

# Half Year 2017 Results Ahead of Plan - FY 2017 Revenue and Net Income Guidance Raised.

Period to June 30th	Q2	Q2	Q2	% Δ	% Δ	H1	H1	H1	% Δ	% Δ
	2017	2017	2016	Actual	Constant	2017	2017	2016	Actual	Constant
	\$m	Adj*	\$m	FX	FX	\$m	Adj*	\$m	FX	FX
Net Revenue	288	288	274	+5	+6	553	553	531	+4	+5
Operating Profit	117	142	97	+21	+19	244	269	198	+23	+23
Net Income	73	89	57	+28	+27	153	169	107	+43	+43
EPS (cents per share)	10	12	8	+25	+27	21	23	15	+40	+43

<sup>\*</sup>Adjusted basis, excluding impact of exceptional SD&A items of \$25m and related taxes of \$9m in Q2 and H1.

#### This announcement contains inside information.

# Strong H1 2017 Financial Results and FY 2017 Guidance Raised

- H1 2017 net revenue of \$553m (H1 2016: \$531m) increased 4% on a reported basis (5% at constant FX) primarily due to continued strong market growth in the US that was partially offset by generic competition in more price sensitive payors in the US (Managed Medicaid).
- H1 2017 operating profit of \$244m (H1 2016: \$198m) increased 23% reflecting higher net revenues and lower expenses (primarily legal and R&D). On an adjusted basis, excluding \$25m of exceptional items in the current period and \$14m in the year-ago period, H1 2017 adjusted operating profit increased 27% to \$269m (Adj. H1 2016: \$212m).
- H1 2017 net income was \$153m (H1 2016: \$107m). On an adjusted basis (excluding exceptional items in both periods), H1 2017 net income increased 25% to \$169m (H1 2016: \$135m).
- \$25m exceptional item booked in Q2/H1 2017 reflecting a legal settlement of antitrust litigation with Amneal Pharmaceuticals LLC (Amneal).
- H1 2017 cash balance of \$792m (FY 2016: \$692); net cash of \$295m (FY 2016: \$131m).
- FY 2017 guidance raised, reflecting strong US market conditions, market share resilience of Suboxone® Film and lower expenses (primarily legal and R&D). FY 2017 net revenue now expected to be in a range of \$1,090m to \$1,120m (previously \$1,050m \$1,080m) and adjusted net income of \$265m to \$285m (previously \$200m-\$220m) assuming no material changes to current market conditions, excluding exceptional items and at constant FX.
- Raised guidance includes \$40m to \$60m of previously announced pre-launch investments for late stage pipeline assets that are largely phased to H2 2017.

# **H1 2017 Operating Highlights**

- US market growth in H1 2017 continued at low double-digit percentage levels.
- Suboxone® Film market share averaged 59% in H1 2017 (H1 2016: 61%), exiting Q2 2017 at 57% primarily due to ongoing generic competition in more price sensitive US payors (Managed Medicaid).
- New drug application (NDA) submitted for RBP-6000 buprenorphine monthly depot for the treatment of opioid use disorder (OUD) on May 30th (priority review being sought).
- Development on RBP-8000 (Cocaine Esterase for Cocaine Intoxication) was terminated due to clinical complexity on this relatively small commercial opportunity; R&D efforts on broader stimulant use disorder treatments continue.
- The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. Please see pages five to seven for a complete Litigation Update.

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

"We have maintained good business momentum and executed well throughout H1 2017, as underlying market growth in our largest market remains strong. This, combined with lower expenses, has allowed us to generate strong overall H1 2017 results and to raise our FY 2017 revenue and net income guidance. We are also pleased in the quarter to have conclusively resolved outstanding litigation with Amneal, which we believe is in the best interest of shareholders and is another step in resolving the legal risks to our business. More importantly, we achieved a major landmark in securing the long-term future of Indivior: the submission of the NDA for RBP-6000 takes us a critical step closer to making this potentially transformational treatment option available to US patients with moderate-to-severe opioid use disorder."

