

May 3, 2016

## INDIVIOR PLC Q1 Financial Results Ahead of Plan. Full Year Guidance Confirmed.

Quarter to March 31	2016 \$m	2015 \$m	% change at actual FX	% change at constant FX
Net Revenue	258	251	+3	+4
Operating Profit	101	115	-12	-12
Net Income	50	77	-35	-34
EPS (cents per share)	7	11	-36	-36

### **Q1 Financial Highlights**

- Net revenue at \$258m (Q1 2015: \$251m) grew 3%. Constant FX net revenue grew by 4%.
- Operating Profit of \$101m (Q1 2015: \$115m). Operating Margin of 39%.
- Net income of \$50m (Q1 2015: \$77m) after tax rate of 36% and exceptional tax of \$5m.
- Cash balance at quarter end of \$543m. Net debt at quarter end \$83m (Year End 2015: \$174m).

### **Q1** Operating Highlights

- US market growth so far in 2016 has been in mid-single digits, compared to the equivalent period last year which was boosted by the impact of the Affordable Care Act.
- Suboxone® Film market share for the quarter was 60% (up from 59% in Q1 2015). Total volume sold in the USA was ahead of the same period last year. Suboxone® Film list price was increased modestly in January 2016, the first price increase since 2012 but this was offset by tactical rebates in connection with formulary access which continued, and by annualisation of prior year rebates, albeit at a lower rate of increase than in 2015.
- New product pipeline progress. Phase III trials of Buprenorphine Monthly Depot continue on track with results of efficacy trial due in Q3. As previously announced on April 28<sup>th</sup>, the development of the Risperidone Monthly Depot, currently concluding its Phase III safety trial, has been delayed by an external manufacturing issue, which will result in a delay in likely approval until mid-2018. The outcome of the Phase I trial on Buprenorphine Hemiadipate was also announced on April 28<sup>th</sup>, showing that the trial did not achieve the required PK profile in humans. The outcome of the Phase IIa trial on Arbaclofen Placarbil for treatment of Alcohol Use Disorder is due in Q3 2016.
- Indivior continues to await the outcome of the ANDA trial against Actavis and Par which is expected in Q2.

### **Guidance**

• Full year Guidance for 2016 is again confirmed: net revenue of \$945m - \$975m and net income in a range of \$155m-\$180m, excluding exceptional items and at constant exchange rates. This guidance assumes; no material change to current market conditions in the US; no disruption to US generic pricing; no generic film entry; and limited impact of branded competition. The guidance also reflects the strategic decision to reinvest at least an additional \$35m in R&D and pre-commercialisation activity for the expected launch of Buprenorphine Monthly Depot for the treatment of Opioid Use Disorder.

Commenting on the results, Shaun Thaxter, CEO of Indivior, said

"We had a good start to the year with Q1 numbers exceeding our plan which anticipated no material deterioration in the trading environment. In the US, generic tablet pricing began to experience some additional discounting but branded competitors had very limited impact although we continued to offer some tactical rebates in connection with formulary access for Suboxone® Film. In January, we took a modest price increase on Suboxone®, our first since 2012.

"Recent proposals from President Obama, HHS and Congress to expand access to medically assisted treatment for opioid dependency are very welcome. Raising the patient cap for appropriately qualified physicians and allowing appropriately qualified nurse practitioners to prescribe would help expand access to care for many untreated opioid dependent patients in the US. We continue to encourage appropriate proposals to be enacted swiftly.

"We made further progress against our key strategic priorities for 2016; our Suboxone® share of 60% in the US is marginally ahead of the exit share for 2015 and reinforces our confidence in the sustainability of Suboxone® Film; the treatment market has grown modestly in the US, but the increased legislative and Governmental attention on the problems of opioid dependency suggest that access to medically assisted treatment should accelerate again as new proposals take effect.

"Our pipeline continues to make progress. Our Buprenorphine Monthly Depot is on track in its Phase III trials with the efficacy trial due to read out in late Q3. This is by far our most important project and it is excellent news that it remains on track for potential approval before the end of 2017, assuming it receives priority review. The delay in the Risperidone Monthly Depot project, due to an external manufacturing issue, is not a fundamental problem, but it will result in a change to our original development timeline. RBP 6300, the oral swallowable capsule of Buprenorphine Hemiadipate, did not achieve the anticipated PK profile in its Phase I trial, demonstrating again the difficulty of developing a swallowable formula of Buprenorphine but we will now evaluate alternative options. In Q3, we will discover much more about the potential of Arbaclofen Placarbil for the treatment of Alcohol Use Disorder, when we get the read-out on the Phase IIa trial.

"We today confirm our financial guidance for the year. Indivior is in good shape for the next phase of its development".

### **Operating Review**

### **US Market Update**

The market for buprenorphine products continued to grow steadily in Q1, showing volume growth in mid-single digits in line with expectation. The market has now passed the impact of The Affordable Care Act and is comparing to a period boosted by it. A key driver of growth remains the certification of new physicians to practice addiction medicine.

A number of proposals to increase access to medically assisted treatment have recently been advanced. Congress has passed proposals which, amongst other things, propose to increase the 100 patient cap and allow nurse practitioner and physician assistant prescribing. President Obama, through HHS/SAMHSA, has issued a proposed rule change to raise the 100 patient cap and consider other changes through a comment process.

Suboxone® Film had a market share of 60% in Q1, compared to 59% in Q1 2015. This was slightly above the exit share at the end of 2015, so market share has been more than maintained through the quarter.

