

May 2, 2018

Q1 2018 results on track. FY 2018 guidance reconfirmed. Encouraging SUBLOCADE™ launch.

Quarter to March 31	2018 \$m	2017 \$m	% change at actual FX	% change at constant FX
Net Revenue	255	265	-4%	-6%
Operating Profit	116	128	-9%	-11%
Net Income	93	80	+16%	+15%
EPS (cents per share)	13	11	+18%	+18%
Adjusted Operating Profit ¹	99	128	-23%	-24%
Adjusted Net Income ¹	78	80	-3%	-5%
Adjusted EPS ¹ (cents per share)	11	11	*	*

¹Adjusted basis excludes the impact of exceptional item as referenced in Notes 3 and 4.

* Not meaningful.

Q1 Financial Highlights

- Net revenue declined 4% (minus 6% at constant currency) to \$255m (Q1 2017: \$265m). Net revenue reflects a continuation of US market dynamics for SUBOXONE® Film (solid market growth and price improvement more than offset by generic tablet competition and unfavorable channel mix) and trade destocking.
- Operating Profit was \$116m (Q1 2017: \$128m). On an adjusted basis, excluding an exceptional gain of \$17m from out-licensing US patents related to nasal naloxone, operating profit was \$99m (Q1 2017: \$128m). The decline primarily reflects lower net revenue and the planned increase in investments for the launch of SUBLOCADE™ and the anticipated launch of RBP-7000. These items were partly offset by lower administrative expenses and the phasing of R&D expenditures to the second half of 2018.
- Net income was \$93m (Q1 2017: \$80m). On an adjusted basis, net income declined 3% to \$78m in Q1 2018 (Q1 2017: \$80m), primarily reflecting a decline in operating income offset by lower financing costs and a reduced overall effective tax rate.
- Cash balance at period end increased to \$895m (FY 2017: \$863m). Net cash at period end was \$407m (FY 2017: \$376m).

Q1 Operating Highlights

- SUBLOCADE™, the first once-monthly buprenorphine extended release injection delivery system for the treatment of moderate to severe opioid use disorder (OUD), was launched in the US during the final week of February 2018; the launch to date is progressing well, with positive patient and physician feedback and strong initial payor coverage.
- SUBLOCADE™ New Drug Submission made to Health Canada; Priority Review granted.
- Behavioral Health business unit established, preparing for launch of RBP-7000 (if approved), a once-monthly risperidone long-acting injection for the treatment of schizophrenia, in advance of July 28, 2018 PDUFA date.
- US buprenorphine market growth rate in Q1 2018 continued at solid low double-digit levels.
- SUBOXONE® Film market share averaged 55% (Q1 2017: 60%; Q4 2017: 56%), primarily due to ongoing generic tablet competition in the most price sensitive US payors (Managed Medicaid).

- Indivior entered into a strategic collaboration with C4X Discovery Holdings PLC, gaining exclusive global license rights to their orexin-1 antagonists, including lead candidate C4X3256.
- Indivior plans to initiate an appeals process against Alvogen after the US District Court for the District of Delaware found that the asserted claims of the '514 and '497 Patents are not infringed by Alvogen's proposed generic buprenorphine/naloxone film. The parties stipulated that Alvogen does not infringe the asserted claims of '150 Patent as those claims were construed by the Court. Alvogen did not present an invalidity case.
- The appeal against Dr. Reddy's US District Court verdict of non-infringement of Patent Nos. '150, '514 and '497 is progressing in the Federal Circuit Court of Appeals, where it has been consolidated with the appeals involving Watson and Par. Indivior's first brief is currently due June 4, 2018.
- Indivior took additional actions to secure its intellectual property position and asserted its new Orange Book-listed patent, US Patent No. 9,931,305 (the '305 patent), covering SUBOXONE® Film against all outstanding abbreviated new drug application (ANDA) filers; Orange Book-listed patents US Patent Nos. 9,687,454 (the `454 patent) and 9,855,221 (the `221 patent) have previously been asserted.
- 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 8 for a complete Litigation Update.

Guidance

- Full year 2018 guidance reconfirmed: net revenue expected in the range of \$1,130m-\$1,170m and net income of \$290m-\$320m (excluding exceptional items and at constant exchange rates). Guidance assumes no material changes in 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.

Comment by Shaun Thaxter, CEO of Indivior PLC

"Indivior's performance in the first quarter of 2018 was in-line with our expectations and puts us on track to deliver our full year financial guidance. As we highlighted in February, this year's performance is likely to be weighted towards the second half as a result of prior year comparisons and the expected timing of uptake of SUBLOCADE™, our novel monthly buprenorphine extended-release injection for moderate to severe opioid use disorder.

