



**Nine Month Financial Results – FY 2017 Revenue and Net Income Guidance Reconfirmed.**

Period to September 30th	Q3 2017 \$m	Q3 2016 \$m	% Δ Actual FX	% Δ Constant FX	YTD 2017 \$m	YTD 2016 \$m	% Δ Actual FX	% Δ Constant FX
Net Revenue	275	268	+3	+2	828	799	+4	+4
Operating Profit	63	(121)	*	*	308	78	*	*
Net Income	50	(149)	*	*	203	(43)	*	*
EPS (cents per share)	7	(21)	*	*	28	(6)	*	*
Adjusted Operating Profit <sup>1</sup>	63	102	-38	-39	333	315	+6	+5
Adjusted Net Income <sup>1</sup>	47	71	-34	-34	216	205	+5	+5
Adjusted EPS <sup>1</sup>	7	10	-30	-35	30	28	+7	+5

<sup>1</sup>Adjusted basis excludes the impact of exceptional items as referenced in Notes 3 and 5.

\* Not meaningful

**Solid YTD 2017 Financial Results and FY 2017 Guidance Reconfirmed**

- YTD 2017 net revenue of \$828m (YTD 2016: \$799m) increased 4% on a reported basis (4% at constant exchange) primarily due to continued strong market growth in the US that was partially offset by generic competition in the most price sensitive US payors (Managed Medicaid) and lower wholesaler stocking activity.
- YTD 2017 operating profit was \$308m (YTD 2016: \$78m) reflecting higher net revenues and lower R&D and legal expenses. On an adjusted basis, excluding \$25m of exceptional items YTD and \$237m in the year-ago period, YTD 2017 adjusted operating profit increased 6% to \$333m (YTD 2016 adj: \$315m).
- YTD 2017 net income was \$203m (YTD 2016 net loss: \$43m). On an adjusted basis, YTD 2017 net income increased 5% to \$216m (YTD 2016 adj: \$205m).
- Cash balance at the end of Q3 2017 was \$806m (FY 2016: \$692m); net cash was \$322m (FY 2016: \$131m).
- FY 2017 guidance reconfirmed. Net revenue expected to be in a range of \$1,090m to \$1,120m and adjusted net income of \$265m to \$285m assuming no material changes to current market conditions, excluding exceptional items and at constant FX. Guidance includes \$40m to \$60m of pre-launch investments for late stage pipeline assets.

**YTD 2017 Operating Highlights**

- US market growth in 2017 continues at low double-digit percentage levels.
- Suboxone® Film market share averaged 58% in YTD 2017 (YTD 2016: 61%), exiting Q3 2017 at 56% primarily due to ongoing generic competition in the most price sensitive US payors (Managed Medicaid).
- RBP-6000 buprenorphine monthly depot for the treatment of opioid use disorder (OUD) recommended for approval at joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee on October 31st; November 30th PDUFA (Prescription Drug User Fee Act) date.
- New drug application (NDA) submitted September 28th for RBP-7000 risperidone monthly depot for the treatment of schizophrenia.
- Indivior initiated the appeals process against Dr Reddy's after the US District Court for the District of Delaware found the asserted claims of Patent Nos. '150, '514 and '497 valid but not infringed by Dr. Reddy's proposed generic buprenorphine/naloxone film. As of November 2nd, 2017, FDA has not announced that it has granted tentative or final marketing authorization to any generic buprenorphine/naloxone film, except

for Actavis's proposed generic version of buprenorphine/naloxone film granted tentative approval on October 24th, 2017, which was enjoined from launch until April 2024 by the Delaware court ruling of 2016.

- Indivior took additional actions to secure its intellectual property position by reaching a settlement with Mylan and asserting its new Orange Book-listed patent covering Suboxone® Film, US Patent No. 9,687,454 (the "'454 patent").
- The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. Please see pages five to eight for a comprehensive Litigation Update.

**Shaun Thaxter, CEO of Indivior commented:**

"Continued solid execution in the quarter against a strong US market backdrop leaves us on track to meet our FY 2017 guidance, which we increased significantly with our H1 2017 results. We have also taken important steps to protect our intellectual property rights by initiating our appeal in the Dr Reddy's ANDA litigation, settling with Mylan, including termination of their IPR, and asserting our recently-granted '454 patent. Most importantly, we have continued to progress our pipeline with the successful NDA submission of RBP-7000 in schizophrenia and, in recent days, by the endorsement of the FDA's Psychopharmacologic Drugs Advisory and Drug Safety and Risk Management Advisory Committees for RBP-6000, our potentially transformational product for the treatment of opioid use disorder. We are finalizing our launch plans and are working closely with our third-party manufacturing partners to ensure appropriate delivery of product to enable our target launch in Q1 2018. We are looking forward to the PDUFA date of November 30th."

**YTD 2017 Operating Review**

**US Market Update**

The market for buprenorphine products continued to grow strongly in 2017, resulting in low double-digit percentage volume growth in the first nine months of 2017 versus the same year-ago period. Market growth continues to benefit from legislative changes that have expanded opioid use disorder treatment capacity. Growth in both the number of physicians waived to administer medication-assisted treatment and those able to treat to the new allowable level of 275 patients (from 100 patients) continued in Q3 2017. In addition, the number of waived nurse practitioners and physician assistants continued to grow in Q3 2017.

Suboxone® Film had an average market share of 58% in YTD 2017, compared to 61% in YTD 2016, and average market share in Q3 2017 was 56%, compared to 60% in Q3 2016. The decline in share during both periods was largely due to continued competition in the most price sensitive payors that have prioritized lower priced generic tablet options. Overall commercial formulary access remains solid for Suboxone® Film. The list price of Suboxone® Film in the US increased modestly in January 2017, but the benefits were mostly offset by tactical rebating in connection with maintaining formulary access.

