**February 15, 2018**

**Full Year 2017 Adjusted Financial Results In-Line with Guidance.**

| Period to December 31st | Q4 2017 $m | Q4 2016 $m | % Δ Actual FX | % Δ Constant FX | FY 2017 $m | FY 2016 $m | % Δ Actual FX | % Δ Constant FX |
|---|---|---|---|---|---|---|---|---|
| Net Revenue | **265** | 259 | +2 | +1 | **1,093** | 1,058 | +3 | +3 |
| Operating (Loss)/Profit | **(115)** | 71 | * | * | **193** | 149 | +30 | +25 |
| Net (Loss)/Income | **(145)** | 78 | * | * | **58** | 35 | +66 | +57 |
| (Loss)/EPS (cents per share) | **(20)** | 11 | * | * | **8** | 5 | +60 | +57 |
| | | | | | | | | |
| Adjusted Operating Profit[1] | **70** | 72 | -3 | -9 | **403** | 387 | +4 | +3 |
| Adjusted Net Income[1] | **54** | 49 | +10 | +7 | **270** | 254 | +6 | +5 |
| Adjusted EPS[1] | **7** | 7 | +10** | +7 | **37** | 35 | +6 | +5 |

[1]***Adjusted basis excludes the impact of exceptional items as referenced in Notes 3, 4 and 5.***

**** Not meaningful. **Due to rounding.***

**This Release Contains Inside Information.**

The Group increased its provision for investigative and antitrust litigation matters to $438m. Because these matters are in various stages, Indivior cannot predict with any certainty the ultimate resolutions, costs, or timing of the ultimate resolution of any of the matters. The final aggregate settlement amount may be materially different from this provision. The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. The Group cannot predict with any certainty whether it will reach an ultimate resolution with the Department of Justice or any or all of the parties to the other matters referred to under the Litigation Update on Page 6.

## Full Year 2017 Financial Highlights

- Net revenue at $1,093m (FY 2016: $1,058m) increased 3% on a reported basis (3% at constant exchange). The increase was primarily due to stronger US market growth and growth in Rest of World (ROW) that was partially offset by share loss to generic competition in price sensitive US payors, unfavorable mix from increased US Medicaid business and continued tactical rebating in the US.
- Operating profit was $193m (FY 2016: $149m) reflecting the impact of exceptionals in both periods. On an adjusted basis, excluding $210m of exceptional items in FY 2017 and $238m in FY 2016, FY 2017 operating profit grew 4% to $403m (FY 2016 adj.: $387m). The improvement was primarily due to increased sales and lower R&D expenses, partially offset by increased pre-launch investments for SUBLOCADE™ and RBP-7000.
- Net income was $58m (FY 2016: $35m) reflecting the impact of exceptionals discussed above as well as one-off refinancing costs, a non-cash charge of $15m related to US tax reform and other tax adjustments. On an adjusted basis, FY 2017 net income grew 6% to $270m (FY 2016 adj.: $254m).
- Indivior entered into an amendment and extension with various lenders to provide replacement term loans that improve the Group's overall financial flexibility; the new arrangements feature a reduced interest coupon, an extended maturity and more favorable covenants.
- Cash balance at period end was $863m (FY 2016: $692m). Net cash was $376m (FY 2016: $131m).

## Full Year 2017 Operating Highlights

- US market growth rate in FY 2017 improved to low double-digits levels.
- SUBOXONE® Film market share averaged 57% in FY 2017 (FY 2016: 61%), exiting the year at 56% (FY 2016: 61%) primarily due to ongoing generic tablet competition in the most price sensitive US payors (Managed Medicaid).

- SUBLOCADE™ became the first once-monthly buprenorphine long-acting injection delivery system approved by FDA for the treatment of moderate-to-severe opioid use disorder (OUD); US launch scheduled for the week of February 26, 2018.
- FDA accepted NDA for RBP-7000, a once-monthly risperidone long-acting injection for the treatment of schizophrenia; PDUFA date of July 28, 2018 established; setting up new business unit.
- Indivior entered into a strategic collaboration with Addex Therapeutics on January 3, 2018 that includes exclusive global license rights to their $GABA_B$ positive allosteric modulator program.
- Indivior initiated an appeals process against Dr. Reddy's after the US District Court for the District of Delaware found asserted claims of Patent Nos. '150, '514 and '497 valid but not infringed by Dr. Reddy's proposed generic buprenorphine/naloxone film. The appeal is progressing in the Federal Circuit Court of Appeals.
- Indivior took additional actions to secure its intellectual property position by reaching a settlement with Mylan, including the termination of their inter partes review (IPR), and is asserting its new Orange Book-listed patents covering SUBOXONE® Film, US Patent Nos. 9,687,454 (the '454 patent) and 9,855,221 (the `221 patent), against the other abbreviated new drug application (ANDA) filers.
- The Group continues in active discussions with the various governmental and other entities about possible resolutions to their investigative and antitrust litigation matters. Please see pages 6 to 9 for a comprehensive Litigation Update.

## FY 2018 Guidance

- FY 2018 guidance: net revenue of $1,130m-$1,170m and net income in a range of $290m-$320m, excluding exceptional items and at constant FX.
- FY 2018 net revenue guidance assumes the following:
    - No material changes in current market conditions in the US, chiefly that an 'at risk' launch of a generic buprenorphine/naloxone film product will not take place during the year;
    - Intensifying competitive pressure in ROW due to continued healthcare austerity measures and increased competition in Europe, partially offset by continued growth in Australasia; and,
    - Initial net revenue expectations for SUBLOCADE™, which as previously indicated by Indivior are likely to be relatively modest in the early stages of launch.
- FY 2018 net income guidance assumes the following:
    - Strategic investments to drive organic growth priorities (SUBLOCADE™ and RBP-7000), increase access to treatment for OUD patients and to support continued compliance enhancements;
    - Finance expense benefits from the recently replaced term loan facilities; and,
    - A high-teens effective tax rate from the recently enacted (effective January 1, 2018) tax law change in the US, along with the Group's existing tax position.