It's still early days in the SUBLOCADE™ launch and, while we have had to manage some expected logistical complexities, we have been very encouraged by initial patient and physician enthusiasm, as well as by the pace of payor coverage. Feedback from the OUD community supports our view that SUBLOCADE™ represents a transformational tool in the fight against the opioid epidemic. While it would be premature to provide SUBLOCADE™ sales information this early in the launch, we aim to begin sharing data, including net revenue, at the half year. We expect the early promise of the launch to translate into accelerating prescription trends in the coming quarters and our confidence that SUBLOCADE™ will achieve at least \$1bn in peak annual net revenue has been further strengthened.

Although the District Court ruling in March in the Alvogen ANDA case was disappointing, we believe our patents are being infringed and are appealing the decision. Furthermore, we have asserted our three recently-granted Orange Book patents against all remaining outstanding challengers. We cannot rule out the possibility of an "at risk" launch of generic SUBOXONE® Film this year, but this is not our current expectation.

With the launch of SUBLOCADE™ and, if approved, our novel once monthly risperidone long-acting injection for the treatment of schizophrenia (RBP-7000), the potential impact of any generic film entry will become progressively less relevant to our long-term prospects."

Operating Review

US Market Update

The market for buprenorphine products continued to grow strongly in Q1 2018 versus the comparable quarter in 2017, showing volume growth of low double-digit percentage levels, in-line with expectations. Market growth continues to benefit from legislative changes that have expanded OUD treatment capacity as well as increased overall public awareness of the opioid epidemic. As a result, growth in both the number of physicians waived to administer medication-assisted treatment and those able to treat to the new permitted level of 275 patients (from 100 patients) continued in Q1 2018. In addition, the number of waived nurse practitioners and physician assistants continued to grow in Q1 2018.

SUBOXONE® Film had an average market share of 55% in Q1 2018, compared to 60% in Q1 2017, and Q1 2018 exit share was 54%, compared to 59% exiting Q1 2017. The decline in share in 2018 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 2018, but this continues to be more than offset by tactical rebating in connection with maintaining formulary access and the mix impact from more US Medicaid patients seeking treatment.

Financial Performance in Q1 2018

Total net revenue was \$255m at actual exchange rates (Q1 2017: \$265m).

US net revenue decreased by 8% to \$197m (Q1 2017: \$215m). Volume was ahead of last year, reflecting low double-digit market growth that was essentially offset by a decline in market share from continued competition in the most price sensitive accounts and wholesaler destocking resulting from a build-up of supply in late 2017. List pricing was up reflecting a modest increase in January, but was more than offset by unfavorable channel mix from increased US Medicaid business and continued tactical rebates in connection with formulary access in both commercial managed care and in certain Medicaid accounts, in response to continued discounting by both branded and generic competitors.

Rest of World net revenue increased 16% to \$58m (Q1 2017: \$50m). The increase was primarily driven by continued growth in Canada and Australasia and by foreign exchange benefits. At constant exchange rates, the increase was 4%. European market share remained resilient, but pricing was negatively impacted by further generic competition.

Gross margin was 91% (Q1 2017: 93%) and was in-line with the rate in FY 2017.

SG&A expenses increased to \$99m (Q1 2017: \$93m). Excluding the \$17m gain from the out-licensing of the intranasal naloxone opioid overdose patents, SG&A expenses were \$116m. The increase mainly reflects planned investments for launching and supporting the growth of SUBLOCADE™, as well as planned investments for the new Behavioural Health unit that is being formed to launch and grow RBP-7000, if approved. These investments were partially offset by lower administrative expenses due to phasing differences versus 2017. Planned incremental growth and support investments related to SUBLOCADE™ and RBP-7000 are expected to continue in FY 2018.

R&D expenses decreased by 36% to \$16m (Q1 2017: \$25m). The decrease reflects anticipated phasing differences versus 2017 that are not expected to continue as regulatory submissions for SUBLOCADE™ in Canada, Australia and Europe are prepared and submitted. In addition, ongoing Post Marketing Requirement (PMR) and Commitment (PMC) studies for SUBLOCADE™ are underway (see R&D update on pages 4 and 5).

Operating profit was \$116m, 9% lower compared to the prior year (Q1 2017: \$128m). On an adjusted basis, excluding the \$17m gain from the out-licensing of the intranasal naloxone opioid overdose patents, operating profit was \$99m, 23% lower compared to the prior year (Q1 2017:

\$128m). The decline primarily reflects lower net revenue and increased investments for SUBLOCADE™ and RBP-7000 that were partially offset by lower R&D expenses. Operating margin was 45% (Q1 2017: 48%). Adjusted operating margin was 39% (Q1 2017: 48%).

EBITDA (operating profit plus depreciation and amortization) was \$119m (Q1 2017: \$130m). EBITDA margin was 47% (Q1 2017: 49%). On an adjusted basis, EBITDA was \$102m (Q1 2017: \$130m). Adjusted EBITDA margin was 40% (Q1 2017: 49%).

