



May 3, 2017

**Q1 Financial Results in line with plan. Full Year Guidance Confirmed.**

<b>Quarter to March 31</b>	<b>2017 \$m.</b>	<b>2016 \$m.</b>	<b>% change at actual FX</b>	<b>% change at constant FX</b>
Net Revenue	265	258	+3%	+4%
Operating Profit	128	101	+27%	+27%
Net Income	80	50	+60%	+61%
EPS (cents per share)	11	7	+57%	+57%

**Q1 Financial Highlights**

- Net revenue growth of 3% to \$265m (Q1 2016: \$258m) primarily reflects strong market growth in the US.
- Operating Profit of \$128m (Q1 2016: \$101m) primarily reflects lower litigation and R&D expenditures, which due to planned phasing of activity, are expected to increase over the remainder of 2017. In addition, planned incremental investments in 2017 of \$40m to \$60m related to key pipeline assets are expected to accelerate from Q2 onwards. Operating margin was 48% (Q1 2016: 39%).
- Net income of \$80m (Q1 2016: \$50m) after tax rate of 32% (Q1 2016: 36% plus exceptional tax of \$5m). On an adjusted basis, net income increased 46% to \$80m (Q1 2016: \$55m adjusted).
- Cash balance at quarter end increased to \$729m (Year End 2016: \$692m). Net cash at quarter end was \$182m (Year End 2016: \$131m).

**Q1 Operating Highlights**

- US market growth of low double-digit percentage levels is in-line with expectations, and was modestly boosted by the impact of the regulatory change to allow qualified physicians to treat up to 275 patients from 100 patients.
- SUBOXONE® Film market share on average for the quarter was 60% (Q1 2016: 60%). Market share at the end of the quarter, however, was 59% primarily due to the loss of a Managed Medicaid account to generic competition. Total volume sold in the US was up despite significant destocking at wholesalers. SUBOXONE® Film list price increased modestly in January 2017, but was offset by tactical rebates as generic and branded discounting continues.
- The NDA for RBP-6000, the monthly depot of buprenorphine for the treatment of opioid use disorder, is on-track and expected to be filed in Q2 2017. The NDA for RBP-7000, the monthly depot of risperidone for the treatment of schizophrenia, is also on-track and expected to be filed in Q4 2017.
- Indivior continues to await the outcome of the trial against Dr. Reddy's Laboratories (Dr. Reddy's) on US Patent Nos. 8,017,150, 8,603,514, and 8,900,497; and against Actavis and Par on US Patent No. 8,900,497, which is expected sometime in Q2.
- 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 ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. Please see pages five to seven for a complete Litigation Update.

## Guidance

- Full year preliminary guidance for 2017 is confirmed: net revenue of \$1,050m-\$1,080m and net income of \$200m-\$220m (excluding exceptional items and at constant exchange rates) and assuming no material change to current US market conditions for SUBOXONE® Film. The guidance also reflects planned incremental investments of \$40m-\$60m related to key pipeline assets that are expected to accelerate from Q2 onwards, as well as litigation and R&D expenditures that are expected to increase over the remainder of 2017.

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

“We are off to a good start to the year. Our Q1 results were in-line with our plan, which assumed no material deterioration in the market environment, and we made progress against key strategic priorities. In the US, SUBOXONE® Film share remains resilient at just under 60% despite ongoing intense competition, particularly in Managed Medicaid. This is a testament to our market leading presence combined with the growing awareness of opioid use disorder as a disease state that is increasingly being helped by legislation and funding at governmental levels. Meanwhile, we continue to turn our energy and resources to Indivior’s future – RBP-6000 (monthly depot of buprenorphine) and RBP-7000 (monthly depot of risperidone). We are on-track to file NDAs for both products with FDA this year and we will invest appropriately to help ensure their successful launch upon approval. Our finances continue to improve with net cash having increased to \$182m at the end of Q1, and we are continuing to enhance our compliance capability to keep pace with the expected market growth. We are pleased today to confirm our financial guidance for the current year. Overall, we have made good progress in the quarter and remain focused on our commitment to empowering patients and striving to improve their quality of life by pioneering innovative, quality, accessible and cost effective treatments.”

## Operating Review

### US Market Update

The market for buprenorphine products continued to grow strongly in Q1 2017, showing volume growth of low double-digit percentage levels, in-line with expectations. The recent regulatory change to raise the patient cap for qualified physicians to 275 from 100, have increased the provision of treatment, while the number of nurse practitioners and physician assistants applying for training as prescribers, as permitted under the CARA legislation, suggests that this provision will also expand treatment access in due course.

SUBOXONE® Film had an average market share of 60% in Q1 2017, which was unchanged compared to Q1 2016, but ended the quarter at 59%. This was below the exit share at the end of Q1 2016 primarily due to the loss of a Managed Medicaid account to generic competition, although commercial formulary access remains solid. The list price of SUBOXONE® Film in the US increased modestly in January 2017.

### Financial Performance in Q1 2017

Total net revenue grew 3% at actual exchange rates to \$265m (Q1 2016: \$258m), and was up 4% on a constant exchange rate basis.

US net revenue grew by 2% to \$215m (Q1 2016: \$211m). Volume was ahead of last year, reflecting market growth that was somewhat offset by wholesaler destocking resulting from a build-up of supply in late 2016 and modest share decline due to the loss of a Managed Medicaid account. List pricing was up reflecting a modest increase in January, but was offset by continued tactical rebates in connection with formulary access in both commercial managed care and in particular Medicaid in response to continued discounting by both branded and generic competitors.

Rest of World net revenue increased 6% to \$50m (Q1 2016: \$47m) as reported in USD. At constant exchange rates, the increase was 13%. The increase was primarily driven by the timing of export revenues in the quarter, mainly related to certain Middle East customers. In Europe, market share was again resilient, but was modestly affected by further generic substitution. Australasia saw steady growth due to growing numbers of patients seeking treatment resulting from ongoing marketing initiatives.

Gross margin was up slightly to 93% (Q1 2016: 92%) primarily due to increased production in the quarter.