**Financial Performance: YTD 2017 & Q3 2017**

Total net revenue in YTD 2017 increased by 4% to \$828m (YTD 2016: \$799m) on both an actual and constant exchange rate basis. Q3 2017 total net revenue increased 3% at actual exchange rates (2% at constant exchange rates) to \$275m (Q3 2016: \$268m). In the YTD 2017 and Q3 2017 periods revenue growth primarily reflected volume gains from stronger market conditions in the US and from growth and one-off shipments in Rest of World markets. These gains were partially offset by a decline in Suboxone® Film market share and lower wholesaler stocking activity in 2017. Price improvement was mostly offset by tactical rebating activity in the US in connection with formulary access. Additionally in Q3 2017, mix was unfavorable due to an increase in the US Medicaid channel as more previously underserved populations are now accessing treatment.

YTD 2017 US net revenue increased by 3% to \$670m (YTD 2016: \$651m) and was unchanged in Q3 2017 at \$219m (Q3 2016: \$219m). In both periods, market growth was ahead of last year primarily reflecting legislative action to expand treatment capacity. YTD volume benefits from increased market growth were partially offset by a decline in Suboxone® Film market share in the most price sensitive payors (Managed Medicaid) and lower

wholesaler stocking activity in 2017. Improved pricing was largely offset by tactical rebating activity in connection with formulary access. In Q3 2017, benefits from volume and pricing were offset by the decline in market share, lower wholesale stocking activity and unfavorable mix from an increase in the Medicaid channel as more previously underserved populations are now accessing treatment.

YTD 2017 Rest of World net revenue increased by 7% at actual exchange rates (8% at constant exchange rates) to \$158m (YTD 2016: \$148m). Continued growth from market share gains in Australasia and one-off shipments primarily drove the overall net revenue improvement. In Q3 2017, Rest of World net revenue increased 14% at actual exchange rates (12% at constant exchange rates) to \$56m (Q3 2016: \$49m).

YTD 2017 gross margin was 91%, ahead of last year (YTD 2016: 90%). This increase primarily reflects exceptional items of \$11m in the year-ago period that related to costs for negative ANDA outcome strategic planning. Excluding the exceptional items last year, gross margin was 92%. In Q3 2017, gross margin was 90% (Q3 2016: 91%). Exceptional items of \$1m were included in costs of sales in Q3 2016.

YTD 2017 SD&A expenses were \$381m (YTD 2016: \$556m). YTD 2017 SD&A includes exceptional items of \$25m, reflecting the legal settlement of the Amneal antitrust matter (booked in Q2 2017). In the year-ago period, results included exceptional items of \$220m for a legal provision related to investigative and antitrust litigation matters (booked in Q3 2016) and \$6m reflecting the costs of negative ANDA outcome strategic planning (\$4m booked in Q2 2016; \$2m booked in Q3 2016). On an adjusted basis, YTD 2017 SD&A expenses increased 8% to \$356m (YTD 2016 adj: \$330m).

Q3 2017 SD&A expenses were \$162m (Q3 2016: \$335m). Q3 2016 SD&A included total exceptional items of \$222m, as described above. On an adjusted basis, Q3 2017 SD&A expenses increased 43% to \$162m (Q3 2016 adj: \$113m). The underlying SD&A increase in both the YTD 2017 and Q3 2017 periods primarily reflects expected pre-launch investments for key investigational drugs, RBP-6000 and RBP-7000, and higher legal expenses related to ongoing ANDA litigation activity and related patent defense costs.

YTD 2017 and Q3 2017 R&D expenses decreased by 23% to \$67m and by 21% to \$23m, respectively (YTD 2016: \$87m; Q3 2016: \$29m). The decreases in both periods reflect lower clinical activity as Phase III trials on key pipeline assets have been completed.

YTD 2017 operating profit of \$308m increased 295% over the prior year (YTD 2016: \$78m). Exceptional items of \$25m and \$237m are included in both the current and year-ago period results, respectively. On an adjusted basis, YTD 2017 operating profit was \$333m (40% margin), a 6% increase versus \$315m (39% margin) in the year-ago period. The underlying year-over-year improvement primarily reflects the benefit of higher net sales and lower R&D expenses offset by higher legal expenses related to ongoing ANDA litigation activity and related patent defense costs.

Q3 2017 operating profit was \$63m, compared to an operating loss in the prior year (Q3 2016: loss of \$121m), which includes exceptional items totaling \$223m. On an adjusted basis, Q3 2017 operating profit declined 38% versus the prior year (Q3 2016 adj: \$102). The decrease primarily reflects expected pre-launch investments for key investigational drugs, RBP-6000 and RBP-7000, and higher legal expenses related to ongoing ANDA litigation activity and related patent defense costs.

YTD 2017 EBITDA was \$317m (YTD 2016: \$90m). Excluding \$25m and \$237m of exceptional items in the current and year-ago period results, respectively, YTD 2017 adjusted EBITDA increased 5% to \$342m (YTD 2016: \$327m).

YTD 2017 finance expense was \$34m (YTD 2016: \$39m) representing the interest and amortization on the \$750m borrowing facility, which was slightly offset by modest interest income and was lower than prior year resulting from the benefit of required repayments of \$86m in YTD 2017. As a result, outstanding borrowing on the facility was reduced to \$484m. Q3 2017 finance expense was \$9m (Q3 2016: \$12m).