Net finance expense in the quarter was \$5m (Q1 2017: \$11m). The decrease was due to the impact of replacing the US- and Euro-denominated term loan facilities in December 2017.

The tax charge in Q1 2018 was \$18m at a rate of 16% (Q1 2017: \$37m, 32%), and \$16m at a rate of 17% on an adjusted basis which excludes the \$17m exceptional item (Q1 2017: \$37m, 32%). The tax rate on an adjusted basis is within the expected full year 2018 rate range. The rate decreased in the current year due to lower US tax rates and increased UK Patent Box benefits, over higher prior year base rate.

Net income for the quarter was \$93m (Q1 2017: \$80m), and \$78m on an adjusted basis excluding \$15m after-tax impact from exceptional item (Q1 2017: \$80m). Lower net revenue and increased new product investments were partially offset by lower administrative, R&D and financing expenses, as well as a lower tax rate.

EPS on a diluted basis were 12 cents, and 10 cents on an adjusted diluted basis (Q1 2017: 11 cents on both a diluted and adjusted diluted basis).

Balance Sheet & Cash Flow

Net working capital (inventory plus trade and other receivables, less trade and other payables) was minus \$290m at end Q1 2018 (minus \$335m at end December 2017). The difference primarily relates to the impact of lower accruals due to wholesaler destocking as well as higher inventory levels due in part to the SUBLOCADE™ launch. Further investment in working capital is anticipated through 2018 to support anticipated volumes of SUBLOCADE™.

Cash and cash equivalents at the period end were \$895m, reflecting a net cash increase of \$32m in the quarter. Borrowings, net of issuance costs, were \$483m (Dec 2017: \$482m) at the quarter end. Net cash was \$407m (Dec 2017: \$376m).

Cash generated from operating activities was \$41m (Q1 2017: \$71m), a decrease of \$30m due to the decline in operating profit, along with increased investment in working capital. Net cash flow from operations was \$25m in the quarter (Q1 2017: \$60m) primarily reflecting the lower cash from operating activities and increased tax payments in the quarter.

R&D / Pipeline Update

Treatment of Opioid Use Disorder (OUD)

- **SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE INJECTION) FOR SUBCUTANEOUS USE CIII:**
 - FDA approval November 30, 2017.
 - Commercial launch initiated week of February 26, 2018.
 - **RECOVER Study (REmission from Chronic Opioid Use: Studying EnVironmental and socioEconomic factors on Recovery):** Topline 12-month longitudinal analysis findings will be available by December 31, 2018.
 - Post Marketing Requirement (PMR) and Commitment (PMC) studies undergoing planning and draft/final protocol phases.
 - SUBLOCADE™ addition to the List of Drugs for an Urgent Public Need for the Canadian correctional service facilities on December 28, 2017.
 - SUBLOCADE™ New Drug Submission (NDS) made to Health Canada; Priority Review status granted by Health Canada.

- Regulatory submissions for Australia and Europe currently being prepared.
- **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. On track for Q4 2018 launch, if approved.

Treatment of Alcohol Use Disorder (AUD)

- **Arbaclofen Placabil:** Preparation for Type C meeting with the FDA to discuss next steps for the development of Arbaclofen Placabil for AUD-induced liver disease with cirrhosis.

Early Stage Asset Development (ESAD)

- License of **ADX71441** from Addex Therapeutics and creation of Joint Research Committee to drive activities for lead identification of additional new positive allosteric modulators at the GABA_B receptor.
- Completed an agreement with C4X Discovery Holdings PLC with exclusive global rights to develop and commercialize C4X's oral orexin-1 receptor antagonist program including lead candidate **C4X3256**.

Other Key Events

- SUBLOCADE™ Phase 3 data presented at the Nevada Psychiatric Association 23rd National Psychopharmacology Update, February 14-17, Las Vegas, NV.
- Top Blue-Ribbon Award received for Poster at the American Society of Clinical Pharmacology and Therapeutics (ASCPT), March 21-24, Orlando, FL: *"Evaluation of RBP-6000 Effects on QT Interval during Treatment for Opioid Use Disorder."*
- SUBLOCADE™ Phase 3 data presented at the Fifth International Congress of the Spanish Society of Dual Disorders (SEPD), March 23-26, Madrid, Spain.
- Patient-Reported Outcomes data on SUBLOCADE™ were presented as a late-breaker at the 49th Annual Conference of the American Society of Addiction Medicine (ASAM) April 12-15, San Diego, CA.
- Completed the out-licensing of intranasal naloxone opioid overdose patents for total consideration of \$17.5 million and additional possible future milestone payments.
- Three peer-reviewed publications submitted and nine in preparation. Twelve Conference abstracts (posters and oral presentations) submitted and either approved or being reviewed.

