1,093**	1,058	**+3**	**265**	259	**+2**
Cost of Sales	(104)	(96)		(32)	(29)	
Gross Profit	**989**	962	**+3**	**233**	230	**+1**
Gross Margin (%)	*90%*	*91%*	*-44 bps*	*88%*	*89%*	*-88 bps*
Selling, Distribution and Administration Expenses	(497)	(456)	+9	(141)	(126)	+12
Research & Development Expenses	(89)	(119)	-25	(22)	(32)	-31
Profit on Ordinary Activities before interest & taxation	**403**	387	**+4**	**70**	72	**-3**
Operating Margin (%)	*37%*	*37%*	*+30 bps*	*26%*	*28%*	*-138 bps*
EBITDA	**416**	401	**+4**	**74**	74	**-**
Net Finance Expense	(42)	(51)		(8)	(12)	
Taxation	(91)	(82)		(8)	(11)	
Effective Tax Rate (%)	*25%*	*25%*		*13%*	*18%*	
Net Income	**270**	254	**+6**	**54**	49	**+10**

* Please see Appendix for full reconciliation of Actual to Adjusted for periods indicated.

Net Revenue – By Region

Net Revenue

($ in mil.)	FY 2017	FY 2016	% ch.	% ch. (Const. FX)
USA	877	857	+2%	NA
Rest of World	216	201	+7%	+7%
Total	1,093	1,058	+3%	+3%

Key Points

USA

- Market growth continued in low double digits on expansion of treatment capacity
- SUBOXONE® Film remained resilient, but ongoing share erosion in price sensitive accounts (Managed Medicaid); FY 17 avg. share 57% vs. 61% in FY 16
- 5% price increase offset by tactical rebating to maintain formulary access
- Negative mix impact from stronger growth in US Medicaid business

Rest of World

- Increase driven by one-off net revenue items in EU, as well as continued strong growth Australasia and Canada

FY 2017 Margins & Operating Costs

FY 2017 Margins

	FY 17 Reported	FY 16 Reported	FY 17 Adjusted	FY 16 Adjusted
Gross margin	**90%**	90%	**90%**	91%
Operating margin	**17%**	14%	**37%**	37%

- Adj. gross margin down slightly YOY primarily due to a greater mix of revenue from Australasia and Canada
- Solid YOY adj. operating margin of 37% – benefits from higher net sales and lower R&D expenses were offset by pre-launch investments and increased legal expenses
- R&D expenses decreased 25% YOY

FY 2017 Operating Costs

($ in mil.)	FY 17	FY 16	% ch.
SD&A (adjusted)	**(497)**	(456)	+9
R&D	**(89)**	(119)	-25
Exceptional items	**(210)**	(227)	-
Depreciation & Amortization (included in SD&A)	***(13)***	*(14)*	-

- SD&A increase primarily driven by expected higher pre-launch investment levels for SUBLOCADE and RBP-7000
- R&D decrease reflects expected lower clinical activity as Phase III trials on key pipeline assets have been completed
- Exceptional items in FY 2017 SD&A totalled $210m ($185m provision related to investigative and antitrust litigation and release of a legacy provision, $25m related to the Amneal settlement); FY 2016 SD&A exceptional items totalled $227m ($220 related to investigative and antitrust litigation matters, $7m related to negative ANDA outcome planning)

Net Income & Tax

FY 2017 Adjusted Net Income

($ in mil.)	FY 17	FY 16
Op. Profit (adj.)	**403**	387
Net Interest (adj.)	**(42)**	(51)
Tax Expense (adj.)	**(91)**	(82)
Tax Rate (adj.)	***25%***	*25%*
Net Income (adj.)	**270**	254

Adj. FY 2017 rate of 25% slightly higher than 24% expected

Reflects mix of profits

FY 2018 tax rate guidance of **high-teens**, excluding exceptional tax charges

Due to new US tax law effective Jan. 1, 2018, along with the Company's existing tax position