SD&A expenses decreased by 11% to \$93m (Q1 2016: \$105m) principally reflecting lower litigation expenditures, which due to planned phasing of activity, are expected to increase from Q2 onwards in 2017, plus lower amortization as the acquisition costs for the Rest of World rights to SUBOXONE® that fully amortized at the end of 2016. There were no exceptional costs included in SD&A in either Q1 2016 or Q1 2017. Planned incremental investments related to key pipeline assets – RBP-6000 buprenorphine monthly depot and RBP-7000 risperidone monthly depot – are expected to accelerate beginning in the current quarter.

R&D expenses decreased by 19% to \$25m (Q1 2016: \$31m), reflecting planned phasing differences versus 2016 that are expected to reverse from Q2 onwards in 2017, as well as the completion of active Phase III trials on RBP-6000 and RBP-7000. The costs of preparing the two NDAs will be incurred through the balance of the year and are included in current FY 2017 guidance.

Operating profit was \$128m, 27% ahead of prior year, primarily reflecting the lower litigation and R&D expenses, which due to planned phasing of activity, are expected to increase from Q2 onwards in 2017. Operating margin was 48% (Q1 2016: 39%).

EBITDA was \$130m (Q1 2016: \$107m). EBITDA margin was 49% (Q1 2016: 42%).

Finance expense in the quarter was \$11m (2016 Q1: \$15m). The decrease was due to the impact of the buyback and paying down some of the term loan facility during 2016.

The tax charge in Q1 was \$37m, at a rate of 32% (Q1 2016: 36% plus exceptional tax of \$5m), reflecting the mix of profits between countries in the period. Currently, we expect our full year effective tax rate to be 25%, consistent with the guidance given in February.

Net income for the quarter was \$80m (Q1 2016: \$50m, and on an adjusted basis excluding the exceptional tax of \$5m: \$55m), an increase of 60% compared to Q1 2016 as reported. At constant exchange rates, the increase was 61%. On an adjusted basis, the increase was 46%.

EPS were 11 cents (Q1 2016: 7 cents, or 8 cents on an adjusted basis) on both a basic and diluted basis.

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

Net working capital (inventory plus trade and other receivables, less trade and other payables) was minus \$327m at end Q1 2017 (minus \$390m at end December 2016). The difference primarily relates to the combination of lower accruals at quarter end due to wholesaler destocking and the timing of payments.

Cash and cash equivalents at the period end were \$729m, reflecting a net cash increase of \$37m in the quarter. Borrowings, net of issuance costs, were \$524m (Dec 2016: \$535m) at the quarter end after debt payback in the quarter of \$11m.

Net cash was \$182m (Dec 2016: \$131m), the increase of \$51m reflecting cash inflow and debt repayment.

Cash generated from operating activities was \$71m (Q1 2016: \$115m), a decrease of \$44m due to higher levels of operating profit of \$128m (Q1 2016: \$101m), offset by a change in net working capital which was a use of cash of \$63m in Q1 2017 (versus a source of cash of \$8m in Q1 2016).

Net cash inflow from operations decreased to \$60m in the quarter (Q1 2016: \$97m) reflecting the lower cash from operating activities offset by lower tax payments in the quarter of \$1m (Q1 2016: \$7m), and after interest and transaction costs relating to the term loan facility of \$10m (Q1 2016: \$11m). After investments of \$8m (Q1 2016: \$4m) and repayment of borrowings of \$16m (Q1 2016: \$17m), the net increase in cash and cash equivalents was \$36m (Q1 2016: \$76m), the lower level of net cash generation being the result of short-term absorption of cash in working capital.

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

### Treatment of Opioid Use Disorder

- **RBP-6000, Monthly Depot Buprenorphine:** Phase III Efficacy Study (RB-US-13-0001); top line results published on August 17th, 2016 showing RBP-6000 achieved both primary and secondary endpoints. Final CSR signed off March 3rd, 2017. PK/PD/Receptor Occupancy analysis and topline HEOR data released March 22nd, 2017.

Phase III Safety Extension Study (RB-US-13-0003) completed with database lock achieved October 31st, 2016. Interim analysis signed off March 23rd, 2017.

**US Fast Track Designation** granted May 23rd, 2016.

Pre-NDA meeting held December 2016. Target NDA submission to FDA Q2-2017.

**Meetings with Regulatory Agencies ex-USA held in Q4-2016:** TGA (Australia); HC (Canada); ANSM (France); MHRA (United Kingdom); MPA (Sweden); BfArM (Germany).

### Treatment of Schizophrenia

- **RBP-7000, Monthly Depot Risperidone:** Topline data from pivotal Phase III Efficacy Study were published on May 5th, 2015.

Phase III Long-term Safety Study (RB-US-13-0005) was completed in September 2016 with database lock achieved October 2016. Final CSR signed off March 31st, 2017.

Pre-NDA meeting held August 2016. Target NDA submission to FDA Q4-2017.

### Overdose Rescue Products

- **Intranasal Naloxone:** NALSCUE® launched in France under Temporary Authorisation for Use (ATU) in July 2016. MAA submitted November 2016. ANSM recommended approval on March 16th, 2017.
- **RBP-8000 Cocaine Esterase:** Second type B meeting with FDA held March 2016. Per agreement with FDA, work has continued with the development of a lyophilized product and first test batch was manufactured in October 2016.

### Treatment of Alcohol Use Disorder

- **Arbaclofen Placarbil:** New Phase I Bioavailability Clinical Study Protocol (INDV-AP-102) of a new formulation of Arbaclofen Placarbil was completed. Results are under evaluation.

### Key Pipeline Dates 2017

Q2	RBP-6000 NDA filing expected
June	CPDD Conference – RBP-6000 Phase III clinical & safety data
Oct	ACoP Conference – RBP-6000 Phase III Exposure/Response data
Nov	AMERSA Conference – RBP-6000 Phase III health economics & outcomes research data
Q4	RBP-7000 NDA filing expected
Q4	PDUFA date for RBP-6000 assuming Priority Review is granted

## Litigation Update

The Group carries a provision of \$218m for the investigative and antitrust litigation matters noted below. The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. The Group cannot predict with any certainty whether it will reach ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this reserve.