YTD 2017 tax charge was \$71m (YTD 2016: \$82m), a rate of 26% (YTD 2016: 210%). The year-ago YTD period tax charge assumes non-deductibility for tax purposes of the exceptional legal provision. Excluding exceptional items in pre-tax income and within taxation totalling \$12m in the YTD 2017 period and an expense of \$11m in the same year-ago period, the rate was 28% (YTD 2016 adj: 26%). The increase was due to changes in the geographic mix of earnings. Q3 2017 tax charge was \$4m (Q3 2016: \$16m), or a rate of 7% (Q3 2016: 12%). Excluding exceptional items of \$3m (Q3 2016: \$16m), the rate was 13%. (Q3 2016 adj: 21%). Based on current projections, the full year effective tax rate is expected to be 24%, excluding exceptional taxation items.

YTD 2017 net income was \$203m (YTD 2016 net loss: \$43m) as reported. Excluding exceptional costs, YTD 2017 net income was \$216m (YTD 2016 adj: \$205m). The current and year-ago periods include \$13m and \$248m of exceptional items, respectively. In Q3 2017, net income was \$50m (Q3 2016 net loss: \$149m). Excluding exceptional costs, net income for the quarter was \$47m (Adj. Q3 2016: \$71m). The current and year-ago quarters include \$3m and \$220m of exceptional items, respectively.

YTD 2017 basic EPS were 28 cents (YTD 2016: loss of 6 cents) and 27 cents on a diluted basis (YTD 2016: loss of 6 cents). On an adjusted basis, excluding the effect of exceptional items, YTD 2017 basic EPS were 30 cents (YTD 2016: 28 cents) and diluted EPS were 29 cents (YTD 2016: 28 cents).

### Balance Sheet & Cash Flow

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative \$332m at the end of Q3 2017, an increase of \$58m since FY 2016 primarily due to phasing of payables and accruals, including those related to trade payables and the completion of Phase III clinical trials.

Cash and cash equivalents at the end of Q3 2017 were \$806m, reflecting an increase of \$114m in YTD 2017 (FY 2016: \$692m). Borrowings, net of issuance costs, were \$470m at the end of Q3 2017 (FY 2016: \$535m), reflecting required repayments of \$86m. Consequently, net cash stood at \$322m at the end of Q3 2017 (FY 2016: \$131).

Cash generated from operations in YTD 2017 was \$274m (YTD 2016: \$359m), a decrease of \$85m primarily due to the increase in working capital.

YTD 2017 net cash inflow from operating activities was \$233m (YTD 2016: \$280m), reflecting the lower cash from operations offset by lower tax payments of \$19m and lower net financing costs of \$22m in YTD 2017.

Cash outflow from investing activities increased \$23m to \$38m. The increase was primarily related to the purchase of certain patent rights from DURECT Corporation that further enhance RBP-7000's IP position.

### R&D / Pipeline Update

#### Treatment of Opioid Use Disorder

- **RBP-6000, Monthly Depot Buprenorphine:** New Drug Application (NDA) submitted May 30th, 2017. Filing accepted by FDA July 31st, 2017 with Priority Review designation with a PDUFA target action date of November 30th, 2017. FDA Advisory Committees recommend approval on October 31st, 2017.
- **HEOR Study** from Phase III (RB-US-13-0001) trial: Findings to be presented at the 41st Association for Medical Education and Research in Substance Abuse National Conference (AMERSA), November 5th–7th, 2017. Final report expected in Q4 2017.
- **RECOVER Study (REmission from Chronic Opioid Use: Studying EnVironmental and socioEconomic factors on Recovery):** Last subject expected to complete the study in January 2018 with final report expected June 2018.
- **Pre-submission meetings related to RBP-6000 held with Regulatory Agencies ex-USA in Q4 2016:** TGA (Australia); HC (Canada); ANSM (France); MHRA (United Kingdom); MPA (Sweden); BfArM (Germany).
- **SUBOXONE® Film:** On June 20<sup>th</sup>, 2017, added to the List of Drugs for an Urgent Public Health Need in British Columbia, Canada.

- **SUBOXONE® Tablet China:** Submission of NDA to Chinese FDA (CFDA) on Dec 27th, 2016. Priority Review granted by CFDA Jun 6th, 2017. NDA review ongoing.

#### Treatment of Schizophrenia

- **RBP-7000, Monthly Depot Risperidone:** NDA submitted to FDA on September 28th, 2017. Planning for Q4 2018 launch.

#### Overdose Rescue Products

- **Intranasal Naloxone:** French regulatory agency ANSM approved marketing authorization on July 31st, 2017.

#### Treatment of Alcohol Use Disorder

- **Arbaclofen Placarbil:** All three parts of the new Phase I Bioavailability Clinical Study Protocol (INDV-AP-102) of a new formulation of Arbaclofen Placarbil are now completed. Data analysis and interpretation ongoing.

#### Other Key Events Q3 2017

- **July 2017:** Redevelopment completed of Research and Development Center in Ft. Collins, Colorado.
- **August 2017:** Officially opened new Research and Development Center in Hull, United Kingdom.

#### Key Pipeline Dates 2017

**Oct. 15th-18th:** American Conference on Pharmacometrics (ACoP) – RBP-6000 Combined Population Pharmacokinetic Analysis; Exposure-Response analysis.

**Oct. 17th-20th:** Colloque International Addictions Toxicomanies Hépatites SIDA (ATHS) – RBP-6000 Phase 3 clinical efficacy and safety.

**Oct. 19th-21st:** Canadian Society of Addiction Medicine (CSAM) - RBP-6000 Phase 3 clinical efficacy and safety.

**Oct. 26th-29th:** 19th Annual Meeting of the International Society of Addiction Medicine (ISAM) - RBP-6000 Phase 3 clinical efficacy and safety and exposure-response analysis.

**Nov. 5th-7th:** Association for Medical Education and Research in Substance Abuse (AMERSA) Conference – RBP-6000 Phase III health economics & outcomes research data.

**Nov. 12th-15th:** Australasian Professional Society on Alcohol and other Drugs (APSAD) - RBP-6000 Phase 3 clinical efficacy and safety and exposure-response analysis.