# **Half Year Operating Review**

# **US Market Update**

The market for buprenorphine products continued to grow strongly in Q2 2017, resulting in low double-digit percentage volume growth in H1 2017 versus the same year-ago period. Market growth has benefited from legislative changes that have expanded opioid use disorder treatment capacity. As a result, more physicians are being waivered to administer medication-assisted treatment and those seeking to raise their patient cap to the new allowable level of 275 (from 100) also are growing. In addition, Q2 2017 saw the first benefits from prescribing nurse practitioners and physician assistants, as permitted under the 2016 CARA legislation.

Suboxone® Film had an average market share of 59% in H1 2017, compared to 61% in H1 2016, and market share exiting Q2 2017 stood at 57%. The decline in share during H1 2017 was largely due to continued competition in more 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 was increased modestly in January 2017, but the benefits were mostly offset by tactical rebating in connection with maintaining formulary access.

#### **Financial Performance in Half Year 2017**

Total net revenue in H1 2017 increased by 4% to \$553m (H1 2016: \$531m) at actual exchange rates, primarily reflecting volume gains from continued strong market conditions in the US and from modest growth in Rest of World markets. These gains were partially offset by a decline in Suboxone® Film market share and wholesaler destocking in the beginning of 2017. Price improvement was mostly offset by tactical rebating activity in the US in connection with formulary access. At constant exchange rates, the increase in H1 2017 net revenue was 5%. In Q2 2017, total net revenue increased 5% at actual exchange rates (6% at constant exchange rates) to \$288m (Q2 2016: \$274m).

US net revenue increased by 4% in H1 2017 to \$452m (H1 2016: \$433m) and by 7% in Q2 2017 to \$237m (Q2 2016: \$222m). Throughout the period, market growth was ahead of last year primarily reflecting legislative action to expand treatment capacity. Volume benefits from solid underlying market growth were partially offset by a decline in Suboxone® Film market share in price sensitive payors (Managed Medicaid) and wholesaler destocking in the beginning of 2017. Improved pricing was largely offset by tactical rebating activity in connection with formulary access.

In H1 2017 Rest of World net revenue increased by 3% at actual exchange rates (8% at constant exchange rates) to \$101m (H1 2016: \$98m). Modest growth in Europe, one-off benefits from the timing of export revenues at the beginning of the year related to certain Middle East customers, continued market share gains in Australasia and one-time collections of overdue payments from certain EU customers primarily drove the overall net revenue improvement. In Q2 2017, Rest of World net revenue decreased 2% at actual exchange rates (+3% at constant exchange rates) to \$51m (Q2 2016: \$52m).

H1 2017 gross margin was 92%, ahead of last year (H1 2016: 90%). This increase primarily reflects exceptional items of \$10m in the year-ago period related to costs for ANDA strategic planning. Excluding the exceptional items last year, gross margin was unchanged at 92%. In Q2 2017, gross margin was 91%, ahead of last year (Q2 2016: 88%), again reflecting exceptional items of \$10m in the year-ago quarter.

H1 2017 SD&A expenses were \$220m (H1 2016: \$221m). Q2 2017 SD&A expenses were \$127m (Q2 2016: \$116m). H1 2017 SD&A includes exceptional items of \$25m, reflecting the legal settlement (booked in Q2 2017) of the Amneal antitrust matter. In the year-ago period, H1 2016 results included exceptional items of \$4m (booked in Q2 2016) reflecting the costs of ANDA strategic planning.

On an adjusted basis (ex.-exceptionals), H1 2017 SD&A expenses decreased 10% to \$195m (Adj. H1 2016: \$217m) and in Q2 2017 SD&A expenses decreased by 9% to \$102m (Adj. Q2 2016: \$112m). The underlying decrease in both recent periods mainly reflects lower legal expenses associated with ongoing litigation. In addition, amortization was lower as the aquisition costs for the Rest of World rights to Suboxone® were fully amortized as of June 2016.

H1 2017 and Q2 2017 R&D expenses decreased by 25% to \$44m and by 32% to \$19m, respectively (H1 2016: \$59m; Q2 2016:\$28m). The decreases in both periods reflect lower clinical activity as Phase III trials on key pipeline assets have been completed.