The list price of Suboxone® Film in the US was increased modestly in January 2016, the first price increase since 2012. The Company continues to offer tactical rebates in connection with formulary access for Suboxone® Film, in the face of continuing aggressive discounting by competitors. Branded competitors have made limited impact on the market. Generic tablet pricing has begun to show

some signs of greater discounting volatility in the generic marketplace. However this has not had a material impact on Suboxone® Film market share in Q1.

### **Reconfirming Full Year Guidance**

Full year 2016 guidance issued on December 9th, 2015 is again confirmed: net revenue of \$945m-\$975m and net income in a range of \$155m-\$180m excluding exceptionals and at constant exchange rates. This guidance assumes; no material change to current market conditions in the US; no material deterioration in US generic tablet pricing; no generic film entry; and limited impact of branded competition. The guidance also reflects a strategic decision to reinvest at least an additional \$35m in R&D and pre-commercialisation activity for the expected launch of Buprenorphine Monthly Depot for opioid dependence in late 2017 or early 2018.

### Financial Performance in Q1, 2016.

Total net revenue grew 3% at actual exchange rates to \$258m (Q1 2015: \$251m) reflecting market growth, marginally higher market share and a price increase on Suboxone® Film offset by higher rebate levels in the US and the impact of adverse translation into US\$s (USD) from weaker currencies in Rest of World (Euro, Australian Dollar and Sterling). At constant exchange rates, the growth in net revenue was 4%.

US net revenue grew by 6% to \$211m (Q1 2015: \$200m). Volume was ahead of last year reflecting market growth and marginally higher market share compared to prior year. Pricing reflected a modest price increase in January, and continuing tactical rebates, albeit not at the rates of increase experienced in 2015, in connection with formulary access in both commercial managed care and Medicaid in the face of discounting by competitors.

Rest of World net revenue declined by 8% to \$47m (Q1 2015: \$51m) as reported in USD but half the decline was due to translation into a much stronger US dollar. At constant exchange, the net revenue decline was 5%, reflecting continuing price constraints from Government austerity measures and forced switching to generics in Europe.

Gross margin increased slightly to 92%, (Q1 2015: 90%) assisted by the price increase in January and channel mix.

SD&A expenses increased by 14% to \$105m (Q1 2015: \$92m). The increase mainly reflects a full period with standalone public company costs versus the build-up of costs last year and higher legal expense. There were no exceptional costs included in SD&A (Q1 2015: \$2m).

R&D expenses increased by 55% to \$31m (Q1 2015: \$20m), reflecting the two pivotal Phase III trials running in Q1 2016 and a more even phasing of R&D investment likely in 2016.

Operating profit was \$101m, 12% below prior year (12% at constant exchange). Excluding exceptional costs in Q1 2015, operating profit was 14% below prior year.

EBITDA was \$107m (Q1 2015: \$121m; excluding the exceptional costs: \$123m).

Operating margin was 39.1% (Q1 2015: 45.8% as reported, 46.6% excluding exceptional costs). This margin reflects higher operating costs, primarily due to the full quarter of the additional costs of operating as a standalone public company.

Finance expenses in the quarter were \$15m (2015 Q1: \$13m) being the interest and amortisation costs for the \$750m borrowing facility marginally reduced by the impact of the buyback of \$75m of that facility last December. The prior year had the benefit of a lower interest rate prior to the finalisation of the debt syndication in mid-March 2015, which also increased the debt issuance costs.

The tax charge in Q1 was \$36m, a rate of 42% (Q1 2015: 25%) on the pretax profit for the period but this included \$5m of exceptional one-off tax costs arising from movement of assets within the group and additional provisions for unresolved tax matters. The underlying rate, excluding the exceptional

tax, was 36%, reflecting the mix of profits between countries in the period. Based on current projections we expect our full year effective tax rate to be 25%, consistent with the guidance given last December.

Net income for the quarter was therefore \$50m (Q1 2015: \$77m), a decline of 35% compared to Q1 2015 as reported. At constant exchange rates, the decline was 35%.

EPS were 7 cents (Q1 2015: 11 cents) as reported, and 8 cents on an adjusted basis.

### **Balance Sheet & Cash Flow**

Net working capital (inventory plus trade and other receivables, less trade and other payables) was minus \$281m at end Q1 2016, an improvement of \$7m on December 2015. This represents a ratio of minus 28% of moving annual total net revenue.

Cash and cash equivalents at the period end were \$543m, reflecting a net cash increase of \$76m in the quarter. Borrowings, net of issuance costs, were \$594m (Dec 2015: \$605m) at the quarter end after debt repurchase in the quarter of \$10m.

The net debt of the Group reflecting the issuance costs was \$83m (Dec 2015: \$174m).

Cash generated from operating activities of \$115m (Q1 2015: \$213m), a decrease of \$98m due to lower levels of operating profit of \$101m (Q1 2015: \$115m), and a much smaller improvement in net working capital with a release of cash of \$8m in Q1 2016 (versus \$91m in Q1 2015).

Net cash inflow from operations decreased to \$97m in the quarter (Q1 2015: \$165m) reflecting the lower cash from operating activities offset by lower tax payments in the quarter of \$7m (Q1 2015: \$14m), and after interest and transaction costs relating to the loan facility of \$11m (\$34m in Q1 2015).

### **R&D / Pipeline Update**

Developments since FY2015 press release on February 18<sup>th</sup>, 2016.