Dates for Upcoming Key Scientific Congresses

- **5th Annual Western Canada Addiction Forum (WCAF):** May 4-5, Kelowna, BC, Canada
- **American Psychiatry Association (APA):** May 5-9, New York, NY
- **American College of Preventive Medicine (ACPM):** May 23-26, Chicago, IL
- **12e Congrès International d'Addictologie de l'Albatros:** June 6-8, Paris, France
- **College on Problems of Drug Dependence (CPDD):** June 9-14, San Diego, CA
- **Nordic Congress of Psychiatry (NCP):** June 13-16, Reykjavik, Iceland
- **The Royal College of Psychiatrists (RCP) International Congress:** June 24-27, Birmingham, England
- **American Association of Nurse Practitioners (AANP):** June 26-July 1, Denver, CO
- **Deutscher Suchtkongress:** September 17-19, Hamburg, Germany
- **American College of Emergency Physicians (ACEP):** October 1-4, San Diego, CA
- **American Academy of Family Physicians (AAFP FMX):** October 9-13, New Orleans, LA
- **American Psychiatric Nurses Association (APNA):** October 24-27, Columbus, OH
- **Canadian Society of Addiction Medicine (CSAM):** October 25-27, Vancouver, BC, Canada
- **American College of Neuropsychopharmacology (ACNP):** December 3-7, Hollywood, FL
- **American Academy of Addiction Psychiatry (AAAP):** December 6-9, Bonita Springs, FL
- **Third Indivior-hosted R&D / Capital Markets Day:** New York, NY, December 5th (TBC)

Litigation Update

The Group maintained its provision for investigative and antitrust litigation matters of \$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 US Patent No. 8,603,514 (the '514 patent) valid and infringed; the asserted claims of US Patent No. 8,017,150 (the '150 patent) valid but not infringed; and the asserted claims of US Patent No. 8,475,832 (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. Actavis and Par 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 its Abbreviated New Drug Application (ANDA) No. 204383 and on November 15th, 2017 it received tentative approval for its 12 mg/3 mg generic product under ANDA No. 207087. A "tentative" approval does not allow the applicant to market the generic drug product; in order to launch and market the product, the applicant must receive "final" approval. Actavis therefore remains enjoined from launching a generic product by the Delaware court ruling, until and unless such time as the ruling is overturned on appeal.
- Trial against Dr. Reddy's, Actavis and Par in the lawsuits involving the process patent, US Patent No. 8,900,497 (the '497 patent), 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 (the '150 patent and the '514 patent) 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. On March 22, 2018, the District Court issued its ruling finding both patents valid but not infringed by Alvogen. Indivior intends to appeal the judgment.
- Alvogen's 30-month stay of FDA approval expired on October 29th, 2017. So far as Indivior is aware, FDA to date has not granted tentative or final marketing authorization to Alvogen's generic SUBOXONE® Film alternative.
- If FDA were to grant final approval to Alvogen, this would enable them to market a generic film alternative to SUBOXONE® Film in the U.S. However, any market launch by Alvogen before the court of appeals renders its decision would be on an "at risk" basis because

Indivior would have a claim for damages against Alvogen if Indivior ultimately prevails after any appeal.

- 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 patent IPR proceedings. On September 29th, 2017, Mylan and MonoSol submitted joint motions to terminate the '514 patent and '497 patent 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 patent and '497 patent 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 patent IPR proceeding. On October 20th, 2017 the Patent Board refused to institute IPR proceedings and dismissed the Dr. Reddy's and Par's petitions.
- 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 for infringement of US Patent No. 9,687,454 (the '454 patent). The Actavis suit has been transferred to the District of Delaware. Par has filed a corresponding declaratory judgment action in the Eastern District of Virginia, which is stayed pending the outcome of Par's motion to transfer the New Jersey case. 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 also filed suit in February 2018 against Dr. Reddy's, Actavis, Par, Alvogen and Teva for infringement of US Patent No. 9,855,221 (the '221 patent) and in April 2018 against the same defendants for infringement of US Patent No. 9,931,305 (the '305 patent). The patents are listed in the FDA's Orange Book and relate 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 of 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 US Patent No. 9,370,512 (the '512 patent). The asserted patent, which was issued in June 2016, claims priority to an application filed in August 2007. Indivior believes this claim is without merit and will continue to vigorously defend this action. On March 16, 2018, Indivior filed a petition for inter partes review with the United States Patent and Trademark Office (USPTO) asserting that all claims of the '512 patent are invalid. The USPTO will decide whether to institute Indivior's petition on or about October 6th, 2018.

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 Directors have reviewed the principal risks and uncertainties for the financial year 2018.

The assumptions in arriving at the Group's financial guidance for the full year 2018 are described in page 2 of this announcement. To the extent that actual market conditions differ from these assumptions, alternative financial outcomes are possible. However, the Group has issued the guidance based on the industry analogues and its own estimates at this time.