H1 2017 operating profit was \$244m, 23% above prior year (H1 2016: \$198m), and 23% higher at constant exchange rates. Q2 2017 operating profit was \$117m, 21% above prior year (Q2 2016: \$97m), and 19% higher at constant exchange rates. Exceptional costs of \$25m and \$14m are included in both the current and year-ago period results, respectively. On an adjusted basis (ex.-exceptionals), H1 2017 operating profit would have been \$269m (49% margin), a 27% increase versus \$212m (40% margin) in the year-ago period on the same basis. The improvement primarily reflects the benefit of higher net sales and lower legal and R&D expenses.

H1 2017 EBITDA increased 18% to \$248m (H1 2016: \$210m). Excluding \$25m and \$14m of exceptional items in the current and year-ago period results, respectively, H1 2017 EBITDA increased 22% to \$273m (H1 2016: \$224m).

Finance expenses in H1 2017 were \$25m (2016 H1: \$26m) representing the full all-in cost of interest and amortization on the \$750m borrowing facility offset by the benefit of required repayments of \$71m in H1 2017, reducing the outstanding borrowing on the facility to \$497m. Q2 2017 finance expenses were \$14m (Q2 2016: \$11m), reflecting the all-in cost for the quarter, which includes accelerated amortization of deferred financing costs relating to repayments in the quarter.

The tax charge in H1 2017 was \$66m, a rate of 30%. Excluding exceptional items, the rate was 31% (H1 2016: 38%; ex.-exceptionals 27%) due to the geographic mix of earnings. The tax charge in Q2 2017 was \$30m, a rate of 29%. Excluding exceptional items, the rate was 30%. (Q2 2016: 34%; ex.-exceptionals 20%). Based on current projections, the full year effective tax rate is expected to be 24%, excluding exceptional taxation.

Net income in H1 2017 increased 43% to \$153m (H1 2016: \$107m). At constant exchange rates, the increase was 43%. The current and year-ago periods include \$16m and \$28m of exceptional items, respectively (net of tax). In Q2 2017, net income increased 28% to \$73m (Q2 2016: \$57). At constant exchange rates, the increase was 27%. The current and year-ago quarters include \$16m and \$23m of exceptional items, respectively.

EPS in H1 2017 were 21 cents (H1 2016: 15 cents) on a basic basis and 20 cents on a fully diluted basis (H1 2016: 14 cents). On an adjusted basis, excluding the effect of exceptional items, basic EPS in H1 2017 were 23 cents (H1 2016: 19 cents) and fully diluted EPS were 23 cents (H1 2016: 18 cents).

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

Net working capital (inventory plus trade and other receivables, less trade and other payables) was minus \$313m at end H1 2017, an increase of \$77m 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 H1 2017 were \$792m, reflecting an increase of \$100m in H1 2017 (H1 2016 \$692m). Borrowings, net of issuance costs, were \$481m at the end of H1 2017 (FY 2016: \$535m), reflecting required repayments of \$71m.

Cash generated from operations in H1 2017 was \$205m (H1 2016: \$230m), a decrease of \$25m due to investments in working capital of \$63m and reduced non-cash expenses of \$8m, partially offset by increased operating profit improvement of \$46m.

H1 2017 net cash inflow from operating activities was \$185m (H1 2016: \$183m), reflecting the lower cash from operating activities (H1 2017: \$205 vs. H1 2016: \$230) offset by lower tax payments of \$20m and lower net financing costs of \$7m in H1 2017.

# **R&D / Pipeline Update**

# **Treatment of Opioid Use Disorder**

- RBP-6000, Monthly Depot Buprenorphine: New Drug Application submitted May 30th, 2017. Filing acceptance expected July 29th, 2017 (FDA has 60 days to accept or reject NDA submission and designate "standard" or "priority" review).
- HEOR Study from Phase III (RB-US-13-0001) trial: Final report expected in Q4 2017.
- **RECOVER Study** (**<u>RE</u>**mission from <u>C</u>hronic <u>O</u>pioid Use: Studying En<u>V</u>ironmental and socio<u>E</u>conomic factors on <u>Recovery</u>): Baseline analysis expected to be completed in Q3 2017. 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).
  Canada filing expected in Q4 2017.
- **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: Clinical and regulatory progress on track. Awaiting decision from Chinese
  government on scheduling on the controlled substances register, which will determine the potential for
  treatment.