### Treatment of Opioid Use Disorder

- **Suboxone**® **Tablet**. *China Efficacy Study (RB-CN-10-0013)*: Database lock end Feb 2016. *Multiple Dose Study (RV-CN-10-0015)*: Database lock expected May 2016.
- RBP-6000, Monthly Depot Buprenorphine: Phase 3 Efficacy study (RB-US-13-0001); Last subject last visit (LSLV) expected May 2016. Phase 3 Safety extension study (RB-US-13-0003): study on track, LSLV expected February 9th, 2016.
- RBP-6300, Oral Swallowable Capsule Buprenorphine Hemiadipate. *PK study (RB-EU-14-0001)* output published April 28<sup>th</sup>. The drug did not achieve the anticipated PK profile in humans to justify proceeding further with this technology. Alternative options for the development of an orally bioavailable buprenorphine-based product with abuse deterrent properties are currently being thoroughly evaluated.

### Overdose Rescue Products

• RBP-8000 Cocaine Esterase for treatment of Cocaine Intoxication. Second type B meeting with FDA held March 16th, 2016.

### <u>Treatment of Alcohol Use Disorder</u>

Arbaclofen Placarbil: Phase 2A study (RB-US-14-0001): Database lock achieved March 2016.

### <u>Treatment of Schizophrenia</u>

• RBP-7000, Monthly Depot Risperidone. Phase 3 pivotal efficacy study (RB-US-09-0010): Completed. Preliminary data from pivotal Phase 3 efficacy study published on May 5th, 2015.

Phase 3 long-term safety study (RB-US-13-0005) on track with LSLV expected in Q3 2016.

The development of the Risperidone Monthly Depot, currently concluding its Phase III safety trial, has been delayed. An external manufacturing issue was identified with one out of six stability batches required for the NDA submission of RBP-7000, the Risperidone Monthly Depot. We believe this issue is now rectified and additional batches will be manufactured to provide the required data. This will result in a delay to the likely approval date until mid-2018. However, the clinical program, currently concluding its Phase III long-term safety trial, is still on track with its original timeline.

### **Recent Publication**

Isitt JJ, Nadipelli VR, Kouassi A, Fava M, Heidbreder C (2016) Health-related quality of life in acute schizophrenia patients treated with RBP-7000 once monthly risperidone: An 8-week, randomized, double-blind, placebo-controlled, multicenter phase 3 study. *Schizophr. Res.* Apr 7<sup>th</sup>, Electronic publication ahead of print. pii: S0920-9964(16)30105-0. <a href="http://dx.goi.org/10.1016/j.schres.2016.03.020">http://dx.goi.org/10.1016/j.schres.2016.03.020</a>.

### **Litigation Update**

### **ANDA Litigation**

- Trial in the lawsuits against Actavis and Par involving the Orange Book-listed patents for Suboxone® Film November and December 2015, and post-trial briefing concluded in March 2016. A decision is expected in Q2 and prior to any potential generic launch. Actavis' 30 month stay of FDA approval expired February 28<sup>th</sup>, 2016. Par's 30 month stay of FDA approval expires on September 25<sup>th</sup>, 2016.
- Trial against Teva, Actavis and Par in the lawsuits involving the two recently granted process patents (US Patent No. 8,906,277 and US Patent No. 8,900,497) scheduled for November 2016.
- Trial against Teva in the lawsuit involving the Orange 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 17<sup>th</sup>, 2017. Indivior believes Teva's 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17<sup>th</sup>, 2017, however, Teva disputes the applicability of the stay to this ANDA.
- Trial against Alvogen in the lawsuit involving the Orange Book-listed patents and process patents for Suboxone® Film scheduled for April 2017, with Alvogen's 30-month stay of FDA approval expiring October 29<sup>th</sup>, 2017.
- Trial against Mylan and Sandoz in the lawsuit involving the Orange Book-listed patents for Suboxone® Film is scheduled for September 25<sup>th</sup>, 2017, with Mylan's stay expiring March 24, 2018 and Sandoz's stay expiring April 2, 2018.
- 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. Indivior filed suit on March 21, 2016 which triggered a 30-month stay of approval of Teva's 505(b)(2) NDA.

### **BDSI Proceedings**

 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.

### • FTC investigation & Class Action

- 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.
- 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.
- Fact discovery is underway in the Class Action litigation.
- Amneal Pharmaceuticals LLC, a manufacturer of generic buprenorphine / naloxone tablets, has
  joined the 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 United States Attorney for the Western District of Virginia has served a number of subpoenas relating to Suboxone® Film, Suboxone® Tablet, Subutex® Tablet, Buprenorphine and the Group's competitors, among other issues. Indivior is 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 the Company. Indivior is cooperating fully with the relevant agencies and prosecutors and will continue to do so.

### **Risk Factors**

The Directors have reviewed the principal risks and uncertainties for the financial year 2016.

The assumptions in arriving at the Company's financial guidance for the full year are described on page 3 of this release. To the extent that actual market conditions differ from these assumptions, alternative financial outcomes are possible. However the Company has issued this guidance based on industry analogues and its own estimates at this time.

Therefore, other than in respect of guidance for the full year 2016, the Directors consider that the principal risks and uncertainties which could have a material impact on the Group's performance in the remaining term of 2016 remain the same as described on pages 47 to 51 of the 2015 Annual Report. These include:-

Business operations and business continuity

- The Group's revenues are primarily derived from sales of Suboxone® Film and any decrease in sales
  due to competition or supply or quality issues could significantly affect the results of operations and
  prospects.
- Competition for qualified personnel in the biotechnology and pharmaceutical industries is intense and high-performing talent in key positions is a business-critical requirement.