Therefore, other than in respect of guidance for the full year 2018, the Directors consider the principal risks and uncertainties which could have a material impact on the Group's performance in 2018 remain the same as described on pages 50 to 56 of the 2017 Annual Report.

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:

Source: Bloomberg	Q1 2018	Q1 2017
GB £ period end	1.4157	1.2434
GB £ average rate	1.3910	1.2390
€ Euro period end	1.2403	1.0766
€ Euro average rate	1.2288	1.0653

Webcast Details

There will be a conference call at 1pm UK time (8am Eastern in the USA) hosted by Shaun Thaxter, CEO. This call will also be webcast live. The details are below and are available on the Indivior website at www.indivior.com.

Webcast link: <https://edge.media-server.com/m6/p/dq3mbvwq>

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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 Group 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 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:

For further product information, see full Prescribing Information including BOXED WARNING and Medication Guide at www.SUBLOCADE.com

Condensed consolidated interim income statement

For the three months ended March 31	Notes	Unaudited 2018 \$m	Unaudited 2017 \$m
Net Revenues	2	255	265
Cost of Sales		(24)	(19)
Gross Profit		231	246
Selling, general and administrative expenses	3	(99)	(93)
Research and development expenses	3	(16)	(25)
Operating Profit		116	128
Operating profit before exceptional items	4	99	128
Exceptional items	3,4	17	-
Finance income		2	1
Finance expense		(7)	(12)
Profit before taxation		111	117
Income tax expense	5	(18)	(37)
Taxation before exceptional items		(16)	(37)
Exceptionals items within taxation	4,5	(2)	-
Net income		93	80
Earnings per ordinary share (cents)			
Basic earnings per share	6	13	11
Diluted earnings per share	6	12	11

Condensed consolidated interim statement of comprehensive income

For the three months ended March 31	Unaudited 2018 \$m	Unaudited 2017 \$m
Net income	93	80
Other comprehensive income		
<i>Items that may be reclassified to profit or loss in subsequent years</i>		
Net exchange adjustments on foreign currency translation	6	2
Other comprehensive income	6	2
Total comprehensive income	99	82

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

Condensed consolidated interim balance sheet

	Notes	Unaudited Mar 31, 2018 \$m	Audited Dec 31, 2017 \$m
ASSETS			
Non-current assets			
Intangible assets		107	92
Property, plant and equipment and other assets		57	54
Deferred tax assets	5	57	58
Other receivables		22	15
		243	219
Current assets			
Inventories		69	52
Trade and other receivables		261	278
Current tax receivable		31	32
Cash and cash equivalents	7	895	863
		1,256	1,225
Total assets		1,499	1,444
LIABILITIES			
Current liabilities			
Borrowings	7	(5)	(5)
Provisions		(138)	(143)
Trade and other payables	9	(620)	(665)
Current tax liabilities	5	(43)	(41)
		(806)	(854)
Non-current liabilities			
Borrowings	7	(478)	(477)
Provisions		(316)	(316)
		(794)	(793)
Total liabilities		(1,600)	(1,647)
Net liabilities		(101)	(203)
EQUITY			
Capital and reserves			
Share capital	10	73	72
Share premium		3	2
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(8)	(14)
Retained Earnings		1,126	1,032
Total equity		(101)	(203)

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

Condensed consolidated interim statement of changes in equity

	Notes	Share capital	Share Premium	Other reserve	Foreign Currency Translation reserve	Retained earnings	Total equity
		\$m	\$m	\$m	\$m	\$m	\$m
Unaudited							
Balance at January 1, 2017		72	-	(1,295)	(22)	950	(295)
Comprehensive income							
Net income		-	-	-	-	80	80
Other comprehensive income		-	-	-	2	-	2
Total comprehensive income		-	-	-	2	80	82
Transactions recognised directly in equity							
Share-based plans		-	-	-	-	3	3
Deferred taxation on share-based plans		-	-	-	-	(1)	(1)
Balance at March 31, 2017		72	-	(1,295)	(20)	1,032	(211)
Balance at January 1, 2018							
		72	2	(1,295)	(14)	1,032	(203)
Comprehensive income							
Net income		-	-	-	-	93	93
Other comprehensive income		-	-	-	6	-	6
Total comprehensive income		-	-	-	6	93	99
Transactions recognised directly in equity							
Share-based plans		1	1	-	-	2	4
Deferred taxation on share-based plans		-	-	-	-	(1)	(1)
Balance at March 31, 2018		73	3	(1,295)	(8)	1,126	(101)