#### **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 remains on track for Q4 2017.

# **Overdose Rescue Products**

- Intranasal Naloxone: NALSCUE® launched in France under Temporary Authorisation for Use (ATU) in July 2016. Marketing Authorization Application (MAA) submitted November 2016. ANSM recommended approval on March 16th, 2017. Responses to final ANSM questions submitted Q2 2017. Expect response to questions in Q3 2017.
- RBP-8000 Cocaine Esterase for Cocaine Intoxication: All development activities were terminated due to
  complexity of clinical development on this relatively small commercial opportunity; compounds and data
  returned to Columbia University for any future development; R&D efforts on broader stimulant use
  disorder treatments continue.

# **Treatment of Alcohol Use Disorder**

• **Arbaclofen Placarbil:** Two out of three parts of the new Phase I Bioavailability Clinical Study Protocol (INDV-AP-102) of a new formulation of Arbaclofen Placarbil are now completed. Study part 3 ongoing.

#### **Key Pipeline Dates 2017**

Oct ACoP Conference – RBP-6000 Phase III Exposure/R	Response data
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Oct CSAM – RBP-6000 clinical efficacy & safety

Nov AMERSA Conference – RBP-6000 Phase III health economics & outcomes research data

Dec ACNP Conference – RBP-6000 PK/PD/RO model

Dec AAAP Conference – Predictors of dropout in RBP-6000 Phase 3 trials

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 \$242m for the investigative and antitrust litigation matters noted below. The provision increased by \$25m compared to Q1 2017, reflecting the distinct and conclusive settlement of antitrust litigation with Amneal Pharmaceuticals LLC (Amneal). Other than adding the Amneal settlement amount, 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 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 State has served additional 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, 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. The Company negotiated a settlement agreement with Amneal, executed on July 26th, that will result in the dismissal of Amneal's claims 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 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 '514 Orange Book-listed patent 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. Indivior has dismissed its claim of infringement of the '150 Orange Book-listed patent against Mylan. 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. Relying on a recent Supreme Court decision relating to venue in patent cases, Mylan has recently sought to renew its motion to transfer the case from the District Court for the District of Delaware to the District Court for the Northern District of West Virginia. Indivior has opposed that request. If Mylan's motion is granted, trial against Mylan could be delayed.
- 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 Monosol 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, and on June 23rd, 2017, the PTAB denied the rehearing request for the '832 patent IPR.
- Mylan has filed a petition seeking an IPR of the '514 patent. On May 12<sup>th</sup>, 2017, the US Patent & Trademark Office decided to institute IPR proceedings. On June 9th and 12th, 2017, Par and Dr. Reddy's filed respective motions to join the Mylan '514 patent IPR. Indivior has opposed Dr. Reddy's joinder request. Par and Dr. Reddy's are time-barred from bringing independent IPR petitions against the Orange Book-listed patents.
- 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 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 RB 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 5-7 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 18-21, 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 5-7 referring to the current status of the investigative and litigation matters involving the Group, as well as the contingent liabilities disclosures on pages 18-21, 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:

	6 Months to June 30,	6 Months to June 30,
	2017	2016
GB £ period end	1.2926	1.3225
GB £ average rate	1.2584	1.4359
€ Euro period end	1.1379	1.1023
€ Euro average	1.0815	1.1166

#### **Webcast Details**

There will be a presentation at 12pm UK time (7am 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.

Webcast link: http://edge.media-server.com/m/p/3hzfgb5o

Confirmation Code: 5143659

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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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

For more information about SUBOXONE® Film, SUBOXONE® (buprenorphine and naloxone) Sublingual Tablets (CIII), or SUBUTEX® (buprenorphine) Sublingual Tablets (CIII), please see the respective <u>full Prescribing Information</u> and <u>Medication Guide</u> at <u>www.suboxoneREMS.com</u>.