Cash & Borrowing Position at End of 2017

($ in mil.)	FY 2017	FY 2016
Cash & Cash Equivalents	**863**	692
Current Borrowings	**(5)**	(101)
Long-term Borrowings	**(477)**	(434)
Other	**(5)**	(26)
Net cash	**$376**	131

- Net cash of $376m at end of FY 17, improvement of $245m in the period
- Retaining cash on balance sheet at present:
  - ✓ Protect against potential ‘at-risk’ generic buprenorphine/naloxone film launch
  - ✓ Flexibility until resolution of legal matters
  - ✓ Flexibility on business development

US and EURO Denominated Term Loan B Replacements

- **Debt maturity extension to Dec. 2022**
- **Balloon payment deferred from Dec. 2019**
- **Lower annual mandatory principal prepayments** ***(1% vs. 10%)***
- **Interest cost saving** ***(pro forma 2018)***
- **Leverage covenant threshold now 3.0x** ***(vs. 2.50x)***
- **Liquidity covenant removed**
- **Cash sweep eliminated (2018)** ***(+ no sweeps if Leverage ratio <1.0x)***

More economical debt service: interest and principal

Greater financial flexibility provided by loosened/removed compliance constraints

Cash Conversion

Twelve months ended December 31st:

Cash Flows from Operating Activities

($ in mil.)

	FY 17	FY 16
Operating Profit	**193**	**149**
Depreciation and amortization	13	14
Reversal of other non-cash items	22	11
Changes in assets and liabilities	(60)	119
Provisions	201	219
Cash generated from Operations	**369**	**512**
Loan expenses and taxes paid	(74)	(105)
Net cash inflow from operating activities	**295**	**407**
Net Cash Flow as % of Adj. Operating Profit	**73%**	**105%**

Current period reflects $55m investment in working capital partially offset by operating improvement of $44m versus a significant working capital release in the year-ago period due to US trade payables.

Guidance for 2018

($ in mil.)	Guidance	% change v. FY 17 (at mid-point)
Net Revenue	$1,130m -$1,170m	+5%
Net Income	$290m - $320m	+13%

Top-line:

- **No material change in US market conditions**
  - ✓ No 'at-risk' generic film entry in 2018
- **Intensifying competitive pressures in ROW**
  - ✓ Increasing competition and austerity in EU, partially offset by growth in Australasia
- **Initial net revenue expectations for SUBLOCADE**
  - ✓ As previously communicated, sales are expected to be modest in the early stages of launch

Expenses:

- **Launch investments for SUBLOCADE and RBP-7000**
- **Lower finance expense**
- **Estimated high-teens tax rate**
- **Before exceptional items and at constant FX**

Javier Rodriguez

Chief Legal Officer

INDIVIOR

Major Litigation

The Group increased its provision for investigative and antitrust litigation matters to $438m during the quarter. Because these matters are in various stages, Indivior cannot predict with any certainty the ultimate resolutions, costs or timing of the resolutions of any of the matters. The final aggregate amount may be materially different from this provision. 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 parties to the other matters below under State Subpoenas and FTC Investigation and Antitrust Litigation.

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

FTC Investigation & Antitrust Litigation (1)

ANDA Litigation & Inter Partes Review (1)

(1) See FY 2017 Results Announcement published 2/15/18, pgs. 6 to 9 “Litigation Update” for complete description
(2) See FY 2017 Results Announcement published 2/15/18 pgs. 9 to 11 “Risk Factors” for a complete description

Christian Heidbreder

Chief Scientific Officer

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POSTMARKETING REQUIREMENTS (PMR) & POSTMARKETING COMMITMENTS (PMC)

Sublocade™ (buprenorphine extended-release) injection for subcutaneous use

Guidance for Industry

Postmarketing Studies and Clinical Trials — Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act

Since FDAAA, the terms *PMR* and *PMC* are used as follows:

- The term *postmarketing requirement* or *PMR* is used to describe **all** required postmarketing studies or clinical trials, including those required under FDAAA and those required under subpart H of 21 CFR part 314, subpart E of 21 CFR part 601, the Pediatric Research Equity Act, and the Animal Efficacy Rule.
- The term *postmarketing commitment* or *PMC* is used to describe studies and clinical trials that applicants have agreed to conduct, but that will generally not be considered as meeting the statutory purposes in 505(o)(3)(B) and so will not be required.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