**Nov. 30th:** PDUFA date for RBP-6000.

**Dec. 3rd - 7th:** Annual Meeting of the American College of Neuropsychopharmacology (ACNP) – RBP-6000 PK/PD/RO model and RBP-7000 Phase 3 Long-Term Safety and Tolerability.

**Dec. 7th - 10th:** 28th Annual Meeting and Scientific Symposium of the American Academy of Addiction Psychiatry (AAAP) – Predictors of dropout in RBP-6000 Phase 3 trials.

#### Litigation Update

**The Group carries a provision of \$217m for the investigative and antitrust litigation matters noted below. The provision was reduced by \$25m compared to period ending Q2 2017, reflecting payment of previously reserved settlement amount to Amneal Pharmaceuticals LLC (Amneal). Other than reducing by the Amneal settlement amount, the Group has not changed the previously recorded provision, as the other litigation and investigations are ongoing. The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. The Group cannot predict with any certainty whether it will reach an ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this provision.**

## 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 State has served additional deposition subpoenas on Indivior in 2017. 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, alleged antitrust violations similar in nature to those alleged in the class action complaints, and Amneal also alleged violations of the U.S. Lanham Act. The Company has settled the dispute with Amneal, and Amneal has dismissed its claims against the Company with prejudice.
- 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 is pending. The States' complaint is similar to the other antitrust complaints, and alleges violations of U.S. state and federal antitrust and consumer protection laws. This lawsuit relates to the antitrust investigation conducted by various states, as discussed in previous filings. Discovery has been coordinated with the antitrust class action litigation, 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. In an August 31st, 2017 ruling, the Court denied motions of **Actavis** and **Par** to reopen the June 2016 judgment.
- Based on the ruling as to the '514 patent, **Actavis** and **Par** are currently enjoined from launching a generic product until April 2024. **Par** and **Actavis** have appealed this ruling, and Indivior has filed notices of cross-appeal. On October 24, 2017 **Actavis** received tentative approval from FDA for at least its 8 mg/2 mg generic product under ANDA 204383. A tentative approval does not allow the applicant to

market the generic drug product and postpones the final approval until all patent/exclusivity issues have been resolved. **Actavis** therefore remains enjoined by the Delaware court ruling.

- 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. The rulings in these trials were issued on August 31st, 2017. The rulings found the asserted claims of the '497, '514, and '150 patents valid but not infringed. **Teva** had filed a 505(b)(2) New Drug Application (NDA) for a 16 mg/4 mg strength of buprenorphine/naloxone film. The parties had agreed that infringement by **Teva's** 16 mg/4 mg dosage strength would be governed by the infringement ruling as to **Dr. Reddy's** 8 mg/2 mg dosage strength that was the subject of the trial in November 2016; therefore, the non-infringement ruling in the **Dr. Reddy's** case means that the **Teva** 16 mg/4 mg dosage strength has been found not to infringe. Indivior intends to appeal.
- **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** generic SUBOXONE® Film alternative.
- If FDA were to grant final approval to **Dr. Reddy's** (or **Teva** for the 16 mg / 4 mg strength of buprenorphine/naloxone film) 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** (or by **Teva**) before the court of appeals renders its decision would be on an "at risk" basis because Indivior would have a claim for damages against **Dr. Reddy's** (or **Teva**) if Indivior ultimately prevails after any appeal.
- Trial against **Alvogen** in the lawsuit involving the '514 Orange Book-listed patent and the '497 process patent for SUBOXONE® Film took place on September 26th-27th, 2017. Trial was limited to the issue of infringement because **Alvogen** did not challenge the validity of either patent. The 30-month stay of FDA approval of **Alvogen's** Abbreviated New Drug Application was set to expire October 29th, 2017. **Alvogen** agreed not to launch until March 29th, 2018 or until it receives a favorable ruling from the District Court. That agreement has been modified in light of a 3 week extension of the post-trial briefing schedule, but the terms are currently under seal.
- 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.
- On September 25th, 2017, Indivior settled its SUBOXONE® Film patent litigation in District Court against **Mylan**.
- **Mylan** filed a petition seeking an inter partes review (IPR) of the '514 and '497 patents. On May 12<sup>th</sup>, 2017, the US Patent & Trademark Office decided to institute the '514 IPR proceedings. On September 29th, 2017, **Mylan** and **MonoSol** submitted joint motions to terminate the '514 and '497 IPRs in light of the parties' settlement of their disputes in the District Court litigation. On October 6th, 2017 the Patent Board terminated both the '514 and '497 IPR proceedings as to **MonoSol** and **Mylan**. **Dr. Reddy's** and **Par** had filed petitions and motions in June 2017 to join the **Mylan** '514 IPR proceeding. On October 20th, 2017 the Patent Board refused to institute IPR proceedings and dismissed **Dr. Reddy** and **Par's** petitions.
- Since August 2017, Indivior received Paragraph IV Notice letters from **Actavis, Par, Alvogen, Mylan, and Dr. Reddy's** for Indivior's recently granted '454 patent. Indivior has filed suit against **Alvogen, Dr. Reddy's, and Par** in the District of New Jersey; and against **Actavis** in the District of Utah. Although a complaint against **Mylan** was filed in the District of West Virginia, it was dismissed in light of the parties' settlement of their disputes in the Delaware District Court litigation. Indivior has also filed suit against **Teva** in the District of New Jersey, although a Paragraph IV Notice letter has not been received yet.