### Department of Justice Investigation

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

### State Subpoenas

- On October 12th, 2016, Indivior was served with a subpoena for records from the State of Connecticut Office of the Attorney General under its Connecticut civil false claims act authority. The subpoena requests documents related to the Group's marketing and promotion of SUBOXONE® products and its interactions with a non-profit third party organization. On November 16th, 2016, Indivior was served with a subpoena for records from the State of California Department of Insurance under its California insurance code authority. The subpoena requests documents related to SUBOXONE® Film, SUBOXONE® Tablet, and SUBUTEX® Tablet. The Group is fully cooperating in these investigations.

### FTC investigation and Antitrust Litigation

- The U.S. Federal Trade Commission's investigation remains pending. Litigation regarding privilege claims has now been resolved. Indivior has produced certain documents that it had previously withheld as privileged; other such documents have not been produced.
- Fact discovery is continuing in the antitrust class action litigation. Plaintiffs allege, among other things, that Indivior violated U.S. federal and state antitrust laws in attempting to delay generic entry of alternatives to SUBOXONE® tablets, and plaintiffs further allege that Indivior unlawfully acted to lower the market share of these products.
- Amneal Pharmaceuticals LLC (Amneal), a manufacturer of generic buprenorphine / naloxone tablets, has alleged antitrust violations similar in nature to those alleged in the class action complaints, and Amneal has also alleged violations of the U.S. Lanham Act. This case has been coordinated with the antitrust class action litigation.
- A group of states, now numbering 41, and the District of Columbia filed suit against Indivior in the same district where the antitrust class action litigation and Amneal cases are pending. The States' complaint is similar to the other pending antitrust complaints, and alleges violations of U.S. state and federal antitrust and consumer protection laws. This lawsuit relates to the investigation conducted by various states, as discussed in previous filings. Discovery has been coordinated with the antitrust class action litigation and Amneal cases, subject to certain stays.

## ANDA Litigation and Inter Partes Review

- The ruling after trial against **Actavis** and **Par** in the lawsuit involving the Orange Book-listed patents for SUBOXONE® Film issued on June 3rd, 2016. The ruling found the asserted claims of the '514 patent valid and infringed; the asserted claims of the '150 patent valid but not infringed; and the asserted claims of the '832 patent invalid, but found that certain claims would be infringed if they were valid.
- Based on the ruling as to the '514 patent, **Actavis** and **Par** are currently enjoined from launching a generic product. **Par** has appealed and **Actavis** is expected to appeal this ruling. The generics have also moved to reopen the judgment based on the claim construction in the **Dr. Reddy's** case. In light of the motions to reopen, **Par's** appeal has been deactivated until the District Court rules on the motions, and the deadline for **Actavis** to file a notice of appeal has been postponed.
- Trial against **Dr. Reddy's, Actavis and Par** in the lawsuits involving the process patent (U.S. Patent No. 8,900,497) took place on November 16th and 21st-23rd, 2016.
- Trial against **Dr. Reddy's** in the lawsuit involving two of the Orange Book-listed patents for SUBOXONE® Film (U.S. Patent Nos. 8,017,150 and 8,603,514) took place on November 7th, 16th, and 21st-23rd, 2016. **Dr. Reddy's** 30-month stay of FDA approval expired on April 17th, 2017. So far as Indivior is aware, FDA to date has not granted tentative or final marketing authorization to **Dr. Reddy's** (or any other generic SUBOXONE® Film alternative). If FDA were to grant final approval to **Dr. Reddy's** this would enable them to market a generic film alternative to SUBOXONE® Film in the U.S. However, any market launch by **Dr. Reddy's** before the District Court renders its decision, or before the court of appeals renders its decision even if **Dr. Reddy's** was to prevail before the District Court, would be on an "at risk" basis because Indivior would have a claim for damages against **Dr. Reddy's** if it ultimately prevails after any appeal.
- A stipulation and proposed order was filed with the District Court on April 28th, 2017, seeking to consolidate the trial against **Alvogen** in the lawsuit involving the '150 and '514 Orange Book-listed patents and the '497 process patent for SUBOXONE® Film with the trial against **Mylan** (discussed below). The District Court approved the stipulation on May 1st, 2017. Accordingly, the trial against **Alvogen** will be scheduled for September 25th-27th, 2017, and will be tried concurrently with the trial against **Mylan**. The 30-month stay of FDA approval of **Alvogen's** Abbreviated New Drug Application is presently set to expire October 29th, 2017.
- By a Court order dated August 22nd, 2016, Indivior's SUBOXONE® Film patent litigation against **Sandoz** has been dismissed without prejudice because **Sandoz** is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE® Film.
- Trial against **Mylan** in the lawsuit involving the '150 and '514 Orange Book-listed patents and the '497 process patent for SUBOXONE® Film is scheduled for September 25th-27th, 2017, and will be tried concurrently with the trial against **Alvogen** pursuant to a stipulation filed with and approved by the District Court. The 30-month stay of FDA approval of **Mylan's** Abbreviated New Drug Application is presently set to expire March 24th, 2018. On January 12th, 2017, the District Court issued a claim construction decision in the **Mylan** action that clarified its earlier construction in the **Dr. Reddy's** case of certain terms in the '514 patent.
- Indivior received a Paragraph IV notification from **Teva**, dated February 8th, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of buprenorphine/naloxone sublingual film. The parties have agreed that infringement by Teva's 16 mg/4 mg dosage strength will be governed by the infringement ruling on the accused 8 mg/2 mg dosage strength in the ANDA now owned by **Dr. Reddy's** that was the subject of the trial in November 2016.



- On May 31st, 2016, **Dr. Reddy's** filed petitions seeking inter parties review (IPR) of the three Orange Book-listed patents covering SUBOXONE® Film. Indivior and Monsol Rx filed Patent Owner Preliminary Responses opposing institution of the IPRs on September 6th, 2016, arguing that institution of the IPRs should be denied. On December 2nd, 2016, the US Patent Trial and Appeal Board (PTAB) denied institution of the IPR as to the '832 Patent, and on December 5th, 2016, the PTAB denied institution of the IPRs as to the '514 and '150 Patents. On January 3rd, 2017, **Dr. Reddy's** filed Requests for Rehearing of the three non-institution decisions. On March 22nd, 2017, the PTAB denied **Dr. Reddy's** request for rehearing of its decisions not to institute its petitions for IPRs of the '150 and '514 patents. This denial by the PTAB resolves **Dr. Reddy's** attempts to seek to invalidate the '150 and '514 patents through IPR proceedings. A separate panel of the PTAB is handling the proceeding on the '832 patent and has not yet issued its decision on **Dr. Reddy's** Rehearing Request in that case.
- **Mylan** has filed a petition seeking an IPR of the '514 patent. A decision by the US Patent & Trademark Office on whether to institute IPR proceedings is expected in May 2017.
- In the event that one or more of the generic companies are successful in their patent challenges, and should there be FDA approval of one or more of the ANDAs and subsequent commercial launch of generic SUBOXONE® Film, and the Group's pipeline products fail to obtain regulatory approval, there is the likelihood that revenues and operating profits of the Group will significantly decline. In these circumstances the Directors believe they would be able to take the required steps to reduce the cost base, however, this would result in a significant change to the structure of the business.