April 2011
Drug Safety

PMR Studies:

- *4 nonclinical studies* to assess the effects of NMP (co-polymer in SUBLOCADE™ formulation) on embryofetal, pre-and post-natal development.
- *2 clinical studies*:
  - ✓ Identification of the patient population that will benefit from the higher SUBLOCADE™ maintenance dose (i.e., 300 mg)
  - ✓ Explore how SUBLOCADE™ can be safely initiated without a period of sublingual (SL) buprenorphine titration

PMC Studies:

- *2 PK modeling & simulation studies* on existing data:
  - ✓ Identification of patients who may benefit from SUBLOCADE™ given at a longer inter-dose interval.
  - ✓ Evaluate the transition of patients with long-term stability on a SL buprenorphine dose to a monthly dose of SUBLOCADE™ without the use of a loading dose.

HEALTH ECONOMICS & OUTCOMES RESEARCH (HEOR) STUDIES

Sublocade™ (buprenorphine extended-release) injection for subcutaneous use

THE RECOVER STUDY™

STEP #1

SUBLOCADE™ (RB-US-13-0001) Pivotal Trial Analysis

Quality of Life

Treatment satisfaction

Resource Use

Employment Status & Health Insurance

STEP #2

SUBLOCADE™ (RB-US-13-0003) Long-Term Safety Trial Analysis

Quality of Life

Treatment satisfaction

Impact of opioid use disorder on daily living

STEP #3

SUBLOCADE™ Targeted HEOR Trial Analysis of 0001/ 0003

Comparison of outcomes in 0001/0003 by: Retention; Opioid use, withdrawal, cravings

STEP #4

RECOVER® Study

Characterize the periods of abstinence over a 12-month observational window, such as # days abstinent, time to relapse, # relapses, and time to return to abstinence after relapse

Economic impact of compliance such as adherence & persistence to MAT

December 2018

LIFECYCLE EVIDENCE GENERATION & OPTIMIZATION (LEGO)

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use

Study	Objective	Start	End
Buprenorphine Abuse, Misuse, Diversion (AMD) Epidemiology	Deep understanding of root causes of abuse, diversion & misuse	Q4-2017	Q3-2019
SUBLOCADE™ VAS craving	Explore how craving VAS and other craving measurement tools might be used as valid clinical endpoint in addiction medicine trials	Q4-2017	Q4-2018
SUBLOCADE™ Emergency Room	Assess efficacy and safety of SUBLOCADE™ in preventing repeat overdose in OUD patients	Q1-2018	Q3-2019
Global Real-World RECOVER® Study	Understand determinants of recovery of patients initiating treatment with SUBLOCADE™ in a naturalistic real-world setting	Q1-2018	Q1-2021

PIPELINE UPDATE

SUBOXONE® Tablet & Film (OUD)

- Submission of SUBOXONE® Tablet NDA to Chinese FDA (CFDA) on Dec 27th, 2016. Priority Review granted by CFDA Jun 6th, 2017.
- SUBOXONE® Film addition to the List of Drugs for an Urgent Public Health Need in British Columbia on Jun 28th, 2017 and for the Canadian correctional facilities on Dec 28th, 2017. Regulatory submission currently being prepared

RBP-7000 (Schizophrenia)

- NDA submitted Sep 28th, 2017
- NDA filing accepted by FDA Dec 12th, 2017
- PDUFA Date Jul 28th, 2018

Arbaclofen Placarbil (AUD-ALD)

- All three parts of the new Phase I Bioavailability Clinical Study Protocol (INDV-AP-102) of a new formulation of Arbaclofen Placarbil are now completed.
- Preparation of Type C meeting with the FDA to seek advice as to the potential development of Arbaclofen Placarbil for AUD-induced liver disease with cirrhosis

ADX71441 (SUD)

Creation of 2 teams:

- ✓ Development strategy of ADX71441 Team
- ✓ GABA-B PAM lead identification research Team