- In the event that one or more of the generic companies are successful in their patent challenges on a final non-appealable basis, 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 December 23rd, 2016 **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 1 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 the remaining term of 2017 remain the same as described on pages 49 to 53 of the 2016 Annual Report, with the addition of a risk factor relating to mutual indemnification obligations with Reckitt Benckiser described below. 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.
- 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 {5-8} 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 {20-22, 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.
- As previously disclosed in the Prospectus dated November 17, 2014, Indivior has indemnification obligations in favour of RB (page 43). The demerger agreement between Indivior and Reckitt Benckiser ("RB") has certain mutual indemnification provisions in respect of any claims and expenses of or incurred by any company within the Indivior Group or the RB Group arising out of or associated with the Indivior Business prior to the Demerger (whether or not in the ordinary course of business) and in respect of certain tax liabilities that may arise after, or as part of, the Demerger. Some of these indemnities are unlimited in terms of amount and duration, and amounts potentially payable by the Indivior Group pursuant to such indemnity obligations could be significant and could have a material adverse effect on the Indivior Group's business, financial condition and/or operating results. Requests for indemnification may be subject to legal challenge.

#### 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 {5-8} referring to the current status of the investigative and litigation matters involving the Group, as well as the contingent liabilities disclosures on pages {20-22, 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:

	9 Months to Sept. 30, 2017	9 Months to Sept. 30, 2016
GB £ period end	1.3387	1.3023
GB £ average rate	1.2748	1.3945
€ Euro period end	1.1748	1.1214
€ Euro average rate	1.1124	1.1162

## Webcast Details

There will be a presentation at 12pm UK time (8am Eastern in the USA) hosted by Shaun Thaxter, CEO. This presentation 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: <https://edge.media-server.com/m6/p/b6jz7h6i>

**Confirmation Code:** **9592820**

Participants, Local - London, United Kingdom: +44(0)20 3427 1901

Participants, Local - New York, United States of America: +1 646 254 3361

## For Further Information

**Investor Enquiries** Jason Thompson VP Investor Relations, +1 804 423 8916  
Indivior PLC jason.thompson@indivior.com

**Media Enquiries** Jonathan Sibun Tulchan +44 207 353 4200  
Communications  
US Media Inquiries +1 804 594 0836  
Indiviormediacontacts@indivior.com

## Corporate Website [www.indivior.com](http://www.indivior.com)

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, including the investigative

and antitrust litigation matters; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

### 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

		Unaudited Q3 2017 \$m	Unaudited Q3 2016 \$m	Unaudited YTD 2017 \$m	Unaudited YTD 2016 \$m
	Notes				
<b>Net Revenues</b>	2	<b>275</b>	268	<b>828</b>	799
Cost of Sales		<b>(27)</b>	(25)	<b>(72)</b>	(78)
<b>Gross Profit</b>		<b>248</b>	243	<b>756</b>	721
Selling, distribution and administrative expenses	3	<b>(162)</b>	(335)	<b>(381)</b>	(556)
Research and development expenses	3	<b>(23)</b>	(29)	<b>(67)</b>	(87)
<b>Operating Profit</b>		<b>63</b>	(121)	<b>308</b>	78
Operating profit before exceptional items		<b>63</b>	102	<b>333</b>	315
Exceptional items	3	-	(223)	<b>(25)</b>	(237)
Operating profit		<b>63</b>	(121)	<b>308</b>	78
Net finance expense		<b>(9)</b>	(12)	<b>(34)</b>	(39)
<b>Profit before taxation</b>		<b>54</b>	(133)	<b>274</b>	39
Income tax expense		(4)	(16)	(71)	(82)
Taxation before exceptional items	4	(7)	(19)	(83)	(71)
Exceptional items within taxation	4	3	3	12	(11)
<b>Net income</b>		<b>50</b>	(149)	<b>203</b>	(43)
<b>Earnings per ordinary share (cents)</b>					
Basic earnings per share	5	<b>7</b>	(21)	<b>28</b>	(6)
Diluted earnings per share	5	<b>7</b>	(20)	<b>27</b>	(6)

## Condensed consolidated interim statement of comprehensive income

		Unaudited Q3 2017 \$m	Unaudited Q3 2016 \$m	Unaudited YTD 2017 \$m	Unaudited YTD 2016 \$m
Net income		<b>50</b>	(149)	<b>203</b>	(43)
<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>3</b>	3	<b>6</b>	3
Other comprehensive income		<b>3</b>	3	<b>6</b>	3
<b>Total comprehensive income</b>		<b>53</b>	(146)	<b>209</b>	(40)

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

## Condensed consolidated interim balance sheet

	Notes	Unaudited Sep 30, 2017 \$m	Audited Dec 31, 2016 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		94	83
Property, plant and equipment and other assets		49	27
Deferred tax assets	4	84	109
Other receivables		6	-
		<b>233</b>	<b>219</b>
<b>Current assets</b>			
Inventories		51	41
Trade and other receivables		247	227
Current tax receivable		30	30
Cash and cash equivalents	6	806	692
		<b>1,134</b>	<b>990</b>
<b>Total assets</b>		<b>1,367</b>	<b>1,209</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	6	(129)	(101)
Provision for liabilities and charges		(219)	(219)
Trade and other payables	8	(630)	(658)
Current tax liabilities	4	(80)	(52)
		<b>(1,058)</b>	<b>(1,030)</b>
<b>Non-current liabilities</b>			
Borrowings	6	(341)	(434)
Provisions for liabilities and charges		(42)	(40)
		<b>(383)</b>	<b>(474)</b>
<b>Total liabilities</b>		<b>(1,441)</b>	<b>(1,504)</b>
<b>Net liabilities</b>		<b>(74)</b>	<b>(295)</b>
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	9	72	72
Share premium		2	-
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(16)	(22)
Retained Earnings		1,163	950
<b>Total equity</b>		<b>(74)</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