#### **Rhodes Pharmaceuticals**

- On March 21st, 2017 **Rhodes Pharmaceuticals** filed a complaint against Indivior in the District of Delaware, alleging that Indivior's sale of SUBOXONE® Film in the U.S. infringes one or more claims of a patent. The asserted patent, which was issued in June 2016 traces back to an application filed in August 2007. Indivior believes this claim is without merit and intends to vigorously defend this action.

#### **Estate of John Bradley Allen**

- On December 27th, 2016, the Estate of John Bradley Allen filed a civil complaint against Indivior, among other parties, in the Northern District of New York seeking relief under Connecticut's products liability and unfair trade practices statutes for damages allegedly caused by SUBOXONE®. Indivior believes this lawsuit is without merit and intends to vigorously defend this action.

#### **Risk Factors**

The Directors have reviewed the principal risks and uncertainties for the financial year 2017.

The assumptions in arriving at the Group's financial guidance for the full year 2017 are described on page 2 of this announcement. To the extent that actual market conditions differ from these assumptions, alternative financial outcomes are possible. However, the Group 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 2017, the Directors consider that the principal risks and uncertainties which could have a material impact on the Group's performance in 2017 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.
- The Group has a single source of supply for buprenorphine, an active ingredient in the Group's products, including SUBOXONE® Film, and any disruption to this source of supply 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 liability, regulation and 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 under Litigation Update on pages {5-7} referring to the current status of the Department of Justice and Federal Trade Commission investigations, state subpoenas, antitrust litigation, ANDA litigation and Inter Partes Reviews, as well as the contingent liabilities disclosures on pages {18-20, 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 under Litigation Update on page {5-7} referring to the current status of the investigative and litigation matters involving the Group, as well as the contingent liabilities disclosures on pages {18-20, note 7}. The Group has taken steps to enhance its compliance capability to handle the expected growth in the business, and will continue to monitor changing compliance requirements due to growth, changes in the business, and changing regulatory requirements.

#### Acquisitions and business development

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

#### Product Safety

- The Group's pharmacovigilance processes has been established to monitor the safety of the Group's products in a comprehensive and thorough manner. This includes capturing safety-related data from multiple sources (e.g. MIU, Market Research, Literature Search and Clinical trials) and entering all adverse events received into a safety database. The Group reports to health authorities across the globe within the required and mandatory time lines and identifies safety signals with an assessment of changes to benefit/risk profile, determines actions needed to optimize the safe and effective use of our product, including communicating any relevant changes to key stakeholders.
- The Group's annual report for the 2016 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, 2017	3 Months to March 31, 2016
GB £ period end	1.2434	1.4153
GB £ average rate	1.2390	1.4323
€ Euro period end	1.0766	1.1176
€ Euro average	1.0653	1.1019

## Webcast Details

There will be a conference call at 1pm UK time (8am Eastern in the USA) hosted by Shaun Thaxter, CEO, and Mark Crossley, CFO. This call will also be webcast live. The details are below and are available on the Company's website at [www.indivior.com](http://www.indivior.com)

*Webcast link:* <http://edge.media-server.com/m/p/cm2hr9w3>

**Confirmation Code:** 7569891  
Participants, Local - London, United Kingdom: +44(0)20 3427 1914  
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This announcement does not constitute an offer to sell, or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

## 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 may or may not occur in the future. Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding the Indivior Group's financial guidance for 2017 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation.

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; 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.

## 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](http://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](http://www.suboxoneREMS.com).

## Condensed consolidated interim income statement

<b>For the three months ended March 31</b>	Notes	<b>Unaudited 2017 \$m</b>	Unaudited 2016 \$m
<b>Net Revenues</b>	2	<b>265</b>	258
Cost of Sales		<b>(19)</b>	(21)
<b>Gross Profit</b>		<b>246</b>	237
Selling, distribution and administrative expenses	3	<b>(93)</b>	(105)
Research and development expenses	3	<b>(25)</b>	(31)
<b>Operating Profit</b>		<b>128</b>	101
Finance expense		<b>(11)</b>	(15)
<b>Profit before taxation</b>		<b>117</b>	86
Taxation	4	<b>(37)</b>	(31)
Exceptionals items within taxation	4	-	(5)
<b>Net income</b>		<b>80</b>	50
<b>Earnings per ordinary share (cents)</b>			
Basic earnings per share	5	<b>11</b>	7
Diluted earnings per share	5	<b>11</b>	7

## Condensed consolidated interim statement of comprehensive income

<b>For the three months ended March 31</b>	<b>Unaudited 2017 \$m</b>	Unaudited 2016 \$m
Net income	<b>80</b>	50
<b>Other comprehensive income</b>		
<i>Items that may be reclassified to profit or loss in subsequent years</i>		
Net exchange adjustments on foreign currency translation	<b>2</b>	(3)
Other comprehensive income	<b>2</b>	(3)
<b>Total comprehensive income</b>	<b>82</b>	47

The notes are an integral part of these condensed consolidated interim financial statements.