## Comment by Shaun Thaxter, CEO of Indivior PLC

"2017 was a year of significant accomplishment for Indivior," said Shaun Thaxter, CEO of Indivior. "By executing strongly across the business, we continued to build our leadership position in treating addiction and its co-occurrences. On an operational basis, we maintained our growth trajectory against a strong US market backdrop, we raised our financial guidance at the half-year stage, and we delivered improved bottom-line results that were in-line with our raised expectations. Additionally, we took major steps to mitigate enterprise risk, including our ongoing effort to settle outstanding litigation, for which we took a further provision, and by making additional investments in our internal compliance systems and processes. We also reduced financial risk by replacing legacy loans with new obligations that enhance our overall financial flexibility. Furthermore, our R&D organization delivered on its key objectives with the FDA approval of SUBLOCADE™ for moderate-to-severe OUD and the successful NDA submission for RBP-7000 targeting schizophrenia.

"We face the future with enthusiasm and we are guiding to another year of top- and bottom-line growth in 2018," said Thaxter. "We look forward to launching SUBLOCADE™ later this month, and we continue to expect peak annual net sales of at least $1 billion. We are also excited about the potential for RBP-7000 based on the

unmet needs we see in schizophrenia. We are establishing a new, stand-alone business unit to launch this asset in the fourth quarter of 2018, assuming approval, and we target peak annual net sales of $200 to $300 million.

“Our 2017 achievements have continued to de-risk our business, enhance our compliance programs, and placed Indivior on a solid path to deliver long-term shareholder value,” concluded Thaxter.

## Full Year 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 FY 2017 versus FY 2016. Market growth continues to benefit from legislative changes that have expanded OUD treatment capacity. Growth in both the number of physicians waivered to administer medication-assisted treatment and those able to treat to the new allowable level of 275 patients (from 100 patients) continued in Q4 2017. In addition, the number of waivered nurse practitioners and physician assistants continued to grow in Q4 2017.

SUBOXONE® Film had an average market share of 57% in 2017, compared to 61% in 2016, and 2017 exit share was 56%, compared to 61% exiting 2016. The decline in share during 2017 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 this was offset by tactical rebating in connection with maintaining formulary access.

### FY 2017 & Q4 2017 Financial Performance

Total net revenue in FY 2017 increased 3% to $1,093m (FY 2016: $1,058m) at actual exchange rates (3% at constant exchange rates). In FY 2017, revenue grew primarily from low double-digit volume improvement in the US, along with ROW growth from one-off net revenue benefits in Europe and strong growth in Australasia and Canada. These net revenue gains were partially offset by a decline in US Suboxone® Film market share, while price in the US was offset by tactical rebating activity in connection with formulary access. Mix was also unfavorable from increased lower margin US Medicaid business. Q4 2017 total net revenue increased 2% at actual exchange rates (1% at constant exchange rates) to $265m (Q4 2016: $259m).

FY 2017 US net revenue increased 2% to $877m (FY 2016: $857m) and grew 1% in Q4 2017 to $207m (Q4 2016: $206m). In FY 2017, 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). Pricing was offset by tactical rebating activity, while mix was unfavorable from increased Medicaid business. In Q4 2017, benefits from market growth and wholesaler stocking were substantially offset by the share decline in SUBOXONE® Film, while improved pricing was more than offset by increased tactical rebating and unfavorable mix.

FY 2017 ROW net revenue increased 7% at actual exchange rates (7% at constant exchange rates) to $216m (FY 2016: $201m). In Q4 2017, ROW net revenue increased 9% at actual exchange rates (2% at constant exchange rates) to $58m (Q4 2016: $53m). In both the FY 2017 and Q4 2017 periods, continued growth in Australasia and Canada and some one-off revenue benefits in Europe drove the overall net revenue improvement.

FY 2017 gross margin was 90%, unchanged from last year (FY 2016: 90%). FY 2016 results include exceptional items of $11m related to costs for negative ANDA outcome strategic planning. Excluding the exceptional items last year, gross margin was 91%; the current year did not include any exceptional items within gross margin. In Q4 2017, gross margin was 88% (Q4 2016: 89%). The modest decline in both periods primarily reflects the geographic mix of net revenue, reflecting the increased portion from Australasia and Canada which is lower margin.

FY 2017 SD&A expenses increased 4% to $707m (FY 2016: $683m). The periods include exceptional items of $210m and $227m, respectively. FY 2017 SD&A included exceptional items of $185m (booked in Q4 2017) for an increased legal provision related to investigative and antitrust litigation matters partially offset by the release of

a legacy litigation reserve. Also included in FY 2017 was the legal settlement of the Amneal antitrust matter of $25m (booked in Q2 2017). FY 2016 results included exceptional items of $220m for a legal provision related to investigative and antitrust litigation matters (booked in Q3 2016) and $7m reflecting the costs of negative ANDA outcome strategic planning ($4m booked in Q2 2016; $2m booked in Q3 2016; $1m booked in Q4 2016). On an adjusted basis, FY 2017 SD&A expenses increased 9% to $497m (FY 2016 adj.: $456m). The increase primarily reflected the expected pre-launch investments for SUBLOCADE™ and RBP-7000 and higher legal expenses related to ongoing ANDA litigation activity and related patent defense costs compared to the prior year.