<b>Unaudited</b>	Share Capital \$m	Share Premium \$m	Other Reserve \$m	Foreign Currency Translation Reserve \$m	Retained Earnings \$m	<b>Total equity \$m</b>
<b>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	-	-	-	-	(43)	(43)
Other comprehensive income	-	-	-	3	-	3
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>3</b>	<b>(43)</b>	<b>(40)</b>
<b>Transactions recognised directly in equity</b>						
Share-based plans	-	-	-	-	6	6
Dividends paid	-	-	-	-	(69)	(69)
<b>Total transactions recognised directly in equity</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(63)</b>	<b>(63)</b>
<b>Balance at September 30, 2016</b>	<b>72</b>	<b>-</b>	<b>(1,295)</b>	<b>(20)</b>	<b>861</b>	<b>(382)</b>
<b>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	-	-	-	-	203	203
Other comprehensive income	-	-	-	6	-	6
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>6</b>	<b>203</b>	<b>209</b>
<b>Transactions recognised directly in equity</b>						
Share-based plans	-	2	-	-	10	12
<b>Total transactions recognised directly in equity</b>	<b>-</b>	<b>2</b>	<b>-</b>	<b>-</b>	<b>10</b>	<b>12</b>
<b>Balance at September 30, 2017</b>	<b>72</b>	<b>2</b>	<b>(1,295)</b>	<b>(16)</b>	<b>1,163</b>	<b>(74)</b>

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

## Condensed consolidated interim cash flow statement

	Unaudited 2017 \$m	Unaudited 2016 \$m
<b>For the nine months ended September 30</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit	308	78
Depreciation and amortization	9	12
Share-based payments	10	9
Impact from foreign exchange movements	6	5
(Increase) in trade and other receivables	(20)	(38)
(Increase)/decrease in inventories	(5)	-
(Decrease)/increase in trade and other payables	(34)	72
Increase in provisions	-	221
<b>Cash generated from operations</b>	<b>274</b>	<b>359</b>
Net financing costs	(22)	(33)
Taxes paid	(19)	(46)
<b>Net cash inflow from operating activities</b>	<b>233</b>	<b>280</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(24)	(23)
Purchase of intangible assets	(14)	-
<b>Net cash (outflow) from investing activities</b>	<b>(38)</b>	<b>(23)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Cash movement in borrowings	(86)	(69)
Dividends paid	-	(69)
Proceeds from issuance of ordinary shares	2	-
<b>Net cash (outflow) from financing activities</b>	<b>(84)</b>	<b>(138)</b>
<b>Net increase in cash and cash equivalents</b>	<b>111</b>	<b>119</b>
Cash and cash equivalents at beginning of the period	692	467
<b>Exchange differences</b>	<b>3</b>	<b>-</b>
<b>Cash and cash equivalents at end of the period</b>	<b>806</b>	<b>586</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 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. The Group prepares its annual accounts in accordance with International Financial Reporting Standards (IFRS) and IFRS Interpretations Committee (IFRIC) interpretations as adopted by the European Union and the Companies Act 2006 (the Act) applicable to companies reporting under IFRS. In preparing these condensed consolidated 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 for interim periods.

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 November 1, 2017.

As disclosed in Note 7, the Group carries a provision of \$217m relating to the Department of Justice and Federal Trade Commission investigations and antitrust litigation. The final settlement 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 have been 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 ('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, intangible assets, and other receivables. Revenues and non-current assets for YTD 2017 and 2016 were as follows:



Revenues from sale of goods:

	<b>Q3</b>	Q3	<b>YTD</b>	YTD
	<b>2017</b>	2016	<b>2017</b>	2016
	<b>\$m</b>	\$m	<b>\$m</b>	\$m
United States	<b>219</b>	219	<b>670</b>	651
ROW	<b>56</b>	49	<b>158</b>	148
<b>Total</b>	<b>275</b>	268	<b>828</b>	799

Non-current assets:

	<b>September 30,</b>	<b>December 31,</b>
	<b>2017</b>	<b>2016</b>
	<b>\$m</b>	<b>\$m</b>
United States	<b>68</b>	64
ROW	<b>81</b>	46
<b>Total</b>	<b>149</b>	110

### 3. OPERATING COSTS AND EXPENSES

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

	<b>Q3</b>	Q3	<b>YTD</b>	YTD
	<b>2017</b>	2016	<b>2017</b>	2016
	<b>\$m</b>	\$m	<b>\$m</b>	\$m
Research and development expenses	<b>(23)</b>	(29)	<b>(67)</b>	(87)
Marketing, selling and distribution expenses	<b>(42)</b>	(39)	<b>(112)</b>	(102)
Administrative expenses	<b>(113)</b>	(294)	<b>(255)</b>	(439)
Depreciation and amortization	<b>(5)</b>	(1)	<b>(9)</b>	(12)
Operating lease rentals	<b>(2)</b>	(1)	<b>(5)</b>	(3)
<b>Total</b>	<b>(162)</b>	(335)	<b>(381)</b>	(556)

### Exceptional Items (Pre-tax)

	<b>Q3</b>	Q3	<b>YTD</b>	YTD
	<b>2017</b>	2016	<b>2017</b>	2016
	<b>\$m</b>	\$m	<b>\$m</b>	\$m
Cost of sales	-	(1)	-	(11)
Legal expenses	-	(220)	<b>(25)</b>	(220)
Consulting costs	-	(2)	-	(6)
<b>Total exceptional items</b>	-	(223)	<b>(25)</b>	<b>(237)</b>

\$25m of year to date 2017 pre-tax exceptional items are for a conclusive legal settlement with Amneal Pharmaceuticals LLC in conjunction with anti-trust litigation. \$237m of pre-tax exceptional items in YTD 2016 include legal provisions, write offs of manufacturing costs and legal and advisory costs related to the exploration of strategic initiatives for the event of a potential negative ANDA ruling.