Launch meeting in Geneva March 1st, 2018

PLANNED CONFERENCES / EVENTS 2018*

Conference	Where?	When?
American Association for the Treatment of Opioid Dependence (AATOD)	New York, NY	Mar 10th – 14th
American Society for Clinical Pharmacology and Therapeutics (ASCPT)	Orlando, FL	Mar 21st – 24th
American Society of Addiction Medicine (ASAM)	San Diego, CA	Apr 12th – 15th
American College of Preventive Medicine (ACPM)	Chicago, IL	May 23rd – 26th
College on Problems of Drug Dependence (CPDD)	San Diego, CA	Jun 9th – 14th
American Association of Nurse Practitioners (AANP)	Denver, CO	June 26th – July 1st
American College of Emergency Physicians (ACEP)	San Diego, CA	Oct 1st – Oct 4th
American Academy of Family Physicians (AAFP FMX)	New Orleans, LA	Oct 9th – Oct 13th
Canadian Society of Addiction Medicine (CSAM)	Vancouver, Canada	Oct 25th – Oct 27th
American Academy of Addiction Psychiatry (AAAP)	Bonita Springs, FL	Dec 6th – 9th
3rd Indivior-hosted R&D / Capital Markets Day	New York, NY	December (date TBD)

** Subject to change*

Shaun Thaxter

Chief Executive Officer

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Indivior PLC – Priorities for 2018

Build on our Leadership Position in Global Addiction Treatment

1.SUBOXONE® Film Resilience

Preserve leading position in USA against 10 generic and 2 branded competitors

2. Ensure Successful Launch for Pipeline Products

- SUBLOCADE™ monthly buprenorphine long-acting injection
- RBP-7000 monthly long-acting risperidone

3. Expand Global Treatment

- Expand treatment access in USA
- Prepare for SUBLOCADE™ launch in Europe, Australia and Canada

4. Focus on Capital Allocation

- Continue to manage risks
- Prepare for possible BD/M&A

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

Appendix

Income Statement: FY2017 vs. FY2016

	FY2017				FY2016		
	2017 Actual	Adjustments	2017 Adjusted	Δ Y-o-Y (adjusted)	2016 Actual	Adjustments	2016 Adjusted
($ in mil. at Actual FX)							
Net Revenues	**1,093**		**1,093**	**+3%**	**1,058**		**1,058**
Cost of Sales	(104)		(104)		(107)	(11) [1]	(96)
Gross Profit	**989**		**989**	**+3%**	**951**		**962**
Gross Margin (%)	*90%*		*90%*		*90%*		*91%*
Selling, Distribution and Administration Expenses	(707)	(210) [1]	(497)		(683)	(227) [2] [3]	(456)
Research & Development Expenses	(89)		(89)		(119)		(119)
Profit on Ordinary Activities before interest & taxation	**193**		**403**	**+4%**	**149**		**387**
Operating Margin (%)	*18%*		*37%*		*14%*		*37%*
EBITDA	**206**		**416**	**+4%**	**163**		**401**
Net interest	(56)	(14) [2]	(42)		(51)		(51)
Taxation	(79)	12 [3]	(91)		(63)	19 [4]	(82)
Effective Tax Rate (%)	*58%*		*25%*		*64%*		*25%*
Net Income	**58**		**270**	**+6%**	**35**		**254**

FY2017 Notes:

(1) Excludes $185 mil. provision for investigative and antitrust matters and the release of a legacy provision and $25 mil. related to the settlement of Amneal antitrust matter
(2)Excludes $14 mil. of exception costs related to the replacement of the Term Loan facilities
(3) Excludes $12 mil. benefit related to exceptional pre-tax and taxation items.

FY2016 Notes:

(1) Excludes $11 mil. write off of manufacturing costs related to potential negative ANDA outcome.
(2) Excludes $7 mil. exceptional items related to costs for ANDA strategic planning.
(3) Excludes $220 mil. provision for investigative and antitrust matters.
(4) Excludes $19 mil. benefit related to exceptional pre-tax and taxation items.