Q4 2017 SD&A expenses increased 157% to $326m (Q4 2016: $127m). Q4 2017 SD&A included total exceptional items of $185m (Q4 2016: $1m), as described above. On an adjusted basis, Q4 2017 SD&A expenses increased 12% to $141m (Q4 2016 adj.: $126m). The increase in underlying SD&A (excluding exceptionals) in Q4 2017 primarily reflected the expected pre-launch investments for SUBLOCADE™ and RBP-7000, which were partially offset by lower legal expenses compared to the prior period.

FY 2017 and Q4 2017 R&D expenses decreased by 25% to $89m and by 31% to $22m, respectively (FY 2016: $119m; Q4 2016: $32m). The decreases in both periods reflect lower clinical activity as key pipeline assets either have entered the commercial phase (SUBLOCADE™) or have been successfully submitted to FDA for approval (RBP-7000).

FY 2017 operating profit of $193m increased 30% over the prior year (FY 2016: $149m). Exceptional items of $210m and $238m are included in the FY 2017 and FY 2016 results, respectively. On an adjusted basis, FY 2017 operating profit was $403m (37% margin), a 4% increase versus $387m (37% margin) in FY 2016. The underlying year-over-year improvement, which excludes exceptionals, primarily reflects the benefit of higher net sales and lower R&D expenses, partially offset by expected pre-launch investments for SUBLOCADE™ and RBP-7000, as well as higher legal expenses related to ongoing ANDA litigation activity and related patent defense costs.

Q4 2017 operating loss was $115m, compared to an operating profit in the prior year (Q4 2016: $71m). On an adjusted basis, which excludes exceptional items totaling $185m, Q4 2017 operating profit declined 3% to $70m versus the prior year on the same basis (Q4 2016 adj. $72m). The decrease primarily reflects expected pre-launch investments for SUBLOCADE™ and RBP-7000, which were partially offset by lower legal and R&D expenses.

FY 2017 EBITDA (operating profit plus depreciation and amortization) was $206m (FY 2016: $163m). Excluding $210m and $238m of exceptional items in the current and year-ago period results, respectively, FY 2017 adjusted EBITDA increased 4% to $416m (adj. FY 2016: $401m).

FY 2017 net finance expense was $56m (FY 2016: $51m), representing the interest and amortization on the Group's term loan borrowing facility, which was slightly offset by modest interest income. FY 2017 interest expense also includes $14m of exceptional costs related to the replacement term loan facilities. In December 2017, Indivior entered into an amendment and extension with various lenders to provide replacement term loans in an aggregate principal amount of approximately $487m, replacing all of the Group's U.S. dollar and Euro denominated term loans outstanding under the existing credit agreement. The new term loan facilities reduce the Group's interest coupon to LIBOR plus 4.50% from LIBOR plus 6.00%. The final maturity date has been extended by three years from December 19, 2019 to December 18, 2022.

On an adjusted basis, FY 2017 net finance expense of $42m was lower than the prior year resulting from the benefit of required repayments during FY 2017. Q4 2017 net finance expense was $22m (Q4 2016: $12m), including exceptional costs described above. On adjusted basis, Q4 2017 net finance expense was $8m.

FY 2017 tax charge was $79m, or a rate of 58% (FY 2016 tax charge: $63m; 64% rate). FY 2017 tax charge reflects a $15m one-time non-cash charge related to the lowering of the US corporate income tax rate to 21%, requiring a revaluation of US deferred tax assets and liabilities. FY 2017 also includes other one-time items related to the release of uncertain tax provisions of $24m upon close out of IRS tax audits. FY 2017 and FY 2016 full-year tax charge also assume non-deductibility for tax purposes of the exceptional legal provisions. Excluding exceptional

items in FY 2017 pre-tax income and taxation totaling $12m (FY 2016: $19m), the adjusted rate was 25% (FY 2016 adj.: 25%). Q4 2017 tax charge was $8m (Q4 2016 credit: $19m), or a rate of 6% (Q4 2016: 32%). There were no net exceptional items in Q4 2017. Q4 2017 tax rate excluding exceptionals was 13%. Q4 2016 included exceptionals of $30m (Q4 2016 adj.: 18%).

FY 2017 net income was therefore $58m (FY 2016: $35m) as reported. Excluding exceptional costs, FY 2017 net income increased 6% to $270m (FY 2016 adj.: $254m). The current and year-ago annual periods include a net amount of $212m and $219m of exceptional items, respectively. In Q4 2017, net loss was $145m (Q4 2016 net income: $78m). Excluding exceptional costs, net income for the most recent quarter was $54m (Q4 2016 adj.: $49m). Q4 2017 and Q4 2016 include a net of $199m and $29m of exceptional items, respectively.

FY 2017 basic EPS were 8 cents (FY 2016: 5 cents) and 8 cents on a diluted basis (FY 2016: 5 cents). On an adjusted basis, excluding the effect of exceptional items, FY 2017 basic EPS were 37 cents (FY 2016: 35 cents) and diluted EPS were 36 cents (FY 2016: 34 cents).

## Balance Sheet & Cash Flow

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative $335m at the end of FY 2017, an increase of $55m from negative $390m in FY 2016 primarily driven by an increase in receivables and inventory.

Cash and cash equivalents at the end of FY 2017 were $863m, reflecting an increase of $171m in 2017 (FY 2016: $692m). Borrowings, net of issuance costs, were $482m at the end of FY 2017 (FY 2016: $535m), reflecting required repayments. Consequently, net cash stood at $376m at the end of FY 2017 (FY 2016: $131).

Cash generated from operations in FY 2017 was $369m (FY 2016: $512m), a decrease of $143m primarily due to the investment in working capital driven by a smaller movement in trade payables compared to the prior year.