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

Condensed consolidated interim cash flow statement

	Unaudited	Unaudited
	2018	2017
For the three months ended March 31	\$m	\$m
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating Profit	116	128
Depreciation and amortization	3	2
Gain on disposal of intangible asset	(17)	-
Share-based payments	1	2
Impact from foreign exchange movements	1	2
Decrease/(Increase) in trade and other receivables	17	(1)
Increase in inventories	(15)	(5)
Decrease in trade and other payables	(59)	(56)
Decrease in provisions	(6)	(1)
Cash generated from operations	41	71
Interest paid	(7)	(11)
Interest received	2	1
Taxes paid	(11)	(1)
Net cash inflow from operating activities	25	60
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(2)	(8)
Purchase of intangible assets	(5)	-
Proceeds from disposal of intangible assets	13	-
Net cash inflow/(outflow) from investing activities	6	(8)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of borrowings	(1)	(16)
Proceeds from the issuance of ordinary shares	1	-
Net cash (outflow) from financing activities	-	(16)
Net increase in cash and cash equivalents	31	36
Cash and cash equivalents at beginning of the period	863	692
Exchange differences	1	1
Cash and cash equivalents at end of the period	895	729

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

Notes to the condensed consolidated interim financial statements

1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

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

These Interim Financial Statements have been prepared in conformity with IAS 34 *Interim Financial Reporting*. The financial information herein has been prepared in the basis of the accounting policies set out in the annual accounts of the Group for the year ended December 31, 2017 and should be read in conjunction with those annual accounts. The Group prepares its annual accounts in accordance with International Financial Reporting Standards (IFRS) and IFRS Interpretations Committee (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 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, 2017, with the exception of changes in estimates that are required in determining the interim provision for income taxes.

This is the first set of the Group's financial statements where IFRS 15 *Revenue from Contracts with Customers* and IFRS 9 *Financial Instruments* have been applied. There have been no adjustments made in the current period or prior year comparative as a result of the adoption of these new standards.

IFRS 16 "Leases", which is effective 1 January 2019, introduces a single, on-balance sheet accounting model for lessees. We will recognize a right-of-use asset and a lease liability for our obligation to make lease payments. There are recognition exemptions for short-term leases and leases of low-value items. The nature of expenses related to those leases will also change because IFRS 16 replaces the straight-line operating lease expense with a depreciation charge for right-of-use assets and interest expense on lease liabilities.

The Group has completed an initial assessment of the potential impact on its consolidated financial statements but has not yet completed its detailed assessment. The actual impact of applying IFRS 16 on the financial statements in the period of initial application will depend on the composition of the Group's lease portfolio at that date, our assessment of whether lease renewal options will be exercised and our use of practical expedients and recognition exemptions. Thus far, the most significant impact identified is that the Group will recognize new assets and liabilities for its operating leases of office facilities.

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, 2017. These Interim Financial Statements have been reviewed and not audited. These Interim Financial Statements were approved for issue as at May 1, 2018.

As disclosed in Note 8, 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, new product launches fail to meet expectations, and pipeline products fail to obtain regulatory approval, all of which could mean the Group would 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 for the Group to 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 issued (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 8; 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, if the uptake of SUBLOCADE™ is slower than expected, and pipeline products fail to obtain regulatory approval. The Group's statutory financial statements for the year ended December 31, 2017 were approved by the Board of Directors on March 6, 2018 and will be delivered to the Registrar of Companies subject to the approval by shareholders at the Annual General Meeting to be held on May 16, 2018.

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-currents assets for the three months to March 31, 2018 and 2017 were as follows:

Revenues from sale of goods:

For the three months ended March 31	2018	2017
	\$m	\$m
United States	197	215
ROW	58	50
Total	255	265

Non-current assets:

	Mar 31, 2018	Dec 31, 2017
	\$m	\$m
United States	66	68
ROW	120	93
Total	186	161

3. OPERATING COSTS AND EXPENSES

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

For the three months ended March 31	2018	2017
	\$m	\$m
Research and development expenses	(16)	(25)
Marketing and selling expenses*	(45)	(33)
Administrative expenses	(50)	(56)
Depreciation and amortization	(3)	(2)
Operating lease rentals	(1)	(2)
Total	(99)	(93)

* In 2018, distribution costs, which were less than \$1m have been reclassified from Operating expenses to Cost of Sales to better reflect the nature of the costs with Sublocade launch. The prior year has not been adjusted as the total amount, which was also less than \$1m, is not material.

Exceptional Items

For the three months ended March 31	2018	2017
	\$m	\$m
Other operating income	17	-
Total exceptional items before taxes	17	-
Tax on exceptional items	(2)	-
Total exceptional items	15	-

\$17m of exceptional items in the year relates to the proceeds received from the out-licensing of nasal naloxone opioid overdose patents to Adapt Pharma Inc which are included within SG&A.

4. ADJUSTED RESULTS

The board and management team use adjusted results and measures to give greater insight to the financial results of the Group and the way it is managed. The tables below show the list of adjustments between the reported and adjusted operating profit and net income for both Q1 2018 and Q1 2017.