Income Statement: Q4 17 vs. Q4 16

	Q4 2017				Q4 2016		
	Q4 2017 Actual	Adjustments	2017 Adjusted	Δ Y-o-Y (adjusted)	2016 Actual	Adjustments	2016 Adjusted
($ in mil. at Actual FX)							
Net Revenues	**265**		**265**	**+2%**	**259**		**259**
Cost of Sales	(32)		(32)		(29)		(29)
Gross Profit	**233**		**233**		**230**		**230**
Gross Margin (%)	*88%*		*88%*		*88%*		*88%*
Selling, Distribution and Administration Expenses	(326)	(185) [1]	(141)		(127)	(1) [1]	(126)
Research & Development Expenses	(22)		(22)		(32)		(32)
Profit on Ordinary Activities before interest & taxation	**(115)**		**70**	**-3%**	**71**		**72**
Operating Margin (%)	*		*26%*		*27%*		*28%*
EBITDA	*		**74**	*	**73**		**74**
Net interest	(22)	(14) [2]	(8)		(12)		(12)
Taxation	(8)		(8)		+19	30 [2]	(11)
Effective Tax Rate (%)	*(6%)*		*13%*		*(32%)*		*18%*
Net Income	**(145)**		**54**	**10%**	**78**		**49**

FY2017 Notes:

(1) Excludes $185 mil. provision for investigative and antitrust matters and release of legacy provision.
(2) Excludes $14 mil. of exception costs related to the replacement of the Term Loan facilities

FY2016 Notes:

(1) Excludes $1 mil. for ANDA strategic planning costs
(2) Excludes a $30 mil. tax benefit related to exceptional pre-tax and taxation items

* Not meaningful

Capital Markets Agenda 2018*

Date	Event
Feb. 15th	FY 2017 Results (London Presentation)
Feb 27th & 28th	CSFB One-on-one Conference (London)
March 12th to 14th	Stifel-sponsored NDR (US)
March 19th	Bank of America Merrill Lynch “Bus Tour” (London)
May 2nd	Q1 2018 Results (Conference Call)
May 8th & 9th	Deutsche Bank US Healthcare Conference (Boston)
June 5th & 6th	Jefferies US Healthcare Conference (New York City)
July 25th	H1 2018 Results (London)
September (TBD)	Morgan Stanley Healthcare Conference (New York City)
November 1st	Q3 2018 Results (Conference Call)
December (TBD)	Indivior-hosted R&D / Capital Markets Mtg. (New York City)

* Subject to updates and changes

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

INDICATION AND USAGE
SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product followed by a dose adjustment period for a minimum of seven days.

SUBLOCADE should be used as part of a complete treatment program that includes counseling and psychosocial support.

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY
•Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.
•Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.

IMPORTANT SAFETY INFORMATION

Prescription use of this product is limited under the Drug Addiction Treatment Act.

CONTRAINDICATIONS
SUBLOCADE should not be administered to patients who have been shown to be hypersensitive to buprenorphine or any component of the ATRIGEL® delivery system

WARNINGS AND PRECAUTIONS
Addiction, Abuse, and Misuse: SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

Respiratory Depression: Life threatening respiratory depression and death have occurred in association with buprenorphine. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with SUBLOCADE.

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome is an expected and treatable outcome of prolonged use of opioids during pregnancy.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Risk of Opioid Withdrawal With Abrupt Discontinuation: If treatment with SUBLOCADE is discontinued, monitor patients for several months for withdrawal and treat appropriately.

Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to and during treatment.

Risk of Withdrawal in Patients Dependent on Full Agonist Opioids: Verify that patient is clinically stable on transmucosal buprenorphine before injecting SUBLOCADE.

Treatment of Emergent Acute Pain: Treat pain with a non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect.

ADVERSE REACTIONS
Adverse reactions commonly associated with SUBLOCADE (in ≥5% of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.

The full prescribing information, including BOXED WARNING, for SUBLOCADE™ can be found at: http://www.indivior.com/wp-content/uploads/2018/01/2018_01_12-CLEAN-USPI-SUBLOCADE.pdf