FY 2017 net cash inflow from operating activities was $295m (FY 2016: $407m), reflecting the lower cash from operations and lower tax payments of $33m in the year compared to $63m last year.

Cash outflow from investing activities increased $8m to $43m. The increase was primarily related to additional investments in the Group's R&D facilities.

## R&D / Pipeline Update

**Treatment of Opioid Use Disorder (OUD)**

- **SUBLOCADE™** (once-monthly buprenorphine long-acting injection):
  - FDA approval November 30, 2017.
  - Commercial launch in the US expected for the week of February 26, 2018.
  - Patient-reported outcomes (PROs) study from open-label, long-term safety and tolerability study of SUBLOCADE™ in 669 treatment-seeking subjects with OUD (NCT# 02510014): Findings to be presented at the 49th Annual Conference of the American Society of Addiction Medicine (ASAM), April 12-15, 2018, San Diego, California.
  - **RECOVER Study** (**RE**mission from **C**hronic **O**pioid Use: Studying En**V**ironmental and socio**E**conomic factors on **R**ecovery): Baseline data have been submitted for peer-reviewed publication and 12-month top-line data will be available by December 31, 2018.
  - Post Marketing Requirement (PMR) and Commitment (PMC) studies undergoing planning and draft protocol phases.
  - Regulatory submissions in Canada, Australia and Europe currently being prepared.
  - SUBLOCADE™ addition to the List of Drugs for an Urgent Public Need for the Canadian correctional service facilities on December 28, 2017.
- **SUBOXONE® Film:** SUBOXONE® Film addition to the List of Drugs for an Urgent Public Health Need in British Columbia on June 28, 2017 and for the Canadian correctional service facilities on December 28, 2017. Regulatory submission currently being prepared.

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

**Treatment of Schizophrenia**

- **RBP-7000, Monthly Long-Acting Risperidone:** NDA filing accepted by FDA on December 12, 2017. PDUFA date of July 28, 2018. Planning for Q4 2018 launch.

**Treatment of Alcohol Use Disorder (AUD)**

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

**Treatment of Stimulant Use Disorder (SUD)**

- Creation of Joint Research Committee with Addex Therapeutics to drive the development of **ADX71441** and the research activities for lead identification of new positive allosteric modulators at the $GABA_B$ receptor.

**Other Key Events 2017**

- Completion and inauguration of extension of Indivior R&D facilities in Fort Collins (CO, USA) (1,700$m^2$/18,500$Ft^2$) and new R&D Center of Excellence in Hull (UK) (5,000$m^2$/54,000$Ft^2$) on July 25, 2017 and August 22, 2017, respectively.
- Additional dosage strengths (SUBOXONE® 12mg/3mg and 16mg/4mg sublingual tablets) approved by Health Canada on Sep 1st, 2017.
- NALSCUE® (intranasal naloxone) MAA approval in France on July 28, 2017.
- 6 peer-reviewed publications and 12 Conference abstracts to support SUBLOCADE™ and RBP-7000.

**Key R&D Dates H1 2018**

**American Association for the Treatment of Opioid Dependence (AATOD):** March 10 to 14, New York City
**American Society for Clinical Pharmacology and Therapeutics (ASCPT):** March 21 to 24, Orlando, Florida
**American Society of Addiction Medicine (ASAM):** April 12 to 15, San Diego, California
**American College of Preventive Medicine (ACPM):** May 23 to 26, Chicago, IL
**College on Problems of Drug Dependence (CPDD):** June 9 to 14, San Diego, CA
**American Association of Nurse Practitioners (AANP):** June 26 to July 1, Denver, CO

## Litigation Update

The Group increased its provision for investigative and antitrust litigation matters to $438m. Because these matters are in various stages, Indivior cannot predict with any certainty the ultimate resolutions, costs or timing of the resolutions of any of the matters. The final aggregate settlement amount may be materially different from this provision. The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. The Group cannot predict with any certainty whether it will reach an ultimate resolution with the Department of Justice or any or all of the parties to the other matters noted below under State Subpoenas and FTC Investigation and Antitrust Litigation.

**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 civil 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 civil 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.

**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 24th, 2017 **Actavis** received tentative approval from FDA for at least its 8 mg/2 mg generic product under ANDA 204383 and on November 15th, 2017 it received tentative approval for its 12 mg/3 mg generic product under ANDA 207087. 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 has appealed the **Dr. Reddy's** and **Teva** rulings.

- **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 extended until April 19th, 2018 in light of a 3-week extension of the post-trial briefing schedule.
- 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 12th, 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**, **Par**, and **Teva** in the District of New Jersey; and against **Actavis** in the District of Utah. Par has filed a corresponding declaratory judgment action in the District of Virginia. Motions to transfer to another District are pending in all the cases. 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 in February 2018 filed suit against Dr. Reddy's, Actavis, Par, Alvogen and Teva for infringement of US Patent No. 9,855,221 (the '221 patent), which is listed in the FDA's Orange Book and relates to certain polymer film compositions having a substantially uniform distribution of active drug.
- 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, including the potential on an 'at-risk' basis, and the Group's pipeline products, including SUBLOCADE™, fail to launch successfully or 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 will continue 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 will continue to vigorously defend this action.

## Risk Factors

The Board of Directors have carried out a robust assessment to ensure that the principal risks, including those that would threaten the Group's business model, future performance, solvency or liquidity are effectively managed and/or mitigated to help ensure the Group is viable. While the Group aims to identify and manage such risks, no risk management strategy can provide absolute assurance against loss.