## Condensed consolidated interim balance sheet

	Notes	Unaudited Mar 31, 2017 \$m	Audited Dec 31, 2016 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		82	83
Property, plant and equipment		34	27
Deferred tax assets		74	109
Prepayments		1	-
		<b>191</b>	<b>219</b>
<b>Current assets</b>			
Inventories		47	41
Trade and other receivables		228	227
Current tax receivable		30	30
Cash and cash equivalents	6	729	692
		<b>1,034</b>	<b>990</b>
<b>Total assets</b>		<b>1,225</b>	<b>1,209</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	6	(101)	(101)
Provision for liabilities and charge		(218)	(219)
Trade and other payables	8	(602)	(658)
Current tax liabilities		(52)	(52)
		<b>(973)</b>	<b>(1,030)</b>
<b>Non-current liabilities</b>			
Borrowings	6	(423)	(434)
Provisions for liabilities and charges		(40)	(40)
		<b>(463)</b>	<b>(474)</b>
<b>Total liabilities</b>		<b>(1,436)</b>	<b>(1,504)</b>
<b>Net liabilities</b>		<b>(211)</b>	<b>(295)</b>
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	9	72	72
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(20)	(22)
Retained Earnings		1,032	950
<b>Total equity</b>		<b>(211)</b>	<b>(295)</b>

The notes are an integral part of these condensed consolidated interim financial statements.

## Condensed consolidated interim statement of changes in equity

	Notes	Share capital	Share Premium	Other reserve	Foreign Currency Translation reserve	Retained earnings	Total equity
		\$m	\$m	\$m	\$m	\$m	\$m
<b>Unaudited</b>							
<b>Balance at January 1, 2016</b>		<b>72</b>	<b>-</b>	<b>(1,295)</b>	<b>(23)</b>	<b>967</b>	<b>(279)</b>
<b>Comprehensive income</b>							
Net income		-	-	-	-	50	50
Other comprehensive income		-	-	-	(3)	-	(3)
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>(3)</b>	<b>50</b>	<b>47</b>
<b>Transactions recognised directly in equity</b>							
Share-based plans		-	-	-	-	3	3
Deferred taxation on share-based plans		-	-	-	-	(1)	(1)
<b>Balance at March 31, 2016</b>		<b>72</b>	<b>-</b>	<b>(1,295)</b>	<b>(26)</b>	<b>1,019</b>	<b>(230)</b>
<b>Balance at January 1, 2017</b>							
		<b>72</b>	<b>-</b>	<b>(1,295)</b>	<b>(22)</b>	<b>950</b>	<b>(295)</b>
<b>Comprehensive income</b>							
Net income		-	-	-	-	80	80
Other comprehensive income		-	-	-	2	-	2
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>2</b>	<b>80</b>	<b>82</b>
<b>Transactions recognised directly in equity</b>							
Share-based plans		-	-	-	-	2	2
<b>Balance at March 31, 2017</b>		<b>72</b>	<b>-</b>	<b>(1,295)</b>	<b>(20)</b>	<b>1,032</b>	<b>(211)</b>

The notes are an integral part of these condensed consolidated interim financial statements.

## Condensed consolidated interim cash flow statement

	Unaudited	Unaudited
	2017	2016
For the three months ended March 31	\$m	\$m
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit	128	101
Depreciation and amortization	2	6
Share-based payments	2	2
Impact from foreign exchange movements	2	(2)
Increase in trade and other receivables	(1)	(35)
Increase in inventories	(5)	-
(Decrease)/increase in trade and other payables	(56)	43
Decrease in provisions	(1)	-
<b>Cash generated from operations</b>	<b>71</b>	<b>115</b>
Net financing costs	(10)	(11)
Taxes paid	(1)	(7)
<b>Net cash inflow from operating activities</b>	<b>60</b>	<b>97</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(8)	(4)
<b>Net cash (outflow) from investing activities</b>	<b>(8)</b>	<b>(4)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Cash movements in borrowings	(16)	(17)
<b>Net cash (outflow) from financing activities</b>	<b>(16)</b>	<b>(17)</b>
<b>Net increase in cash and cash equivalents</b>	<b>36</b>	<b>76</b>
Cash and cash equivalents at beginning of the period	692	467
<b>Exchange differences</b>	<b>1</b>	<b>-</b>
<b>Cash and cash equivalents at end of the period</b>	<b>729</b>	<b>543</b>

The notes are an integral part of these condensed consolidated interim financial statements.



## Notes to the condensed consolidated interim financial statements

### 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

Indivior PLC (the 'Company') is a public limited company that was 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, 2016 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, 2016, with the exception of changes in estimates that are required in determining the provision for income taxes.

The Interim 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, 2016. These Interim Financial Statements have been reviewed and not audited. These Interim Financial Statements have been approved for issue as at May 2, 2017.

As disclosed in Note 7, the Group carries a provision of \$218m relating to the Department of Justice and Federal Trade Commission investigations and antitrust litigation. The final amount may be materially higher than this reserve. This could impact the Group's ability to operate, which would be further adversely impacted should revenues decline and pipeline products fail to obtain regulatory approval, all of which could mean the Group could not continue in business without taking necessary measures to reduce its cost base and improve its cash flow. As such, this indicates a material uncertainty that may cast significant doubt on the Group's ability to continue as a going concern. However, the Directors believe they have the ability to carry out the measures that would be necessary and 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, which do not include any adjustments that might result from the outcome of this uncertainty.

The financial information contained in this document does not constitute statutory accounts as defined in section 434 and 435 of the Act. The auditors issued an unqualified opinion and did not contain a statement under section 498 of the Act on the Group's statutory financial statements for the year ended December 31, 2016. The Group's statutory financial statements for the year ended December 31, 2016 were approved by the Board of Directors on March 7, 2017 and will be delivered to the Registrar of Companies subject to the approval by shareholders at the Annual General Meeting to be held on May 17, 2017.