- Failures or disruptions to the Group's systems or the systems of third parties on whom the Group relies, due to any number of causes, particularly if prolonged, could result in a loss of key data and/or affect operations.
- The Group's computer systems, software and networks may be vulnerable to unauthorized access, computer viruses or other malicious code or cyber threats that could have a security impact. All of these could be costly to remedy and we may be subject to litigation.

### Product safety, regulation & litigation

- As an innovative pharmaceutical company, the Group seeks to obtain appropriate intellectual property protection for its products. Its ability to obtain and enforce patents and other proprietary rights particularly for its products, drug formulation and delivery technologies and associated manufacturing processes is critical to business strategy and success. Specifically see disclosures above on page 5 under litigation update referring to the current status of ANDA litigation and to the going concern statement on page 15 note 1, which discusses the risks associated with current ANDA litigation, and the contingent liabilities disclosures on pages 17-18, note 7.
- The manufacture of the Group's products is highly exacting and complex due in part to strict regulatory and manufacturing requirements. Active Pharmaceutical Ingredients (API) in many of the Group's products and product candidates are controlled substances that are subject to extensive regulation in all the countries in which the Group markets its products.
- The testing, manufacturing, marketing, and sales of pharmaceutical products entail a risk of product liability claims, product recalls, litigation, and associated adverse publicity, each of which could have a material adverse impact on the business, prospects, results of operations and financial condition.

### Product development

• The regulatory approval process for new pharmaceutical products and expansion of existing pharmaceutical products is expensive, time-consuming and uncertain. Even if product candidates are approved there is no guarantee that they will be able to achieve expected market acceptance.

### Commercial and Governmental payor account, pricing and reimbursement pressure

- The Group's revenues are partly dependent on the availability and level of coverage provided to the Group by private insurance companies and governmental reimbursement schemes for pharmaceutical products, such as Medicare and Medicaid in the US.
- Changes to governmental policy or practices could adversely affect the Group's revenues, financial
  condition and results of operations. In addition, the reimbursement of treatment established by
  healthcare providers, private health insurers and other organizations may be reduced.

### Compliance with law and ethical behaviour

Business practices in the pharmaceutical industry are subject to increasing scrutiny by government
authorities. Failure to comply with applicable laws and rules and regulations in any jurisdiction may
result in fines, civil and/or criminal legal proceedings. Specifically see disclosures above on page 6
under litigation update referring to the current status of FTC Investigation and Department of Justice
Investigation, and the contingent liabilities disclosures on pages 17-18, note 7

### Acquisitions and business development

• The Group may seek to acquire businesses or products as part of our strategy to enhance our current portfolio.

The Group's annual report for the 2015 financial year contains additional detail on these principal business risks together with a report on risk appetite.

### **Exchange Rates**

The average and period end exchange rates used for the translation of currencies into US dollars that have most significant impact on the Group's results were: -

	3 Months to March 31,	3 Months to March 31,
	2016	2015
GB £ period end	1.4153	1.4849
GB £ average rate	1.4323	1.5164
€ Euro period end	1.1176	1.0884
€ Euro average	1.1019	1.1279

### **Webcast Details**

There will be a conference call at 1pm UK time (8am EST in the USA) hosted by Shaun Thaxter, CEO, and Cary Claiborne, CFO. This call will also be webcast live. The details are below and are available on the Company's website at <a href="https://www.indivior.com">www.indivior.com</a>

<u>Webcast link:</u> <u>http://edge.media-server.com/m/p/fm7ntf4p</u>

Conference call: Participant Access: Dial in 5-10 minutes prior to the start time using the number / Conference ID

below.

Confirmation Code: 3673824

Participants, Local - London, United Kingdom: +44(0)20 3427 0503
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### **For Further Information**

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### 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<sup>®</sup> 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 SUBOXONE® 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 withdrawal has been reported following the use of buprenorphine by the mother during pregnancy. Before taking SUBOXONE® 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® 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 <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a> 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 <a href="https://www.RBPREMS.com">www.RBPREMS.com</a>.

### **About Indivior**

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy, health policy and evidence-based best practice models that have revolutionized modern addiction treatment. The name is the fusion of the words individual and endeavour, and the tagline "Focus on you" makes the company's commitment clear. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its robust, global opioid dependence portfolio featuring Suboxone® (buprenorphine and naloxone) Sublingual Film (CIII), Suboxone® (buprenorphine and naloxone) Sublingual Tablet, and Subutex® (buprenorphine) Sublingual Tablet, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic diseases of addiction – including opiate overdose, alcohol use disorders and cocaine intoxication. It also is pursuing novel product candidates in related mental health disorders such as schizophrenia. Headquartered in the United States in Richmond, Va., Indivior employs more than 700 individuals globally and its portfolio is available in over 40 countries worldwide. Visit www.Indivior.com to learn more.

### www.indivior.com

### **Forward-Looking Statements**

This announcement 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 the Indivior Group's financial guidance for 2016 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 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.