Set out below are what the Group considers to be the principal risks that could cause the Group's business model, future performance and solvency or liquidity to differ materially from expected and historical results, and how the risks relate to the Group's strategic priorities. Additional risks, not listed here, that the Group cannot presently identify or does not believe to be equally significant, may materially and adversely affect the business, results of operations and financial position. The principal risk factors and uncertainties are not listed in order of significance.

**Business operations and business continuity**

- The Group's revenues are expected to be primarily derived from sales of SUBOXONE® Film and SUBLOCADE™ and any decrease in sales due to competition or supply or quality issues could significantly affect the results of operations and prospects.
- Competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and high-performing talent in key positions is a business-critical requirement.
- Failures or disruptions to the Group's systems, or the systems of third parties on whom the Group relies, due to any number of causes, particularly if prolonged, could result in a loss of key data and/or affect operations.
- The Group's 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 could subject the Group to litigation.
- 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 Group's results, operations, and prospects.
- Indivior utilizes contract manufacturers for SUBOXONE® Film and SUBLOCADE™ and material interruptions could impact the Group's results, operations, and prospects.

**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 6-9 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 22-24, 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. Specifically, see disclosures under Litigation Update on pages {6-9} 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 22-24, note 7.
- 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.
- SUBLOCADE™ requires a very different reimbursement and logistics system that is unfamiliar for current OUD prescribing physicians. A significant amount of revenue could be dependent upon HCP offices learning and adopting these new processes so that they are able to prescribe SUBLOCADE™.

**Compliance with law and ethical behavior**

- 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 each of which could have a material adverse impact on the business, prospects, results of operations and financial condition. Specifically, see disclosures under Litigation Update on page {6-9} referring to the current status of the DOJ investigation and other investigative and anti-trust litigation matters involving the Group, as well as the contingent liabilities disclosures on pages 22-24, 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 pharmacovigilance process 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. Medical Information Unit (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 timelines and identifies safety signals with an assessment of changes to benefit/risk profile and determines actions needed to optimize the safe and effective use of our products, including communicating any relevant changes to key stakeholders.

The Group's annual report for the 2017 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:

| | FY 2017 | FY 2016 |
|---|---|---|
| GB £ period end | 1.3513 | 1.2340 |
| GB £ average rate | 1.2881 | 1.3579 |
| | | |
| € Euro period end | 1.2001 | 1.0519 |
| € Euro average rate | 1.1287 | 1.1070 |

## 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 Indivior's website at www.indivior.com.

*Webcast link:* https://edge.media-server.com/m6/p/es78akq6

| | |
|---|---|
| **Confirmation Code:** | **8967922** |
| Participants, Local - London, United Kingdom: | +44(0)330 336 9105 |
| Participants, Local - New York, United States of America: | +1 646 828 8156 |

## For Further Information


| | | | |
|---|---|---|---|
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**Corporate Website** **www.indivior.com**



## Forward-Looking Statements

This announcement contains certain statements that are forward-looking and which should be considered, amongst other statutory provisions, in light of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty as they relate to events or circumstances that may or may not occur in the future. Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding the Indivior Group's financial guidance for 2018 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation.

Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Indivior Group's products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome

of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including the ongoing investigative and antitrust litigation matters; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

**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 (i.e., 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 www.suboxoneREMS.com. for a complete list.

*To report pregnancy or side effects associated with taking SUBOXONE® Film, please call 1-877-782-6966. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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

## INDICATION AND USAGE

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

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

**WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE™ RISK EVALUATION AND MITIGATION STRATEGY**

- **Serious harm or death could result if administered intravenously. SUBLOCADE™ forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.**
- **Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE™ is only available through a restricted program called the SUBLOCADE™ REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE™ must be certified in this program and comply with the REMS requirements.**

## IMPORTANT SAFETY INFORMATION

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

## CONTRAINDICATIONS

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

## WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

## ADVERSE REACTIONS

Adverse reactions commonly associated with SUBLOCADE™ (in ≥5% of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.
The full prescribing information, including BOXED WARNING, for SUBLOCADE™ can be found here:

**http://www.indivior.com/wp-content/uploads/2018/01/2018_01_12-CLEAN-USPI-SUBLOCADE.pdf**

# Condensed consolidated income statement

| | Notes | **Unaudited Q4 2017 $m** | Unaudited Q4 2016 $m | **Unaudited FY 2017 $m** | Audited FY 2016 $m |
|---|---|---|---|---|---|
| **Net Revenues** | 2 | **265** | 259 | **1,093** | 1,058 |
| Cost of Sales | | **(32)** | (29) | **(104)** | (107) |
| **Gross Profit** | | **233** | 230 | **989** | 951 |
| Selling, distribution and administrative expenses | 3 | **(326)** | (127) | **(707)** | (683) |
| Research and development expenses | 3 | **(22)** | (32) | **(89)** | (119) |
| **Operating (Loss)/Profit** | | **(115)** | 71 | **193** | 149 |
| Operating profit before exceptional items | | **70** | 72 | **403** | 387 |
| Exceptional items | 3 | **(185)** | (1) | **(210)** | (238) |
| Net finance expense | | **(22)** | (12) | **(56)** | (51) |
| Net finance expense before exceptional items | | **(8)** | (12) | **(42)** | (51) |
| Exceptional items | 3 | **(14)** | - | **(14)** | - |
| **(Loss)/Profit before taxation** | | **(137)** | 59 | **137** | 98 |
| Income tax expense/(credit) | | **(8)** | 19 | **(79)** | (63) |
| Taxation before exceptional items | 4 | **(8)** | (11) | **(91)** | (82) |
| Exceptional items within taxation | 4 | **-** | 30 | **12** | 19 |
| **Net (Loss)/income** | | **(145)** | 78 | **58** | 35 |
| | | | | | |
| **Earnings per ordinary share (cents)** | | | | | |
| Basic earnings per share | 5 | **(20)** | 11 | **8** | 5 |
| Diluted earnings per share | 5 | **(20)** | 10 | **8** | 5 |