# **Condensed consolidated interim income statement**

		Unaudited	Unaudited	Unaudited	Unaudited
		Q2	Q2	H1	H1
		2017	2016	2017	2016
	Notes	\$m	\$m	\$m	\$m
Net Revenues	2	288	274	553	531
Cost of Sales		(25)	(33)	(45)	(53)
Gross Profit		263	241	508	478
Selling, distribution and administrative	3	(127)	(116)	(220)	(221)
Research and development expenses	3	(19)	(28)	(44)	(59)
Operating Profit		117	97	244	198
Operating profit before exceptional items		142	111	269	212
Exceptional items	3	(25)	(14)	(25)	(14)
Operating profit		117	97	244	198
Finance expense		(14)	(11)	(25)	(26)
Profit before taxation		103	86	219	172
Income tax expense		(30)	(29)	(66)	(65)
Taxation before exceptional items	4	(39)	(20)	(75)	(51)
Exceptional items within taxation	4	9	(9)	9	(14)
Net income		73	57	153	107
Earnings per ordinary share (cents)					
Basic earnings per share	5	10	8	21	15
Diluted earnings per share	5	10	8	20	14

# Condensed consolidated interim statement of comprehensive income

	Unaudited Q2 2017 \$m	Unaudited Q2 2016 \$m	Unaudited H1 2017 \$m	Unaudited H1 2016 \$m
Net income	73	57	153	107
Other comprehensive income				
Items that may be reclassified to profit or loss in subsequent years:				
Net exchange adjustments on foreign currency translation	1	3	3	-
Other comprehensive income	1	3	3	
Total comprehensive income	74	60	156	107

# **Condensed consolidated interim balance sheet**

		Unaudited June 30, 2017	Audited Dec 31, 2016
	Notes	\$m	\$m
ASSETS			
Non-current assets			
Intangible assets		82	83
Property, plant and equipment and other assets		43	27
Deferred tax assets		91	109
		216	219
Current assets			
Inventories		49	41
Trade and other receivables		241	227
Current tax receivable		31	30
Cash and cash equivalents	6	792	692
		1,113	990
Total assets		1,329	1,209
LIABILITIES			
Current liabilities			
Borrowings	6	(129)	(101)
Provision for liabilities and charges		(242)	(219)
Trade and other payables	8	(603)	(658)
Current tax liabilities		(95)	(52)
		(1,069)	(1,030)
Non-current liabilities			
Borrowings	6	(352)	(434)
Provisions for liabilities and charges		(41)	(40)
		(393)	(474)
Total liabilities		(1,462)	(1,504)
Net liabilities		(133)	(295)
EQUITY			
Capital and reserves			
Share capital	9	72	72
Share preminum		1	-
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(19)	(22)
Retained Earnings		1,108	950
Total equity		(133)	(295)

# Condensed consolidated interim statement of changes in equity

				Foreign		
				Currency		
	Share	Share	Other	Translation	Retained	Total
Unaudited	Capital	Premium	Reserve	Reserve	Earnings	equity
	\$m	\$m	\$m	\$m	\$m	\$m
At January 1, 2016	72	-	(1,295)	(23)	967	(279)
Comprehensive income						_
Net income	-	-	-	-	107	107
Other comprehensive income	-	-	-	-	-	
Total comprehensive income	-	-	-	-	107	107
Transactions recognised directly in equity						_
Share-based plans	-	-	-	-	5	5
Balance at June 30, 2016	72	-	(1,295)	(23)	1,079	(167)
At January 1, 2017	72	-	(1,295)	(22)	950	(295)
Comprehensive income						
Net income	-	-	-	-	153	153
Other comprehensive income	-	-	-	3	-	3
Total comprehensive income	-	-	-	3	153	156
Transactions recognised directly in equity						
Share-based plans	-	1	-	-	5	6
Total transactions recognised directly in equity	-	1	-	-	5	6
Balance at June 30, 2017	72	1	(1,295)	(19)	1,108	(133)