### **Condensed consolidated interim income statement**

		Unaudited	Unaudited
- 4 4 4 4 4 4		2016	2015
For the three months to March 31	Notes	\$m	\$m
Net Revenues	2	258	251
Cost of Sales		(21)	(24)
Gross Profit		237	227
Selling, distribution and administrative expenses	3	(105)	(92)
Research and development expenses	3	(31)	(20)
Operating Profit		101	115
Operating profit before exceptional items		101	117
Exceptional items	3	-	(2)
Operating profit		101	115
Finance expense		(15)	(13)
Net finance expense		(15)	(13)
Profit before taxation		86	102
Taxation	4	(31)	(25)
Exceptionals items within taxation	4	(5)	-
Net income		50	77
Earnings per ordinary share (cents)			
Basic earnings per share	5	7	11
Diluted earnings per share	5	7	11

# Condensed consolidated interim statement of comprehensive income

For the three months to March 31	Unaudited 2016 \$m	Unaudited 2015 \$m
Net income	50	77
Other comprehensive income		
Items that may be reclassified to profit or loss in subsequent years		
Net exchange adjustments on foreign currency translation	(3)	(9)
Other comprehensive income	(3)	(9)
Total comprehensive income	47	68

## **Condensed consolidated interim balance sheet**

		Unaudited Mar 31, 2016	Audited Dec 31, 2015
	Notes	\$m	\$m
ASSETS			
Non-current assets			
Intangible assets		55	62
Property, plant and equipment		36	32
Deferred tax assets		100	122
		191	216
Current assets			
Inventories		48	48
Trade and other receivables		241	206
Cash and cash equivalents		543	467
		832	721
Total assets		1,023	937
LIABILITIES			
Current liabilities			
Borrowings	6	(52)	(34)
Trade and other payables	8	(570)	(528)
Current tax liabilities		(48)	(41)
		(670)	(603)
Non-current liabilities		, ,	· ,
Borrowings	6	(542)	(571)
Provisions for liabilities and charges		(41)	(42)
-		(583)	(613)
Total liabilities		(1,253)	(1,216)
Net liabilities		(230)	(279)
EQUITY			
Capital and reserves			
Share capital	9	72	72
Other Reserves	3	(1,295)	(1,295)
Foreign currency translation reserve		(26)	(23)
Retained Earnings		1,019	967
			907

# **Condensed consolidated interim statement of changes in equity**

	Notes	Share	Share Premium		Foreign Currency Translation		Total equity
Unaudited	Notes	\$m	\$m	\$m	\$m	J	\$m
At January 1, 2015		1,437		(1,295)	(16)	•	(475)
Comprehensive income							
Net income		-	-	-	-	77	77
Other comprehensive income		-	-	-	(1)	(9)	(10)
Total comprehensive income		-	-	-	(1)	68	67
Transactions recognised directly in equity							
Capital reduction		(1,365)	-	-	-	1,365	-
Balance at March 31, 2015		72	-	(1,295)	(17)	832	(408)
At January 1, 2016		72		(1,295)	(23)	967	(279)
Comprehensive income				., .			
Net income		-	-	_	-	50	50
Other comprehensive income		-	-	-	(3)	-	(3)
Total comprehensive income		-	-	-	(3)	50	47
Transactions recognised directly in equity							
Share-based plans		-	-	-	-	3	3
Deferred taxation on share-based plans		-	-	-	-	(1)	(1)
Total transactions recognised directly in equity		-	-	-	-	2	2
Balance at March 31, 2016		72	-	(1,295)	(26)	1,019	(230)

## **Condensed consolidated interim cash flow statement**

	Unaudited	Unaudited
	2016	2015
For the three months to March 31	\$m	\$m
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating Profit	101	115
Depreciation and amortization	6	6
Share-based payments	2	-
Impact from foreign exchange movements	(2)	1
(Increase)/decrease in trade and other receivables	(35)	26
Decrease in inventories	-	1
Increase in trade and other payables and provisions	43	64
Cash generated from operations	115	213
Interest paid	(11)	(11)
Transaction costs related to loan	-	(23)
Taxes paid	(7)	(14)
Net cash inflow from operating activities	97	165
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(4)	-
Net cash (outflow) from investing activities	(4)	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Cash movements on overdraft	-	(9)
Cash movements in borrowings	(17)	(9)
Net cash (outflow) from financing activities	(17)	(18)
Net increase in cash and cash equivalents	76	147
Cash and cash equivalents at beginning of the period	467	331
Exchange differences	-	(12)
		ι,

#### Notes to the condensed consolidated Interim Financial Statements

### 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

Indivior PLC (the 'Company') is a public limited company incorporated and domiciled in the United Kingdom on September 26, 2014. In these condensed consolidated interim financial statements ('Interim Financial Statements'), reference to the 'Group' means the Company and all its subsidiaries.

These interim financial statements have been prepared in conformity with IAS 34 *Interim Financial Reporting*. The financial information herein has been prepared in the basis of the accounting policies set out in the annual accounts of the Group for the year ended December 31, 2015 and should be read in conjunction with those annual accounts. The Group prepares its annual accounts in accordance with International Financial Reporting Standards (IFRS) and IFRS Interpretations Committee (IFRS IC) interpretations as adopted by the European Union and the Companies Act 2006 (the Act) applicable to companies reporting under IFRS. In preparing these condensed interim financial statements, the significant judgments made by management in applying the group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the consolidated financial statements for the year ended December 31, 2015, with the exception of changes in estimates that are required in determining the provision for income taxes.

The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual financial statements as at December 31, 2015. These interim condensed consolidated financial statements have been reviewed and not audited. These interim condensed consolidated financial statements have been approved for issue as at April 29, 2016.