### 2. SEGMENT INFORMATION

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

The Indivior Group is engaged in a single business activity, which is the development, manufacture and sale of buprenorphine-based prescription drugs for treatment of opioid dependence. The CEO reviews financial information on a geographic basis for evaluating financial performance and allocating resources. The Group has a single reportable 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 amortization, 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, 2017 and 2016 were as follows:

Revenues from sale of goods:

<b>For the three months ended March 31</b>	<b>2017</b>	<b>2016</b>
	<b>\$m</b>	<b>\$m</b>
United States	215	211
ROW	50	47
<b>Total</b>	<b>265</b>	<b>258</b>

Non-current assets:

	<b>Mar 31 2017</b>	<b>Dec 31 2016</b>
	<b>\$m</b>	<b>\$m</b>
United States	65	64
ROW	51	46
<b>Total</b>	<b>116</b>	<b>110</b>

### 3. OPERATING COSTS AND EXPENSES

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

<b>For the three months ended March 31</b>	<b>2017</b>	<b>2016</b>
	<b>\$m</b>	<b>\$m</b>
Research and development expenses	<b>(25)</b>	<b>(31)</b>
Marketing, selling and distribution expenses	<b>(33)</b>	<b>(32)</b>
Administrative expenses	<b>(56)</b>	<b>(66)</b>
Depreciation and amortization	<b>(2)</b>	<b>(6)</b>
Operating lease rentals	<b>(2)</b>	<b>(1)</b>
<b>Total</b>	<b>(93)</b>	<b>(105)</b>

### 4. TAXATION

The Group calculates tax expense for interim periods using the expected full year rates, considering the pre-tax income and statutory rates for each jurisdiction. The resulting expense is allocated between current and deferred taxes based upon the forecasted full year ratio.

In the three months ended March 31, 2017, tax on total profits amounted to \$37m and represented a quarterly effective tax rate of 32% (Q1 2016: 36%, excluding exceptionals). The Group's balance sheet at March 31, 2017 included a tax payable liability of \$52m, tax receivables of \$30m, and deferred tax asset of \$74m. The reduction in deferred tax assets of \$35m relates primarily to temporary differences on unrealized profit on the sale of inventory between Group entities. This reduction is expected to be sustained.

The decrease in the effective tax rate to 32% was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the quarter.

The United Kingdom ('UK') decision to withdraw from the European Union ('EU') could have a material effect on our taxes. The impact of the withdrawal will not be known until both the EU and the UK develop the exit plan and the related changes in tax laws are enacted. We will adjust our current and deferred income taxes when tax law changes related to the UK withdrawal are substantively enacted and/or when EU law ceases to apply in the UK.

### 5. EARNINGS PER SHARE

<b>For the three months ended March 31</b>	<b>2017</b>	<b>2016</b>
	<b>cents</b>	<b>cents</b>
Basic earnings per share	<b>11</b>	<b>7</b>
Diluted earnings per share	<b>11</b>	<b>7</b>
Adjusted basic earnings per share	<b>11</b>	<b>8</b>
Adjusted diluted earnings per share	<b>11</b>	<b>8</b>

#### 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.

#### 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.

	<b>2017</b>	<b>2016</b>
	<b>Average</b>	<b>Average</b>
	<b>number of</b>	<b>number of</b>
	<b>shares</b>	<b>shares</b>
On a basic basis	<b>720,064,760</b>	718,577,618
Dilution for Long Term Incentive Plan	<b>27,263,710</b>	12,692,955
Employee Sharesave Scheme	<b>1,050,182</b>	-
On a diluted basis	<b>748,378,653</b>	731,270,573

#### 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:

<b>For the three months ended March 31</b>	<b>2017</b>	<b>2016</b>
	<b>\$m</b>	<b>\$m</b>
Net income	<b>80</b>	50
Exceptional items within taxation	-	5
<b>Adjusted net income</b>	<b>80</b>	<b>55</b>

## 6. FINANCIAL LIABILITIES – BORROWINGS

<b>Current</b>	<b>Mar 31</b>	<b>Dec 31</b>
	<b>2017</b>	<b>2016</b>
	<b>\$m</b>	<b>\$m</b>
Bank loans	<b>(101)</b>	(101)
	<b>(101)</b>	<b>(101)</b>
<b>Non-current</b>	<b>Mar 31</b>	<b>Dec 31</b>
	<b>2017</b>	<b>2016</b>
	<b>\$m</b>	<b>\$m</b>
Bank loans	<b>(423)</b>	(434)
	<b>(423)</b>	<b>(434)</b>
<b>Analysis of net debt</b>	<b>Mar 31</b>	<b>Dec 31</b>
	<b>2017</b>	<b>2016</b>
	<b>\$m</b>	<b>\$m</b>
Cash and cash equivalents	<b>729</b>	692
Borrowings*	<b>(547)</b>	(561)
	<b>182</b>	<b>131</b>

\*Borrowings reflects the principal amount drawn, before debt issuance costs

<b>Reconciliation of net debt</b>	<b>Mar 31</b>	<b>Dec 31</b>
	<b>2017</b>	<b>2016</b>
	<b>\$m</b>	<b>\$m</b>
The movements in the period were as follows:		
Net debt at beginning of period	<b>131</b>	(174)
Increase in cash and cash equivalents	<b>37</b>	225
Net repayment of borrowings and overdraft	<b>16</b>	78
Exchange adjustments	<b>(2)</b>	2
Net debt at end of period	<b>182</b>	<b>131</b>

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. The terms of the loan in effect at March 31, 2017 are as follows:

	<b>Currency</b>	<b>Nominal interest margin</b>	<b>Maturity</b>	<b>Required annual repayments</b>	<b>Maximum leverage ratio</b>	<b>Minimum liquidity \$m</b>
Term loan facility	USD	Libor (1%) + 6%	2019	10%	2.75	150
Term loan facility	EUR	Libor (1%) + 6%	2019	10%	2.75	150

- The maximum leverage ratio is a financial covenant to maintain net secured leverage below a specified maximum (Adjusted net debt to Adjusted EBITDA ratio) which will step down to 2.50x on June 30, 2017
- The minimum liquidity covenant requires the Group to maintain cash on hand plus the undrawn amount available under the Group's \$50 million revolving credit facility of at least \$150 million.

## 7. CONTINGENT LIABILITIES

The Group is currently subject to other legal proceedings and investigations, including through subpoenas and other information requests, by various governmental authorities. It is not possible at this time to predict with any certainty the potential impact of these matters on the Group, or to quantify the ultimate cost of a resolution of these matters. The Group carries a provision of \$218m for the investigative and antitrust litigation matters noted below. The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. The Group cannot predict with any certainty whether we will be able to reach ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this reserve.