### 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 YTD 2017, tax on total profits amounted to \$71m (YTD 2016: \$82m) and represented a year to date effective tax rate of 26% (YTD 2016: 210%); \$9m of these relate to the tax effects of the exceptional items within operating profit (YTD 2016: \$5m); \$3m relates to release of provisions for unresolved tax matters, related primarily to favorable developments in an IRS position. Prior YTD tax expense also included an exceptional benefit of \$19m related to the tax effect on the movement of assets within the Group and additional provisions for unresolved tax matters. The reduction in deferred tax assets of \$24m 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 26% was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the third quarter. Excluding exceptional items of \$3m (Q3 2016: \$16m), the tax rate was 13% (Q3 2016 adj: 21%) in the third 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>Q3 2017 cents</b>	Q3 2016 cents	<b>YTD 2017 cents</b>	YTD 2016 cents
Basic earnings per share	<b>7</b>	(21)	<b>28</b>	(6)
Diluted earnings per share	<b>7</b>	(20)	<b>27</b>	(6)
Adjusted basic earnings per share	<b>7</b>	10	<b>30</b>	28
Adjusted diluted earnings per share	<b>6</b>	10	<b>29</b>	28

### 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 Average number of shares</b>	2016 Average number of shares
On a basic basis	<b>721,011,124</b>	720,597,566
Dilution for Long Term Incentive Plan (LTIP)	<b>26,627,518</b>	22,614,143
Employee Sharesave Scheme	<b>1,050,182</b>	-
On a diluted basis	<b>748,688,824</b>	743,211,709

## Adjusted Earnings

The Directors believe that diluted earnings per share, adjusted for the impact of exceptional items after the appropriate tax amount, provides more meaningful 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:

	Q3 2017 \$m	Q3 2016 \$m	YTD 2017 \$m	YTD 2016 \$m
Net income	50	(149)	203	(43)
Exceptional items	-	223	25	237
Tax effect of exceptional items	-	-	(9)	(5)
Exceptional items within taxation	(3)	(3)	(3)	16
<b>Adjusted net income</b>	<b>47</b>	<b>71</b>	<b>216</b>	<b>205</b>

## 6. FINANCIAL LIABILITIES – BORROWINGS

	September 30 2017 \$m	December 31 2016 \$m
<b>Current</b>		
Bank loans	(129)	(101)
	<b>(129)</b>	<b>(101)</b>

	September 30 2017 \$m	December 31 2016 \$m
<b>Non-current</b>		
Bank loans	(341)	(434)
	<b>(341)</b>	<b>(434)</b>

	September 30 2017 \$m	December 31 2016 \$m
<b>Analysis of net cash</b>		
Cash and cash equivalents	806	692
Borrowings*	(484)	(561)
Net cash at end of period	<b>322</b>	<b>131</b>

\*Borrowings reflects the outstanding principal amount drawn, before debt issuance costs of \$14m and \$26m, respectively.

	September 30 2017 \$m	December 31 2016 \$m
<b>Reconciliation of net cash/(debt)</b>		
The movements in the period were as follows:		
Net cash/(debt) at beginning of period	131	(174)
Increase in cash and cash equivalents	114	225
Net repayment of/(increase in) borrowings and overdraft	86	78
Exchange adjustment	(9)	2
Net cash at end of period	<b>322</b>	<b>131</b>

The net carrying value of current borrowings before issuance costs 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 September 30, 2017 are as follows:

	Currency	Nominal interest margin	Maturity	Required annual repayments	Maximum leverage ratio	Minimum liquidity \$m
Term loan facility	USD	Libor (1%) + 6%	2019	10%	2.50	150
Term loan facility	EUR	Libor (1%) + 6%	2019	10%	2.50	150

- Nominal interest margin is calculated over 3m LIBOR, subject to a 1% floor.
- 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 stepped 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.
- An annual cash sweep may be required depending on the Group's leverage ratio.

## 7. CONTINGENT LIABILITIES

**The Group carries a provision of \$217m for the investigative and antitrust litigation matters noted below. The provision was reduced by \$25m compared to period ending Q2 2017, reflecting payment of previously reserved settlement amount to Amneal Pharmaceuticals LLC (Amneal). Other than reducing by the Amneal settlement amount, the Group has not changed the previously recorded provision, as the other litigation and investigations are ongoing. The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. The Group cannot predict with any certainty whether it will reach an ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this provision.**