Subject to the following matter, after making appropriate enquiries, the Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. However, as disclosed on page 5 and Note 7 relating to the ANDA litigation, the outcome remains uncertain. In the event of a negative ruling against the Group and, should there be a regulatory approval and subsequent commercial launch of generic Suboxone Film, there is the likelihood that revenues and operating profits will decline. In these circumstances the Group has the ability to take necessary measures to reduce its cost base and improve its cash flow to ensure that the Group can continue as a going concern for the foreseeable future. Accordingly, the Directors continue to adopt the going concern basis for accounting in preparing these financial statements.

The financial information contained in this document does not constitute statutory accounts as defined in section 434 and 435 of the Companies Act 2006. The auditors issued an unqualified opinion and did not contain a statement under section 498 of the Companies Act 2006 on the Group's statutory financial statements for the year ended December 31, 2015. The Group's statutory financial statements for the year ended December 31, 2015 were approved by the Board of Directors on March 8, 2016 and will be delivered to the Registrar of Companies.

### 2. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker (CODM), who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer (CEO).

As the Indivior Group is engaged in a single business activity, which is the development, manufacture and sale of prescription drugs that are based on Buprenorphine for treatment of opioid dependence, the CEO reviews financial information presented on a combined basis for evaluating financial performance and allocating resources. Accordingly, the company reports as a single reporting segment.

### Revenues

Revenues are attributed to countries based on the country where the sale originates. The following table represents revenue from continuing operations attributed to countries based on the country where the sale originates and non-current assets, net of accumulated depreciation and amortisation, by country. Non-current assets for this purpose consist of property, plant and equipment and intangible assets. Revenues and non-currents assets for the three months to March 31, 2016 and 2015 were as follows:

Revenues from sale of goods:

For the three months to March 31	2016 \$m	2015 \$m_
United States	211	200
ROW	47	51
Total	258	251

Non-current assets:

	Mar 31 2016 \$m	Dec 31 2015 \$m
United States	82	80
ROW	9	14
Total	91	94

### 3. OPERATING COSTS AND EXPENSES

The table below sets out selected operating costs and expenses information:

For the three months to March 31	2016 \$m	2015 \$m
Research and development expenses	(31)	(20)
Marketing, selling and distribution expenses	(32)	(38)
Administrative expenses	(66)	(47)
Depreciation and amortisation	(6)	(6)
Operating lease rentals	(1)	(1)
Total	(105)	(92)

### **Exceptional Items**

For the three months to March 31	2016 \$m	2015 \$m_
Reconfiguration and separation costs	<u>-</u> _	2
Total Exceptional items	-	2

2015 exceptional items relate to reconfiguration and separation costs consists primarily of legal and advisory costs related to business reconfiguration activities which have been included within operating expenses.

#### 4. TAXATION

In the three months ended March 31, 2016, tax on total profits amounted to \$36m and represented a quarterly effective tax rate of 42% (Q1 2015: 25%); \$5m of these relate to movement of assets within the group and additional provisions for unresolved tax matters and are considered to be exceptional. The Group's balance sheet at March 31, 2016 included a tax payable liability of \$48m and deferred tax asset of \$100m.

The increase in the effective tax rate, excluding exceptionals, to 36% was primarily driven by income mix between countries in the quarter, but this income mix is expected to change in the full year.

### 5. EARNINGS PER SHARE

For the three months to March 31	2016 cents	Cents
Basic earnings per share	7	11
Diluted earnings per share	7	11
Adjusted basic earnings per share	8	11
Adjusted diluted earnings per share	8	11

### Basic

Basic earnings per share ("EPS") is calculated by dividing profit for the period attributable to owners of the Company by the weighted average number of ordinary shares in issue during the period. 718,577,618 shares were issued on the demerger.

### Diluted

Diluted earnings per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. The Company has dilutive potential ordinary shares in the form of stock options. The weighted average number of shares is adjusted for the number of shares granted assuming the exercise of stock options.

	2016	2015
	Average	Average
	number of	number of
	shares	shares
On a basic basis	718,577,618	718,577,618
Dilution for Long Term Incentive Plan	12,692,955	5,307,010
On a diluted basis	731,270,573	723.884.628

### **Adjusted Earnings**

The Directors believe that diluted earnings per share, adjusted for the impact of exceptional items after the appropriate tax amount, provides additional useful information on underlying trends to shareholders in respect of earnings per ordinary share.

A reconciliation of net income to adjusted net income is as follows:

For the three months to March 31	2016 \$m	2015 \$m
Net income	50	77
Exceptional items	-	2
Tax effect of exceptional items	5	_
Adjusted net income	55	79
6. FINANCIAL LIABILITIES – BORROWINGS		
	Mar 31 2016	Dec 31 2015
Current	\$m	\$m
Bank loans	(52)	(34)
	(52)	(34)
	Mar 31	Dec 31
Non-current	2016 \$m	2015 \$m
Bank loans	(542)	(571)
Dankidans	(542)	(571)
	Mar 31	Dec 31
Analysis of net debt	2016 \$m	2015 \$m
Cash and cash equivalents	543	467
Borrowings*	(626)	(641)
	(83)	(174)
*Borrowings reflects the principal amount drawn, before debt issuance costs		
	Mar 31 2016	Dec 31 2015
Reconciliation of net debt	\$m	2013 \$m
The movements in the period were as follows:		
Net debt at beginning of period	(174)	(428)
Increase in cash and cash equivalents	76	136

The carrying value less provision of current borrowings and cash at bank, as well as trade receivables and trade payables are assumed to approximate their fair values.