# **Condensed consolidated interim cash flow statement**

	Unaudited	Unaudited
	2017	2016
For the six months ended June 30	\$m	\$m
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating Profit	244	198
Depreciation and amortization	4	12
Share-based payments	5	5
Impact from foreign exchange movements	2	2
(Increase) in trade and other receivables	(11)	(43)
(Increase)/decrease in inventories	(5)	1
(Decrease)/Increase in trade and other payables	(57)	55
Increase in provisions	23	-
Cash generated from operations	205	230
Net financing costs	(16)	(23)
Taxes paid	(4)	(24)
Net cash inflow from operating activities	185	183
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(15)	(13)
Purchase of intangible assets	(1)	-
Net cash (outflow) from investing activities	(16)	(13)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of borrowings	(71)	(60)
Net cash (outflow) from financing activities	(71)	(60)
rece cash (outliers) from mancing activities	(72)	(00)
Net increase in cash and cash equivalents	98	110
Cash and cash equivalents at beginning of the period	692	467
Exchange differences	2	
Cash and cash equivalents at end of the period	792	577

#### 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 (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 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.

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 July 26, 2017.

As disclosed in Note 7, the Group carries a provision of \$242m 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 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 and intangible assets. Revenues and non-currents assets for the six months to June 30, 2017 and 2016 were as follows:

Revenues from sale of goods:

	Q2	Q2	H1	H1
	2017	2016	2017	2016
	\$m	\$m	\$m	\$m
United States	237	222	452	433
ROW	51	52	101	98
Total	288	274	553	531

#### Non-current assets:

	June 30,	December 31,
	2017	2016
	\$m	\$m
United States	67	64
ROW	58	46
Total	125	110

#### 3. OPERATING COSTS AND EXPENSES

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

	Q2	Q2	H1	H1
	2017	2016	2017	2016
	\$m	\$m	\$m	\$m
Research and development expenses	(19)	(28)	(44)	(59)
Marketing, selling and distribution expenses	(37)	(32)	(69)	(64)
Administrative expenses	(86)	(77)	(143)	(143)
Depreciation and amortization	(2)	(6)	(4)	(12)
Operating lease rentals	(2)	(1)	(4)	(2)
Total	(127)	(116)	(220)	(221)

# **Exceptional Items**

	Q2	Q2	H1	H1
	2017	2016	2017	2016
	\$m	\$m	\$m	\$m
Cost of sales	-	10	-	10
Legal expenses	25	-	25	-
Consulting costs	-	4	-	4
Total exceptional items	25	14	25	14

\$25m of pre-tax exceptional items in Q2 2017 and H1 2017 are for a conclusive legal settlement with Amneal Pharmaceuticals LLC in conjunction with anti-trust litigation. \$14m of pre-tax exceptional items in Q2 2016 and H1 2016 are for 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. These have been included within administrative expenses and costs of sales.

#### 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 six months ended June 30, 2017, tax on total profits amounted to \$66m (H1 2016: \$65m) and represented a half year effective tax rate of 30% (H1 2016: 38%); \$9m of these relate to the tax effects of the exceptional items within operating profit (H1 2016: \$5m). Prior year 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 Group's balance sheet at June 30, 2017 included a tax payable liability of \$95m, tax receivables of \$31m, and deferred tax asset

of \$91m. The reduction in deferred tax assets of \$18m relates primarily to temporary differences on unrealized profit on the sale of inventory between Group entities. This reduction is expected to be sustained.

The increase in the effective tax rate to 30% was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the half-year.

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

	Q2	Q2	H1	H1
	2017	2016	2017	2016
	cents	cents	cents	cents
Basic earnings per share	10	8	21	15
Diluted earnings per share	10	8	20	14
Adjusted basic earnings per share	12	11	23	19
Adjusted diluted earnings per share	12	11	23	18

#### **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.

	2017	2016
	Average	Average
	number of	number of
	shares	shares
On a basic basis	720,713,885	720,597,566
Dilution for Long Term Incentive Plan (LTIP)	26,879,526	24,845,443
Employee Sharesave Scheme	1,050,182	-
On a diluted basis	748,643,593	745,443,009