### 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 State has served additional deposition subpoenas on Indivior in 2017. 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, alleged antitrust violations similar in nature to those alleged in the class action complaints, and Amneal also alleged violations of the U.S. Lanham Act. The Company has settled the dispute with Amneal, and Amneal has dismissed its claims against the Company with prejudice.
- 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 is pending. The States' complaint is similar to the other antitrust complaints, and alleges violations of U.S. state and federal antitrust and consumer protection laws. This lawsuit relates to the antitrust investigation conducted by various states, as discussed in previous filings. Discovery has been coordinated with the antitrust class action litigation, 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. In an August 31st, 2017 ruling, the Court denied motions of **Actavis** and **Par** to reopen the June 2016 judgment.
- Based on the ruling as to the '514 patent, **Actavis** and **Par** are currently enjoined from launching a generic product until April 2024. **Par** and **Actavis** have appealed this ruling, and Indivior has filed notices of cross-appeal. On October 24, 2017 **Actavis** received tentative approval from FDA for at least its 8 mg/2 mg generic product under ANDA 204383. A tentative approval does not allow the applicant to market the generic drug product and postpones the final approval until all patent/exclusivity issues have been resolved. **Actavis** therefore remains enjoined by the Delaware court ruling.
- 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. The rulings in these trials issued on August 31st, 2017. The rulings found the asserted claims of the '497, '514, and '150 patents valid but not infringed. **Teva** had filed a 505(b)(2) New Drug Application (NDA) for a 16 mg/4 mg strength of buprenorphine/naloxone film. The parties had agreed that infringement by **Teva's** 16 mg/4 mg dosage strength would be governed by the infringement ruling as to **Dr. Reddy's** 8 mg/2 mg dosage strength that was the subject of the trial in November 2016; therefore, the non-infringement ruling in the **Dr. Reddy's** case means that the **Teva** 16 mg/4 mg dosage strength has been found not to infringe. Indivior intends to appeal.
- **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** generic SUBOXONE® Film alternative.
- If FDA were to grant final approval to **Dr. Reddy's** (or **Teva** for the 16 mg / 4 mg strength of buprenorphine/naloxone film) 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** (or by **Teva**) before the court of appeals renders its decision would be on an "at risk" basis because Indivior would have a claim for damages against **Dr. Reddy's** (or **Teva**) if Indivior ultimately prevails after any appeal.
- Trial against **Alvogen** in the lawsuit involving the '514 Orange Book-listed patent and the '497 process patent for SUBOXONE® Film took place on September 26th-27th, 2017. Trial was limited to the issue of infringement because **Alvogen** did not challenge the validity of either patent. The 30-month stay of FDA approval of **Alvogen's** Abbreviated New Drug Application was set to expire October 29th, 2017. **Alvogen** agreed not to launch until March 29th, 2018 or until it receives a favourable ruling from the District Court. That agreement has been modified in light of a 3 week extension of the post-trial briefing schedule, but the terms are currently under seal.
- 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.
- On September 25th, 2017, Indivior settled its SUBOXONE® Film patent litigation in District Court against **Mylan**.
- **Mylan** filed a petition seeking an inter partes review (IPR) of the '514 and '497 patents. On May 12<sup>th</sup>, 2017, the US Patent & Trademark Office decided to institute the '514 IPR proceedings. On September 29th, 2017, **Mylan** and

**MonoSol** submitted joint motions to terminate the '514 and '497 IPRs in light of the parties' settlement of their disputes in the District Court litigation. On October 6th, 2017 the Patent Board terminated both the '514 and '497 IPR proceedings as to **MonoSol** and **Mylan**. **Dr. Reddy's** and **Par** had filed petitions and motions in June 2017 to join the **Mylan** '514 IPR proceeding. On October 20<sup>th</sup>, 2017 the Patent Board refused to institute IPR proceedings and dismissed **Dr. Reddy** and **Par's** petitions.

- Since August 2017, Indivior received Paragraph IV Notice letters from **Actavis**, **Par**, **Alvogen**, **Mylan**, and **Dr. Reddy's** for Indivior's recently granted '454 patent. Indivior has filed suit against **Alvogen**, **Dr. Reddy's**, and **Par** in the District of New Jersey; and against **Actavis** in the District of Utah. Although a complaint against **Mylan** was filed in the District of West Virginia, it was dismissed in light of the parties' settlement of their disputes in the Delaware District Court litigation. Indivior has also filed suit against **Teva** in the District of New Jersey, although a Paragraph IV Notice letter has not been received yet.
- In the event that one or more of the generic companies are successful in their patent challenges on a final non-appealable basis, 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 December 23rd, 2016 **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 2015, the IRS issued notices of a proposed adjustment for the disallowance of certain manufacturing deductions claimed by the Group following its audit of the 2010 to 2014 income tax years. The company has appealed the proposed disallowance and as now completed its appeals process with the IRS. The Group has evaluated its positions with respect to the IRS closing agreement and has provided \$19m 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

	September 30	December 31
	2017	2016
	\$m	\$m
Sales returns and rebates	(377)	(402)
Trade payables	(41)	(33)
Accruals	(194)	(212)
Other tax and social security payables	(18)	(11)
<b>Total</b>	<b>(630)</b>	<b>(658)</b>

Sales 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	Nominal value \$m
Issued and fully paid		
<b>At January 1, 2017</b>	<b>720,597,566</b>	<b>72</b>
Allotments	865,167	-
<b>At September 30, 2017</b>	<b>721,462,733</b>	<b>72</b>

	Equity ordinary shares	Nominal value \$m
Issued and fully paid		
At January 1, 2016	718,577,618	72
Allotments	2,019,948	-
At September 30, 2016	720,597,566	72

### Allotment of ordinary shares

During the period, 865,167 ordinary shares (2016: 2,019,948) were allotted to satisfy vestings/exercises under the Group's Long Term Incentive Plan and US Employee Stock Purchase Plan.

## 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 YTD 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 \$5m.

## 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 (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 2016. There have been no changes in the period.

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

November 1, 2017



# 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 Q3 Financial Results of Indivior PLC for the three and nine month periods ended 30 September 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.

---

### 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 \$217 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 than 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 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.

---

### 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 7 that describes the uncertain outcome of the ongoing ANDA patent litigation over Suboxone® Film. In the event that one or more of the generic companies are successful in their patent challenges on a final non-appealable basis, and should there be FDA approval of one or more of the ANDAs and subsequent commercial launch of generic Suboxone® Film, and if 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. As a result of this potential decline and the extent of its impact, the Directors are prepared to change the structure of the business and to reduce its cost base, as also described in note 7.

---

### What we have reviewed

The Interim Financial Statements comprise:

- the Condensed consolidated interim balance sheet as at 30 September 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 Q3 Financial Results 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**

---

### **Our responsibilities and those of the directors**

The Q3 Financial Results, including the Interim Financial Statements, are the responsibility of, and have been approved by, the Directors. The Directors are responsible for preparing the Q3 Financial Results 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 Q3 Financial Results 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, 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 Q3 Financial Results and considered whether it contains any apparent misstatements or material inconsistencies with the information in the Interim Financial Statements.

PricewaterhouseCoopers LLP  
Chartered Accountants London

1 November 2017