## Department of Justice Investigation

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

## State Subpoenas

- On October 12th, 2016, Indivior was served with a subpoena for records from the State of Connecticut Office of the Attorney General under its Connecticut civil false claims act authority. The subpoena requests documents related to the Group's marketing and promotion of SUBOXONE® products and its interactions with a non-profit third party organization. On November 16th, 2016, Indivior was served with a subpoena for records from the State of California Department of Insurance under its California insurance code authority. The subpoena requests documents related to SUBOXONE® Film, SUBOXONE® Tablet, and SUBUTEX® Tablet. The Group is fully cooperating in these investigations.

## FTC investigation and Antitrust Litigation

- The U.S. Federal Trade Commission's investigation remains pending. Litigation regarding privilege claims has now been resolved. Indivior has produced certain documents that it had previously withheld as privileged; other such documents have not been produced.
- Fact discovery is continuing in the antitrust class action litigation. Plaintiffs allege, among other things, that Indivior violated U.S. federal and state antitrust laws in attempting to delay generic entry of alternatives to SUBOXONE® tablets, and plaintiffs further allege that Indivior unlawfully acted to lower the market share of these products.
- Amneal Pharmaceuticals LLC (Amneal), a manufacturer of generic buprenorphine / naloxone tablets, has alleged antitrust violations similar in nature to those alleged in the class action complaints, and Amneal has also alleged violations of the U.S. Lanham Act. This case has been coordinated with the antitrust class action litigation.
- A group of states, now numbering 41, and the District of Columbia filed suit against Indivior in the same district where the antitrust class action litigation and Amneal cases are pending. The States' complaint is similar to the other pending antitrust complaints, and alleges violations of U.S. state and federal antitrust and consumer protection laws. This lawsuit relates to the investigation conducted by various states, as discussed in previous filings. Discovery has been coordinated with the antitrust class action litigation and Amneal cases, subject to certain stays.

## ANDA Litigation and Inter Partes Review

- The ruling after trial against **Actavis** and **Par** in the lawsuit involving the Orange Book-listed patents for SUBOXONE® Film issued on June 3rd, 2016. The ruling found the asserted claims of the '514 patent valid and infringed; the asserted claims of the '150 patent valid but not infringed; and the asserted claims of the '832 patent invalid, but found that certain claims would be infringed if they were valid.
- Based on the ruling as to the '514 patent, **Actavis** and **Par** are currently enjoined from launching a generic product. **Par** has appealed and **Actavis** is expected to appeal this ruling. The generics have also moved to reopen the judgment based on the claim construction in the **Dr. Reddy's** case. In light of the motions to reopen, **Par's** appeal has been deactivated until the District Court rules on the motions, and the deadline for **Actavis** to file a notice of appeal has been postponed.
- Trial against **Dr. Reddy's**, **Actavis** and **Par** in the lawsuits involving the process patent (U.S. Patent No. 8,900,497) took place on November 16th and 21st-23rd, 2016.
- Trial against **Dr. Reddy's** in the lawsuit involving two of the Orange Book-listed patents for SUBOXONE® Film (U.S. Patent Nos. 8,017,150 and 8,603,514) took place on November 7th, 16th, and 21st-23rd, 2016. **Dr. Reddy's** 30-month stay of FDA approval expired on April 17th, 2017. So far as Indivior is aware, FDA to date has not granted tentative or final marketing authorization to **Dr. Reddy's** (or any other generic SUBOXONE® Film alternative). If FDA were to grant final approval to **Dr. Reddy's** this would enable them to market a generic film alternative to SUBOXONE® Film in the U.S. However, any market launch by **Dr. Reddy's** before the District Court renders its decision, or before the court of appeals renders its decision even if **Dr. Reddy's** was to prevail before the District Court, would be on an "at risk" basis because Indivior would have a claim for damages against **Dr. Reddy's** if it ultimately prevails after any appeal.
- A stipulation and proposed order was filed with the District Court on April 28th, 2017, seeking to consolidate the trial against **Alvogen** in the lawsuit involving the '150 and '514 Orange Book-listed patents and the '497 process

patent for SUBOXONE® Film with the trial against **Mylan** (discussed below). The District Court approved the stipulation on May 1st, 2017. Accordingly, the trial against **Alvogen** will be scheduled for September 25th-27th, 2017, and will be tried concurrently with the trial against **Mylan**. The 30-month stay of FDA approval of **Alvogen's** Abbreviated New Drug Application is presently set to expire October 29th, 2017.

- By a Court order dated August 22nd, 2016, Indivior's SUBOXONE® Film patent litigation against **Sandoz** has been dismissed without prejudice because **Sandoz** is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE® Film.
- Trial against **Mylan** in the lawsuit involving the '150 and '514 Orange Book-listed patents and the '497 process patent for SUBOXONE® Film is scheduled for September 25th-27th, 2017, and will be tried concurrently with the trial against **Alvogen** pursuant to a stipulation filed with and approved by the District Court. The 30-month stay of FDA approval of **Mylan's** Abbreviated New Drug Application is presently set to expire March 24th, 2018. On January 12th, 2017, the District Court issued a claim construction decision in the **Mylan** action that clarified its earlier construction in the **Dr. Reddy's** case of certain terms in the '514 patent.
- Indivior received a Paragraph IV notification from **Teva**, dated February 8th, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of buprenorphine/naloxone sublingual film. The parties have agreed that infringement by Teva's 16 mg/4 mg dosage strength will be governed by the infringement ruling on the accused 8 mg/2 mg dosage strength in the ANDA now owned by **Dr. Reddy's** that was the subject of the trial in November 2016.
- On May 31st, 2016, **Dr. Reddy's** filed petitions seeking inter parties review (IPR) of the three Orange Book-listed patents covering SUBOXONE® Film. Indivior and Monsol Rx filed Patent Owner Preliminary Responses opposing institution of the IPRs on September 6th, 2016, arguing that institution of the IPRs should be denied. On December 2nd, 2016, the US Patent Trial and Appeal Board (PTAB) denied institution of the IPR as to the '832 Patent, and on December 5th, 2016, the PTAB denied institution of the IPRs as to the '514 and '150 Patents. On January 3rd, 2017, **Dr. Reddy's** filed Requests for Rehearing of the three non-institution decisions. On March 22nd, 2017, the PTAB denied **Dr. Reddy's** request for rehearing of its decisions not to institute its petitions for IPRs of the '150 and '514 patents. This denial by the PTAB resolves **Dr. Reddy's** attempts to seek to invalidate the '150 and '514 patents through IPR proceedings. A separate panel of the PTAB is handling the proceeding on the '832 patent and has not yet issued its decision on **Dr. Reddy's** Rehearing Request in that case.
- **Mylan** has filed a petition seeking an IPR of the '514 patent. A decision by the US Patent & Trademark Office on whether to institute IPR proceedings is expected in May 2017.
- In the event that one or more of the generic companies are successful in their patent challenges, and should there be FDA approval of one or more of the ANDAs and subsequent commercial launch of generic SUBOXONE® Film, and the Group's pipeline products fail to obtain regulatory approval, there is the likelihood that revenues and operating profits of the Group will significantly decline. In these circumstances the Directors believe they would be able to take the required steps to reduce the cost base, however, this would result in a significant change to the structure of the business.