# Condensed consolidated statement of comprehensive income

| | **Unaudited Q4 2017 $m** | Unaudited Q4 2016 $m | **Unaudited FY 2017 $m** | Audited FY 2016 $m |
|---|---|---|---|---|
| Net (loss)/income | **(145)** | 78 | **58** | 35 |
| **Other comprehensive income** | | | | |
| *Items that may be reclassified to profit or loss in subsequent years:* | | | | |
| Net exchange adjustments on foreign currency translation | **2** | (2) | **8** | 1 |
| Other comprehensive income | **2** | (2) | **8** | 1 |
| **Total comprehensive (loss)/income** | **(143)** | 76 | **66** | 36 |

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

# Condensed consolidated balance sheet

| | Notes | Unaudited 2017 $m | Audited 2016 $m |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible assets | | **92** | 83 |
| Property, plant and equipment and other assets | | **54** | 27 |
| Deferred tax assets | 4 | **58** | 109 |
| Other receivables | | **15** | - |
| | | **219** | 219 |
| **Current assets** | | | |
| Inventories | | **52** | 41 |
| Trade and other receivables | | **278** | 227 |
| Current tax receivable | | **32** | 30 |
| Cash and cash equivalents | 6 | **863** | 692 |
| | | **1,225** | 990 |
| **Total assets** | | **1,444** | 1,209 |
| | | | |
| **LIABILITIES** | | | |
| **Current liabilities** | | | |
| Borrowings | 6 | **(5)** | (101) |
| Provision for liabilities and charges | | **(143)** | (219) |
| Trade and other payables | 8 | **(665)** | (658) |
| Current tax liabilities | 4 | **(41)** | (52) |
| | | **(854)** | (1,030) |
| **Non-current liabilities** | | | |
| Borrowings | 6 | **(477)** | (434) |
| Provisions for liabilities and charges | | **(316)** | (40) |
| | | **(793)** | (474) |
| **Total liabilities** | | **(1,647)** | (1,504) |
| **Net liabilities** | | **(203)** | (295) |
| | | | |
| **EQUITY** | | | |
| **Capital and reserves** | | | |
| Share capital | 9 | **72** | 72 |
| Share premium | | **2** | - |
| Other Reserves | | **(1,295)** | (1,295) |
| Foreign currency translation reserve | | **(14)** | (22) |
| Retained Earnings | | **1,032** | 950 |
| **Total equity** | | **(203)** | (295) |

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

# Condensed consolidated statement of changes in equity

| Audited | Share Capital $m | Share Premium $m | Other Reserve $m | Foreign Currency Translation Reserve $m | Retained Earnings $m | **Total equity $m** |
|---|---|---|---|---|---|---|
| **At January 1, 2016** | **72** | **-** | **(1,295)** | **(23)** | **967** | **(279)** |
| **Comprehensive income** | | | | | | |
| Net income | - | - | - | - | 35 | 35 |
| Other comprehensive income | - | - | - | 1 | - | 1 |
| **Total comprehensive income** | **-** | **-** | **-** | **1** | **35** | **36** |
| **Transactions recognised directly in equity** | | | | | | |
| Share-based plans | - | - | - | - | 10 | 10 |
| Deferred taxation on share-based plans | - | - | - | - | 7 | 7 |
| Dividends paid | - | - | - | - | (69) | (69) |
| **Total transactions recognised directly in equity** | **-** | **-** | **-** | **-** | **(52)** | **(52)** |
| **Balance at December 31, 2016** | **72** | **-** | **(1,295)** | **(22)** | **950** | **(295)** |
| | | | | | | |
| Unaudited | | | | | | |
| **At January 1, 2017** | **72** | **-** | **(1,295)** | **(22)** | **950** | **(295)** |
| **Comprehensive income** | | | | | | |
| Net income | - | - | - | - | 58 | 58 |
| Other comprehensive income | - | - | - | 8 | - | 8 |
| **Total comprehensive income** | **-** | **-** | **-** | **8** | **58** | **66** |
| **Transactions recognised directly in equity** | | | | | | |
| Share-based plans | - | 2 | - | - | 16 | 18 |
| Deferred taxation on share-based plans | - | - | - | - | 8 | 8 |
| **Total transactions recognised directly in equity** | **-** | **2** | **-** | **-** | **24** | **26** |
| **Balance at December 31, 2017** | **72** | **2** | **(1,295)** | **(14)** | **1,032** | **(203)** |

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

# Condensed consolidated cash flow statement

| For the twelve months ended December 31 | Unaudited 2017 $m | Audited 2016 $m |
|---|---|---|
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | |
| Operating Profit | **193** | 149 |
| Depreciation and amortization | **13** | 14 |
| Share-based payments | **16** | 10 |
| Impact from foreign exchange movements | **6** | 1 |
| (Increase) in trade and other receivables | **(59)** | (27) |
| (Increase)/decrease in inventories | **(6)** | 4 |
| Increase in trade and other payables | **5** | 142 |
| Increase in provisions | **201** | 219 |
| **Cash generated from operations** | **369** | 512 |
| Net financing costs | **(36)** | (42) |
| Transaction costs related to loan | **(5)** | - |
| Taxes paid | **(33)** | (63) |
| **Net cash inflow from operating activities** | **295** | 407 |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | |
| Purchase of property, plant and equipment | **(30)** | (20) |
| Purchase of intangible assets | **(13)** | (15) |
| **Net cash (outflow) from investing activities** | **(43)** | (35) |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | |
| Proceeds from borrowings | **487** | - |
| Repayment of borrowings | **(573)** | (78) |
| Dividends paid | **-** | (69) |
| Proceeds from issuance of ordinary shares | **2** | - |
| **Net cash (outflow) from financing activities** | **(84)** | (147) |
| **Net increase in cash and cash equivalents** | **168** | 225 |
| Cash and cash equivalents at beginning of the period | **692** | 467 |
| **Exchange differences** | **3** | - |
| **Cash and cash equivalents at end of the period** | **863** | 692 |

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

## Notes to the condensed consolidated 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 financial statements ('Financial Statements'), reference to the 'Group' means the Company and all its subsidiaries.