Reconciliation of operating profit to adjusted operating profit

For the three months ended March 31	2018	2017
	\$m	\$m
Operating profit	116	128
Exceptional operating Income	(17)	-
Adjusted operating profit	99	128

Reconciliation of net income to adjusted net income

For the three months ended March 31	2018	2017
	\$m	\$m
Net income	93	80
Exceptional operating income	(17)	-
Tax on exceptional items	2	-
Adjusted net income	78	80

5. TAXATION

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

In the three months ended March 31, 2018, tax on total profits amounted to \$16m excluding the tax effect on exceptionals and represented a quarterly effective tax rate of 17% (Q1 2017: 32% excluding exceptionals). The Group's balance sheet at March 31, 2018 included a current tax payable of \$43m (FY 2017: \$41m), current tax receivable of \$31m (FY 2017: \$32m), and deferred tax asset of \$57m (FY 2017: \$58m).

The decrease in the effective tax rate to 16% was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the quarter, along with the impacts of US Tax Reform rate reduction, and UK reduced rate due to patent box benefit. While there may be fluctuations in the rate from quarter to quarter, this rate reduction is expected to be materially sustained for the full 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.

6. EARNINGS PER SHARE

For the three months ended March 31	2018	2017
	cents	cents
Basic earnings per share	13	11
Diluted earnings per share	12	11
Adjusted basic earnings per share	11	11
Adjusted diluted earnings per share	10	11

Basic

Basic earnings per share ("EPS") is calculated by dividing profit for the period attributable to owners of the Company by the weighted average number of ordinary shares in issue during the period.

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.

	2018	2017
	thousands	thousands
Weighted average number of shares		
On a basic basis	723,933	720,065
Dilution share awards and options	24,779	28,314
On a diluted basis	748,712	748,379

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 included in Note 4.

7. FINANCIAL LIABILITIES – BORROWINGS

	Mar 31 2018 \$m	Dec 31 2017 \$m
Current		
Bank loans	(5)	(5)
	(5)	(5)
Non-current		
Bank loans	(478)	(477)
	(478)	(477)
Analysis of net debt		
Cash and cash equivalents	895	863
Borrowings*	(488)	(487)
	407	376

*Borrowings reflects the principal amount drawn, before debt issuance costs of \$5m (FY 2017: \$5m).

	Mar 31 2018 \$m	Dec 31 2017 \$m
Reconciliation of net debt		
The movements in the period were as follows:		
Net cash at beginning of period	376	131
Increase in cash and cash equivalents	32	171
Net repayment of borrowings	1	86
Exchange adjustments	(2)	(12)
Net cash at end of period	407	376

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 March 31, 2018 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 aggregated net debt to Adjusted EBITDA ratio) which stands at 3.0x, following the debt restructuring.

8. CONTINGENT LIABILITIES

The Group maintained its provision for investigative and antitrust litigation matters of \$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 US Patent No. 8,603,514 (the '514 patent) valid and infringed; the asserted claims of US Patent No. 8,017,150 (the '150 patent) valid but not infringed; and the asserted claims of US Patent No. 8,475,832 (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. Actavis and Par 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 its Abbreviated New Drug Application (ANDA) No. 204383 and on November 15th, 2017 it received tentative approval for its 12 mg/3 mg generic product under ANDA No. 207087. A "tentative" approval does not allow the applicant to market the generic drug product; in order to launch and market the product, the applicant must receive "final" approval. Actavis therefore remains enjoined from launching a generic product by the Delaware court ruling, until and unless such time as the ruling is overturned on appeal.
- Trial against Dr. Reddy's, Actavis and Par in the lawsuits involving the process patent, US Patent No. 8,900,497 (the '497 patent), 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 (the '150 patent and the '514 patent) 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. On March 22, 2018, the District Court issued its ruling finding both patents valid but not infringed by Alvogen. Indivior intends to appeal the judgment.

- Alvogen’s 30-month stay of FDA approval expired on October 29th, 2017. So far as Indivior is aware, FDA to date has not granted tentative or final marketing authorization to Alvogen’s generic SUBOXONE® Film alternative.
- If FDA were to grant final approval to Alvogen, this would enable them to market a generic film alternative to SUBOXONE® Film in the U.S. However, any market launch by Alvogen before the court of appeals renders its decision would be on an “at risk” basis because Indivior would have a claim for damages against Alvogen if Indivior ultimately prevails after any appeal.
- 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 patent IPR proceedings. On September 29th, 2017, Mylan and MonoSol submitted joint motions to terminate the ’514 patent and ’497 patent 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 patent and ’497 patent 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 patent IPR proceeding. On October 20th, 2017 the Patent Board refused to institute IPR proceedings and dismissed the Dr. Reddy’s and Par’s petitions.
- 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 for infringement of US Patent No. 9,687,454 (the ’454 patent). The Actavis suit has been transferred to the District of Delaware. Par has filed a corresponding declaratory judgment action in the Eastern District of Virginia, which is stayed pending the outcome of Par’s motion to transfer the New Jersey case. 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 also filed suit in February 2018 against Dr. Reddy’s, Actavis, Par, Alvogen and Teva for infringement of US Patent No. 9,855,221 (the ’221 patent) and in April 2018 against the same defendants for infringement of US Patent No. 9,931,305 (the ’305 patent). The patents are listed in the FDA’s Orange Book and relate 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 of 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 US Patent No. 9,370,512 (the ’512 patent). The asserted patent, which was issued in June 2016, claims priority to an application filed in August 2007. Indivior believes this claim is without merit and will continue to vigorously defend this action. On March 16, 2018, Indivior filed a petition for inter partes review with the United States Patent and Trademark Office (USPTO) asserting that all claims of the ’512 patent are invalid. The USPTO will decide whether to institute Indivior’s petition on or about October 6th, 2018.