#### **Rhodes Pharmaceuticals**

- On March 21st, 2017 **Rhodes Pharmaceuticals** filed a complaint against Indivior in the District of Delaware, alleging that Indivior's sale of SUBOXONE® Film in the U.S. infringes one or more claims of a patent. The asserted patent, which was issued in June 2016 traces back to an application filed in August 2007. Indivior believes this claim is without merit and intends to vigorously defend this action.

#### **Estate of John Bradley Allen**

- On December 27th, 2016, the Estate of John Bradley Allen filed a civil complaint against Indivior, among other parties, in the Northern District of New York seeking relief under Connecticut's products liability and unfair trade practices statutes for damages allegedly caused by SUBOXONE®. Indivior believes this lawsuit is without merit and intends to vigorously defend this action.

#### **IRS Notice on Manufacturing Deductions**

- In August 2015, the IRS issued notices of a proposed adjustment for the disallowance of certain manufacturing deductions claimed by the Group following its audit of 2011 and 2012 income tax years. During the 4th quarter of 2015, the Group was notified by the IRS of their intention to disallow these claims as part of the 2013 and 2014 audit cycle. The Group has appealed the proposed disallowance. The Group has evaluated its positions with respect to these claims and has provided \$22m tax reserve for amounts claimed on all open periods as its best estimate of its expected settlement position for this issue.

## 8. TRADE AND OTHER PAYABLES

	Mar 31 2017 \$m	Dec 31 2016 \$m
Sales returns and rebates	(401)	(402)
Trade payables	(23)	(33)
Accruals	(168)	(212)
Other tax and social security payables	(10)	(11)
<b>Total</b>	<b>(602)</b>	<b>(658)</b>

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 direct and indirect customers. Accruals are made at the time of sale but the actual amounts to be paid are based on claims made some time after the initial recognition of the sale. The estimated amounts may not fully reflect the final outcome and are subject to change dependent upon, amongst other things, the payor channel (e.g. Medicaid, Medicare, Managed Care, etc) and product mix. Accrual balances are 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			
<b>At January 1, 2017</b>	<b>720,597,566</b>	<b>\$0.10</b>	<b>72</b>
Allotments	180,198	\$0.10	-
<b>At March 31, 2017</b>	<b>720,777,764</b>	<b>\$0.10</b>	<b>72</b>

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

## 10. RELATED PARTIES

Indivior's former parent, Reckitt Benckiser Group PLC, was a related party through 2016 as a result of certain transition management agreements. During Q1 2016, Indivior purchased certain services such as office space rental and other operational services on commercial terms and on an arm's length basis. The amount included within administrative expenses in respect of these services was \$2m.

## 11. POST BALANCE SHEET EVENTS

There have been no material post balance sheet events.

## 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 Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority

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

Indivior PLC's Directors are listed in the Annual Report and Accounts for 2016.

Details of all current Directors are available on our website at [www.indivior.com](http://www.indivior.com)

By order of the Board

Shaun Thaxter  
Chief Executive Officer

Mark Crossley  
Chief Financial Officer

May 2, 2017



# Independent review report to Indivior PLC

## Report on the condensed consolidated interim financial statements

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### Our conclusion

We have reviewed Indivior PLC's condensed consolidated interim financial statements (the "interim financial statements") in the Q1 Financial Results Release of Indivior PLC for the 3 month period ended 31 March 2017. 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 Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

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### Emphasis of matter – Going concern

In forming our conclusion 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. As more fully stated in note 7 the Group is involved in investigations by the Department of Justice and the Federal Trade Commission as well as antitrust litigation. An amount of \$218 million has been established as a provision for potential settlement for all of these matters. The amount accepted in the final agreed settlement might be materially higher from this provision. This could impact the Group's ability to operate, which would be further adversely impacted should revenues decline and pipeline products fail to obtain regulatory approval, all of which could mean the Group cannot continue in business without taking necessary measures to reduce its cost base and improve its cash flow. The directors believe that they are able to carry out the necessary measures and 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 interim financial statements. These conditions, along with the other matters explained in note 1 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.

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### Emphasis of matter – Outcome of litigation

In forming our conclusion on the interim financial statements, which is not modified, we draw your attention to note 1 that describes the uncertain outcome of the ongoing ANDA patent litigation over Suboxone<sup>®</sup> Film. In the event of a negative ruling against the Group, and should there be a regulatory approval and subsequent commercial launch of generic Suboxone<sup>®</sup> Film, and pipeline products fail to obtain regulatory approval there is the likelihood that revenues and operating profits may decline. In these circumstances the directors believe they would be able to take the required steps to reduce the cost base, however this would result in a significant change to the structure of the business. As a result of this decline and extent of its impact, the directors would consider a change in the structure of the business and methods to reduce its cost base, as also described in note 7.

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### What we have reviewed

The interim financial statements comprise:

- the Condensed consolidated interim balance sheet as at 31 March 2017;
- the Condensed consolidated interim income statement and Condensed consolidated interim statement of comprehensive income for the period then ended;
- the Condensed consolidated interim cash flow statement 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 Q1 Financial Results Release have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook 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

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### Our responsibilities and those of the directors

The Q1 Financial Results Release, including the interim financial statements, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the Q1 Financial Results Release in accordance with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express a conclusion on the interim financial statements in the Q1 Financial Results Release 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 Guidance and Transparency Rules sourcebook 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 Q1 Financial Results Release and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP  
Chartered Accountants  
London  
03 May 2017