On March 16, 2015, the Company completed syndication of its \$750 million debt facility. As a result of the syndication the new terms of the loan are as follows:

17

(2)

(83)

121

(174)

(3)

	Currency	Nominal interest margin	Maturity	Scheduled repayments*	Issuance cost \$m	Face value \$m	Carrying amount \$m
Unsecured bank loan	USD	Libor (1%) + 6%	5 years	5%	40	644	644
Unsecured bank loan	EUR	Libor (1%) + 6%	5 years	5%	6	106	106

<sup>\*</sup>For years 1 and 2 only; 10% thereafter

Net repayment of borrowings and overdraft

Exchange adjustments

Net debt at end of period

Also included within the terms of the loan were:

- •A financial covenant to maintain a net secured leverage covenant (Net debt to Adjusted EBITDA ratio) of 3.25x with step down to 3.00x on June 30, 2016
- •An additional covenant requiring minimum liquidity of \$150 million (defined as cash on hand plus the undrawn amount available under the Company's \$50 million revolving credit facility).

### 7. CONTINGENT LIABILITIES

The Indivior Group is currently subject to other legal proceedings and investigations, including through subpoenas and other information requests, by various governmental authorities.

The Indivior business (previously Reckitt Benckiser Pharmaceuticals (RBP)) was demerged from Reckitt Benckiser Group plc (RB) on December 23<sup>rd</sup> 2014 and Indivior PLC became the new ultimate holding company of the group.

In 2011, the USAO-NJ issued a subpoena to Reckitt Benckiser Pharmaceuticals (RBP) requesting production of certain documents in connection with a non-public investigation related, among other things, to the promotion, marketing and

sale of Suboxone® Film, Suboxone® Tablet and Subutex Tablet. RBP responded to the USAO-NJ by producing documents and other information and has had no communication from USAO-NJ since March 2013.

In late 2012, the FTC and the Attorney General of the State of New York commenced non-public investigations of RB, RBP and various other entities in the RB Group focusing on business practices relating to Suboxone® Film, Suboxone® Tablet and Subutex Tablet, including alleged involvement in a scheme to delay FDA approval of generic versions of Suboxone® Tablet. RBP has responded to both the FTC and to the Attorney General of the State of New York by producing documents and other information. 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 and the Attorney General of the State of New York. The existing investigation of these same issues by the State of New York has now been incorporated within this multi-state investigation. The investigations are ongoing, and as yet no decision has been made by either agency on whether to pursue any legal action for enforcement.

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 United States Attorney for the Western District of Virginia has served a number of subpoenas relating to Suboxone® Film, Suboxone® Tablet, Subutex® Tablet, Buprenorphine and the Group's competitors, among other issues. Indivior is 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 the Company. Indivior is cooperating fully with the relevant agencies and prosecutors and will continue to do so.

During the 4th quarter of 2015, the company was notified by the Internal Revenue Service (IRS) of their intent to audit 2013 and 2014 income tax years where the company has claimed certain manufacturing deductions that the IRS has proposed to disallow in the previous audit cycle. The group has not been notified of any proposed disallowance for the 2013-2014 audit period and the company believes it has sufficient documentation having taken appropriate professional advice to claim the deductions in 2013, 2014, and subsequent years. Therefore no provisions have been recorded for the 2013-2014 IRS audit period and subsequent years with respect to this issue.

### **ANDA Litigation**

- Trial in the lawsuits against Actavis and Par involving the Orange Book-listed patents for Suboxone® Film November and December 2015, and post-trial briefing concluded in March 2016. A decision is expected in Q2 and prior to any potential generic launch. Actavis' 30 month stay of FDA approval expired February 28<sup>th</sup>, 2016. Par's 30 month stay of FDA approval expires on September 25<sup>th</sup>, 2016.
- Trial against Teva, Actavis and Par in the lawsuits involving the two recently granted process patents (US Patent No. 8,906,277 and US Patent No. 8,900,497) scheduled for November 2016.
- Trial against Teva in the lawsuit involving the Orange 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 17<sup>th</sup>, 2017. Indivior believes Teva's 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17<sup>th</sup>, 2017, however, Teva disputes the applicability of the stay to this ANDA.
- Trial against Alvogen in the lawsuit involving the Orange Book-listed patents and process patents for Suboxone® Film scheduled for April 2017, with Alvogen's 30-month stay of FDA approval expiring October 29<sup>th</sup>, 2017.
- Trial against Mylan and Sandoz in the lawsuit involving the Orange Book-listed patents for Suboxone® Film is scheduled for September 25<sup>th</sup>, 2017, with Mylan's stay expiring March 24, 2018 and Sandoz's stay expiring April 2, 2018.
- 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. Indivior filed suit on March 21, 2016 which triggered a 30-month stay of approval of Teva's 505(b)(2) NDA.

Given the limited information available to the Indivior Group regarding the foregoing civil and criminal investigations, it is not possible at this time to predict with any certainty if there will be a liability associated with these investigations nor, if one were to occur, is there an ability to quantify the potential impact on the financial statements of the Indivior Group.