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. No standards or interpretations have been adopted before the required implementation date. 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 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 periods.

The consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual financial statements as at December 31, 2016. These consolidated financial statements have been authorized for issue as at February 14, 2018.

As disclosed in Note 7, the Group carries a provision of $438m relating to the Department of Justice and Federal Trade Commission investigations and antitrust litigation. The final settlement amount may be materially different 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 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. For the Group's financial statements for the year ended December 31, 2017, the auditors expect to issue (1) an emphasis of matter dealing with the outcome of the Department of Justice and Federal Trade Commission investigations and antitrust litigation details of which are included above and in note 7; and (2) a material uncertainty related to going concern section dealing with the existence of a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern in relation to the Group's involvement in investigations by the Department of Justice and the Federal Trade Commissions as well as antitrust litigation, which would be further adversely impacted should revenues decline, pipeline products fail to obtain regulatory approval and if the uptake of SUBLOCADE™ is slower than expected. The inclusion of the above in the auditors' report would not represent a modification to the auditors' report.

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. Emphasis of matters were included with respect to the outcome of the ANDA litigation, as well as in respect of a material uncertainty which may have cast doubt on the Group's ability to continue as a going concern in relation to the Department of Justice and Federal Trade Commission investigations and antitrust litigation. The auditors' report on the Group's statutory financial statements for the year ended December 31, 2016 was not modified in this respect.

### 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 FY 2017 and 2016 were as follows:

Revenues from sale of goods:

| | **Q4 2017 $m** | Q4 2016 $m | **FY 2017 $m** | FY 2016 $m |
|---|---|---|---|---|
| United States | **207** | 206 | **877** | 857 |
| ROW | **58** | 53 | **216** | 201 |
| **Total** | **265** | 259 | **1,093** | 1,058 |

Non-current assets:

| | **2017 $m** | **2016 $m** |
|---|---|---|
| United States | **68** | 64 |
| ROW | **93** | 46 |
| Total | **161** | 110 |

## 3. OPERATING COSTS AND EXPENSES

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

| | **Q4 2017 $m** | Q4 2016 $m | **FY 2017 $m** | FY 2016 $m |
|---|---|---|---|---|
| Research and development expenses | **(22)** | (32) | **(89)** | (119) |
| Marketing, selling and distribution expenses | **(51)** | (42) | **(163)** | (144) |
| Administrative expenses | **(270)** | (81) | **(525)** | (520) |
| Depreciation and amortization | **(4)** | (2) | **(13)** | (14) |
| Operating lease rentals | **(1)** | (2) | **(6)** | (5) |
| **Total** | **(326)** | (127) | **(707)** | (683) |

### Exceptional Items (Pre-tax)

| | **Q4 2017 $m** | Q4 2016 $m | **FY 2017 $m** | FY 2016 $m |
|---|---|---|---|---|
| Cost of sales | **-** | - | **-** | (11) |
| Legal expenses | **(185)** | - | **(210)** | (220) |
| Consulting costs | **-** | (1) | **-** | (7) |
| Financing costs | **(14)** | - | **(14)** | - |
| **Total exceptional items** | **(199)** | (1) | **(224)** | **(238)** |

$210m of FY 2017 pre-tax exceptional items are for investigative and antitrust litigation matters set out in Note 7. $14m of financing costs are non-cash and relate to demerger debt issuance costs written off early due to the debt restructuring. $238m of pre-tax exceptional items in FY 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

In the year to December 2017, tax on total profits amounted to $79m and represented a full year effective tax rate of 58% (2016: 64%). A benefit of $9m is included relating to a release of provisions for unresolved tax matters, netted by the impact of the re-measurement of deferred tax assets, and are exceptional. The company also benefited by $3m for Research credits in both the US and the UK. Excluding the impact of exceptional items, the effective tax rate for the year ended December 31, 2017 is 25% (2016: 25%). The prior year included exceptionals of $19m in the full year and $30m in the quarter.

The Group's balance sheet at December 31, 2017 included a tax payable liability of $41m, corporate tax receivable of $32m, and deferred tax assets of $58m.

On December 22, 2017, the US Tax Cuts and Jobs Act (H.R. 1), the tax reform bill (the "Act"), was signed into law. The Act includes numerous changes in existing tax law, including a permanent reduction in the federal corporate income tax rate from 35% to 21%. The rate reduction takes effect on January 1, 2018. As a result of the reduction of federal corporate income tax rates, the Group has recorded a one-time non-cash charge to tax expense for the revaluation of the Group's deferred tax assets of $15m.