# **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:

	Q2	Q2	H1	H1
	2017	2016	2017	2016
	\$m	\$m	\$m	\$m
Net income	73	57	153	107
Exceptional items	25	14	25	14
Tax effect of exceptional items	(9)	(5)	(9)	(5)
Exceptional items within taxation	-	14	-	19
Adjusted net income	89	80	169	135

#### 6. FINANCIAL LIABILITIES - BORROWINGS

Current	June 30 2017 \$m	December 31 2016 \$m
Bank loans	(129)	(101)
	(129)	(101)
	June 30	December 31
	2017	2016
Non-current	\$m	\$m
Bank loans	(352)	(434)
	(352)	(434)
	June 30	December 31
Analysis of net debt	2017 \$m	2016 \$m
Cash and cash equivalents	792	692
Borrowings*	(497)	(561)
	295	131

<sup>\*</sup>Borrowings reflects the outstanding principal amount drawn, before debt issuance costs.

	June 30	December 31
Reconciliation of net debt	2017	2016
Reconciliation of flet debt	\$m	\$m
The movements in the period were as follows:		
Net debt at beginning of period	131	(174)
Increase in cash and cash equivalents	100	225
Net repayment of/(increase in) borrowings and overdraft	71	78
Exchange adjustment	(7)	2
Net debt at end of period	295	131

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 June 30, 2017 are as follows:

		Nominal		Required	Maximum	Minimum
		interest		annual	leverage	liquidity
	Currency	margin	Maturity	repayments	ratio	\$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 \$242m for the investigative and antitrust litigation matters noted below. The provision increased by \$25m compared to Q1 2017, reflecting the distinct and conclusive settlement of antitrust litigation with

Amneal Pharmaceuticals LLC (Amneal). Other than adding the Amneal settlement amount, 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 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 State has served additional 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, 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. The Company negotiated a settlement agreement with Amneal,
  executed on July 26th, that will result in the dismissal of Amneal's claims 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 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<sup>-</sup>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 '514 Orange Book-listed patent 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. Indivior has dismissed its claim of infringement of the '150 Orange Book-listed patent against Mylan. 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. Relying on a recent Supreme Court decision relating to venue in patent cases, Mylan has recently sought to renew its motion to transfer the case from the District Court for the District of Delaware to the District Court for the Northern District of West Virginia. Indivior has opposed that request. If Mylan's motion is granted, trial against Mylan could be delayed.
- 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 Monosol 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, and on June 23rd, 2017, the PTAB denied the rehearing request for the '832 patent IPR.
- Mylan has filed a petition seeking an IPR of the '514 patent. On May 12<sup>th</sup>, 2017, the US Patent & Trademark Office decided to institute IPR proceedings. On June 9th and 12th, 2017, Par and Dr. Reddy's filed respective motions to join the Mylan '514 patent IPR. Indivior has opposed Dr. Reddy's joinder request. Par and Dr. Reddy's are time-barred from bringing independent IPR petitions against the Orange Book-listed patents.
- 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

	<b>June 30</b> De	December 31
	2017	2016
	\$m	\$m
Sales returns and rebates	(394)	(402)
Trade payables	(30)	(33)
Accruals	(160)	(212)
Other tax and social security payables	(19)	(11)
Total	(603)	(658)

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	Nominal	
		value	
	shares	\$m	
Issued and fully paid			
At January 1, 2017	720,597,566	72	
Allotments	390,817	-	
At June 30, 2017	720,988,383	72	

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

# Allotment of ordinary shares

During the period, 390,817 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 H1 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

The Company reached a legal settlement of antitrust litigation with Amneal Pharmaceuticals LLC.

# **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

By order of the Board

Shaun Thaxter Mark Crossley

Chief Executive Officer Chief Financial Officer

July 26, 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 Half Yearly Results of Indivior PLC for the three and six month periods ended 30 June 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 \$242 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 of a negative ruling against the Group, and should there be a regulatory approval and subsequent commercial launch of generic Suboxone® 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.

#### What we have reviewed

The Interim Financial Statements comprise:

- the Condensed consolidated interim balance sheet as at 30 June 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 Half Yearly 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 Half Yearly Results, including the Interim Financial Statements, is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the Half Yearly 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 Half Yearly 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 Half Yearly 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 26 July 2017