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.

EU State Aid

- The European Commission has announced their intention to open a State Aid investigation into the UK’s controlled foreign company (“CFC”) financing exemption. Management does not believe that there is sufficient certainty at this stage to quantify any potential future liability that may arise following the conclusion of this investigation and so no provision has been made at this time. We will continue to monitor developments in this area.

9. TRADE AND OTHER PAYABLES

	Mar 31 2018 \$m	Dec 31 2017 \$m
Sales returns and rebates	(404)	(433)
Trade payables	(40)	(40)
Accruals	(161)	(179)
Other tax and social security payables	(15)	(13)
Total	(620)	(665)

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 while 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 actual experience of 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.

10. SHARE CAPITAL

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2018	721,462,733	\$0.10	72
Allotments	5,999,688	\$0.10	1
At March 31, 2018	727,462,421	\$0.10	73

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2017	720,597,566	\$0.10	72
Allotments	180,198	\$0.10	-
At March 31, 2017	720,777,764	\$0.10	72

Allotment of ordinary shares

During the period, 5,999,688 ordinary shares (2017: 180,198) were allotted to satisfy vestings/exercises under the Group's Long Term Incentive Plan and US Employee Stock Purchase Plan.

11. POST BALANCE SHEET EVENTS

There have been no material post balance sheet events.

DIRECTORS' RESPONSIBILITY STATEMENT

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

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

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

Indivior's PLC's Directors are listed in the Annual Report and Accounts for 2017.

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

By order of the Board

Shaun Thaxter
Chief Executive Officer

Mark Crossley
Chief Financial Officer

May 1, 2018

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 Q1 Financial Results Release of Indivior PLC for the 3-month period ended 31 March 2018. 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 – Outcome of litigation

Without modifying our conclusion on the interim financial statements, we draw your attention to Note 8 that describes the uncertain outcome of the ongoing investigations by the Department of Justice and the Federal Trade Commission as well as antitrust litigation. An amount of \$438 million has been established as a provision for potential settlement for all of these matters. The final aggregate settlement amount may be materially different to this provision.

Material uncertainty relating to Going Concern

Without modifying our conclusion on the interim financial statements, we have considered the adequacy of the disclosure made in Note 8 that describes the uncertain outcome of the ongoing investigations by the Department of Justice and Federal Trade Commission and antitrust litigation. This could impact the Group's ability to operate, which would be further adversely impacted in the event that one or more of the generic companies are successful in their patent challenges on a final non-appealable basis, should there be FDA approval of one or more of the ANDAs and subsequent commercial launch of generic Suboxone® Film, if the Group's pipeline products fail to obtain regulatory approval, together with the market acceptance of SUBLOCADE™ being slower than expected. As explained in Note 1 to the interim financial statements, the above factors indicate the existence of a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern. In these circumstances, the Directors believe they would be able to take the required steps to reduce the cost base. However, this would result in a significant change to the structure of the business. As a result of this potential decline and the extent of its potential impact, the Directors are prepared to change the structure of the business and to reduce its cost base, as also described in Note 1 to the interim financial statements. The interim financial statements do not include the adjustments that would result if the Group were unable to continue as a going concern.

What we have reviewed

The interim financial statements comprise:

- the Condensed consolidated interim balance sheet as at 31 March 2018;
- the Condensed consolidated interim income statement and Condensed consolidated statement of comprehensive income for the period then ended;
- the Condensed consolidated interim cash flow statement for the period then ended;
- the Condensed consolidated interim statement of changes in equity for the period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the Q1 Financial Results Release have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

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

Responsibilities for the Interim Financial Statements and the review

Our responsibilities and those of the directors

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

Our responsibility is to express a conclusion on the interim financial statements in the Q1 Financial Results Release based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

What a review of interim financial statements involves

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

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

We have read the other information contained in the Q1 Financial Results Release and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP
Chartered Accountants
London
1 May 2018