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

| | **Q4 2017 cents** | Q4 2016 cents | **FY 2017 cents** | FY 2016 cents |
|---|---|---|---|---|
| Basic earnings per share | **(20)** | 11 | **8** | 5 |
| Diluted earnings per share | **(20)** | 10 | **8** | 5 |
| Adjusted basic earnings per share | **7** | 7 | **37** | 35 |
| Adjusted diluted earnings per share | **7** | 7 | **36** | 34 |

### 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 and awards. The weighted average number of shares is adjusted for the number of shares granted assuming the exercise of stock options.

| Weighted average number of shares | **2017 thousands** | 2016 thousands |
|---|---|---|
| On a basic basis | **721,126** | 719,875 |
| Dilution for share awards and options | **27,356** | 23,346 |
| On a diluted basis | **748,482** | 743,220 |

### 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:

| | **Q4 2017 $m** | Q4 2016 $m | **FY 2017 $m** | FY 2016 $m |
|---|---|---|---|---|
| Net (loss)/income | **(145)** | 78 | **58** | 35 |
| Exceptional items | **199** | 1 | **224** | 238 |
| Tax effect of exceptional items | **6** | (1) | **(3)** | (6) |
| Exceptional items within taxation | **(6)** | (29) | **(9)** | (13) |
| **Adjusted net income** | **54** | 49 | **270** | 254 |

## 6. FINANCIAL LIABILITIES – BORROWINGS

| **Current** | **December 31 2017 $m** | December 31 2016 $m |
|---|---|---|
| Bank loans | **(5)** | (101) |
| | **(5)** | (101) |

| **Non-current** | **December 31 2017 $m** | December 31 2016 $m |
|---|---|---|
| Bank loans | **(477)** | (434) |
| | **(477)** | (434) |

| **Analysis of net cash** | **December 31 2017 $m** | December 31 2016 $m |
|---|---|---|
| Cash and cash equivalents | **863** | 692 |
| Borrowings* | **(487)** | (561) |
| Net cash at end of period | **376** | 131 |

*Borrowings reflects the outstanding principal amount drawn, before respective issuance costs of $5m and $26m, respectively.

| **Reconciliation of net cash/(debt)** | **December 31 2017 $m** | December 31 2016 $m |
|---|---|---|
| The movements in the period were as follows: | | |
| Net cash/(debt) at beginning of period | **131** | (174) |
| Increase in cash and cash equivalents | **171** | 225 |
| Net repayment of borrowings and overdraft | **86** | 78 |
| Exchange adjustment | **(12)** | 2 |
| Net cash at end of period | **376** | 131 |

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 December 31, 2017 are as follows:

| | Currency | Nominal interest margin | Maturity | Required annual repayments | Maximum leverage ratio |
|---|---|---|---|---|---|
| Term loan facility | USD | LIBOR (1%) + 4.5% | 2022 | 1% | 3.0 |
| Term loan facility | EUR | LIBOR (0%) + 4.5% | 2022 | 1% | 3.0 |

• Nominal interest margin is calculated over 3m LIBOR subject to the LIBOR 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 stands at 3.0x, following the debt restructuring.

## 7. CONTINGENT LIABILITIES

The Group increased its provision for investigative and antitrust litigation matters to $438m. Because these matters are in various stages, Indivior cannot predict with any certainty the ultimate resolutions, costs or timing of the resolutions of any of the matters. The final aggregate settlement amount may be materially different from this provision. The Group continues in discussions with the Department of Justice about a possible resolution to its investigation. The Group cannot predict with any certainty whether it will reach an ultimate resolution with the Department of Justice or any or all of the parties to the other matters noted below under State Subpoenas and FTC Investigation and Antitrust Litigation.

**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 civil 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 civil 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.

**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 24th, 2017 **Actavis** received tentative approval from FDA for at least its 8 mg/2 mg generic product under ANDA 204383 and on November 15th, 2017 it received tentative approval for its 12 mg/3 mg generic product under ANDA 207087. 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 has appealed the **Dr. Reddy’s** and **Teva** rulings.
- **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 extended until April 19th, 2018 in light of a 3-week extension of the post-trial briefing schedule.
- 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 12th, 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**, **Par**, and **Teva** in the District of New Jersey; and against **Actavis** in the District of Utah. Par has filed a corresponding declaratory judgment action in the District of Virginia. Motions to transfer to another District are pending in all the cases. 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 in February 2018 filed suit against Dr. Reddy's, Actavis, Par, Alvogen and Teva for infringement of US Patent No. 9,855,221 (the '221 patent), which is listed in the FDA's Orange Book and relates to certain polymer film compositions having a substantially uniform distribution of active drug.
- 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, including the potential on an 'at-risk' basis, and the Group's pipeline products, including SUBLOCADE™, fail to launch successfully or 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 will continue 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 will continue 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 IRS audits for income tax years 2010 to 2014 have now been completed and the company has accrued for all taxes due for the agreed audit adjustments, and have no unagreed audit positions for these periods. The company continues to maintain tax reserves for uncertain tax positions in open tax periods.

## 8. TRADE AND OTHER PAYABLES

| | **December 31 2017 $m** | December 31 2016 $m |
|---|---|---|
| Sales returns and rebates | **(433)** | (402) |
| Trade payables | **(40)** | (33) |
| Accruals | **(179)** | (212) |
| Other tax and social security payables | **(13)** | (11) |
| Total | **(665)** | (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 shares | Nominal value $m |
|---|---|---|
| Issued and fully paid | | |
| **At January 1, 2017** | **720,597,566** | **72** |
| Allotments | 865,167 | - |
| **At December 31, 2017** | **721,462,733** | **72** |

| | Equity ordinary shares | Nominal value $m |
|---|---|---|
| Issued and fully paid | | |
| At January 1, 2016 | 718,577,618 | 72 |
| Allotments | 2,019,948 | - |
| At December 31, 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 FY 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 $4m.

## 11. POST BALANCE SHEET EVENTS

Indivior entered into an agreement on January 3, 2018 to secure exclusive global license rights to Addex Therapeutics' $GABA_B$ positive allosteric modulator program. Under the terms of the agreement, Indivior is making an upfront payment to Addex of $5m, and will also invest in joint research efforts.