### 8. TRADE AND OTHER PAYABLES

	Mar 31 2016 \$m	Dec 31 2015 \$m
Sales returns and rebates	(321)	(287)
Trade payables	(102)	(113)
Accruals	(132)	(116)
Other tax and social security payables	(15)	(12)
Total	(570)	(528)

Customer return and rebate accruals, primarily in the US, are provided for by the Group at the point of sale in respect of the estimated rebates, discounts or allowances payable to customers. Accruals are made at the time of sale but the actual

amounts paid are based on claims made some time after the initial recognition of the sale. As the amounts are estimated they may not fully reflect the final outcome and are subject to change dependent upon, amongst other things, the channel (e.g. Medicaid, Medicare, Managed Care, etc) and product mix. The level of accrual is reviewed and adjusted quarterly in the light of historical experience of actual rebates, discounts or allowances given and returns made and any changes in arrangements. Future events could cause the assumptions on which the accruals are based to change, which could affect the future results of the Group.

### 9. SHARE CAPITAL

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2016	718,577,618	\$0.10	72
At March 31, 2016	718,577,618	\$0.10	72
	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2015	718,577,618	\$2.00	1,437
Nominal value reduction	-	(\$1.90)	(1,365)
At March 31, 2015	718,577,618	\$0.10	72

The holders of ordinary shares (par value \$0.10) are entitled to receive dividends as declared from time to time and are entitled to one vote per share at meetings of the Parent Company.

The initial shareholders resolved, by a special resolution, passed on October 30, 2014, to reduce Indivior's share capital by decreasing the nominal value of each Indivior Ordinary Share from \$2.00 to \$0.10. This created distributable reserves on the balance sheet which will provide Indivior with, among other things, capacity for the payment of future dividends.

As required under section 645 of the Companies Act, the High Court of Justice has confirmed the reduction of the Company's share capital. Following the registration of the Order of the Court with the Companies House, the Capital Reduction became effective on January 21, 2015.

### **10. RELATED PARTIES**

Subsequent to the demerger from former parent, RB, on December 23, 2014, Indivior continues to receive certain services like office space rental and other operational services on commercial terms and on an arm's length basis. Adrian Hennah, the RB CFO, also sits on the Indivior PLC Board of Directors. The amount included within administrative expenses in respect of these services is \$2M.

### 11. POST BALANCE SHEET EVENTS

In April 2016, the Company repurchased an additional \$20M of its syndicated debt in the market at a discount, retiring this debt early.

### **DIRECTORS' RESPONSIBILITY STATEMENT**

The Directors declare that, to the best of their knowledge:

- This condensed set of interim financial statements, which have been prepared in accordance with IAS 34 "Interim Financial Reporting" as adopted by the European Union, gives a true and fair view of the assets, liabilities, financial position, and profit or loss of Indivior; and
- The interim management report gives a fair review of the information required pursuant to regulations 4.2.7 and 4.2.8 of the Disclosure and Transparency Rules (DTR)

The Directors are responsible for the maintenance and integrity of the Company's website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Indivior's Directors are listed in the Annual Report and Accounts for 2015.

Details of all current Directors are available on our website at www.indivior.com

By order of the Board

Shaun Thaxter Chef Executive Officer Cary J. Claiborne Chief Financial Officer

April 29, 2016

### Independent review report to Indivior PLC

# Report on the condensed consolidated interim financial statements

### **Our conclusion**

We have reviewed Indivior PLC's condensed consolidated interim financial statements (the "interim financial statements") in the quarterly financial report of Indivior PLC for the 3 month period ended 31 March 2016. Based on our review, nothing has come to our attention that causes us to believe that the interim financial statements are not prepared, in all material respects, in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure Rules and Transparency Rules of the United Kingdom's Financial Conduct Authority.

### **Emphasis of matter**

Without modifying our conclusion on the interim financial statements, in forming our opinion on the interim financial statements, which is not modified, we have considered the adequacy of the disclosure made in note 1 to the interim financial statements concerning the group's ability to continue as a going concern. This relates to the ANDA litigation where the outcome remains uncertain. In the event of a negative ruling against the Group and, should there be a regulatory approval and subsequent commercial launch of generic Suboxone Film, there is the likelihood that revenues and operating profits may decline. These conditions, along with the other matters explained in note 7 to the interim financial statements, indicate the existence of a material uncertainty which may cast significant doubt about the group's ability to continue as a going concern. The interim financial statements do not include the adjustments that would result if the group was unable to continue as a going concern.

### What we have reviewed

The interim financial statements comprise:

- the condensed consolidated interim balance sheet as at 31 March 2016;
- the condensed consolidated interim income statement and condensed consolidated statement of comprehensive income for the period then ended;
- the condensed consolidated interim statement of cash flows for the period then ended;
- the condensed consolidated interim statement of changes in equity for the period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the quarterly financial report have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure Rules and Transparency Rules of the United Kingdom's Financial Conduct Authority.

As disclosed in note 1 to the interim financial statements, the financial reporting framework that has been applied in the preparation of the full annual financial statements of the Group is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union.

## Responsibilities for the interim financial statements and the review

### Our responsibilities and those of the directors

The quarterly financial report, including the interim financial statements, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the quarterly financial report in accordance with the Disclosure Rules and Transparency Rules of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express a conclusion on the interim financial statements in the quarterly financial report based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure Rules and Transparency Rules of the United Kingdom's Financial Conduct Authority and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

### What a review of interim financial statements involves

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, 'Review of Interim Financial Information Performed by the Independent Auditor of the Entity' issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures.

A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

We have read the other information contained in the quarterly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP Chartered Accountants London 29 April 2016

- a) The maintenance and integrity of the Indivior PLC website is the responsibility of the directors; the work carried out by the auditors does not involve consideration of these matters and, accordingly, the auditors accept no responsibility for any changes that may have occurred to the interim financial statements since they were initially presented on the website.
- b) Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.