

July 25, 2018

Indivior Announces H1 2018 Results

Period to June 30th	Q2 2018 \$m	Q2 2017 \$m	% Δ Actual FX	% Δ Constant FX	H1 2018 \$m	H1 2017 \$m	% Δ Actual FX	% Δ Constant FX
Net Revenue	268	288	-7	-8	524	553	-5	-7
Operating Profit	84	117	-28	-29	200	244	-18	-20
Net Income	70	73	-4	-10	162	153	6	3
EPS (cents/share)	10	10	-	-8	22	21	5	3
Adj. Operating Profit	84	142	-41	-42	183	269	-32	-34
Adj. Net Income	70	89	-21	-25	147	169	-13	-16
Adj. EPS	10	12	-17	-25	20	23	-13	-16

**Adjusted basis excludes the impact of exceptional items as referenced in Notes 3 and 4*

This announcement contains inside information
H1 2018 Financial Results

- H1 2018 net revenue of \$524m (H1 2017: \$553m) decreased 5% on a reported basis and by 7% at constant FX; strong U.S. market growth (largely driven by the Medicaid channel) and Rest of World growth was more than offset by tactical rebating and unfavourable mix due to increased growth in the most price sensitive channel (Medicaid).
- H1 2018 adjusted operating profit decreased by 32% to \$183m (H1 2017: \$269m); lower net revenue, the expected annualization of SUBLOCADE™ investments and the on-going setup of the Behavioural Health unit to launch RBP-7000 (if approved) were partially offset by lower R&D expenses.
- H1 2018 adjusted net income declined 13% to \$147m (H1 2017: \$169m), helped by a lower net interest expense and a lower effective tax rate.
- H1 2018 cash balance of \$951m (FY 2017: \$863m); net cash of \$469m (FY 2017: \$376m).

H1 2018 Operating Highlights

- U.S. market growth in H1 2018 continued at low double-digit percentage levels primarily driven by the Medicaid channel.
- SUBOXONE® Film market share averaged 54% in H1 2018 (H1 2017: 59%), exiting Q2 2018 at 52%. Current SUBOXONE® Film share as of July 13th, 2018, stands at 49%, reflecting the market impact of Dr. Reddy's Laboratories' (DRL) generic buprenorphine/naloxone sublingual film sold into the U.S. market prior to the U.S. District Court of New Jersey (the District Court) granting Indivior's request for a temporary restraining order (TRO) on June 15th. A preliminary injunction (PI) was subsequently granted by the District Court on July 13th. The adverse impact on Indivior's FY 2018 net revenue is anticipated to be at least \$25m and could be materially higher. Under the PI granted by the District Court, DRL is unable to use, import, sell or offer to sell its generic buprenorphine/naloxone sublingual film product, pending the outcome of recently-filed litigation against DRL related to U.S. Patent No. 9,931,305 (the '305 Patent), or a decision of the U.S. Court of Appeals for the Federal Circuit (CAFC) dissolving the injunction. DRL has appealed the grant of the PI and the bond amount to the CAFC, and has asked for an expedited briefing. DRL has also asked the CAFC to stay the PI pending the appeal. On July 24th, Indivior filed its opposition to the motions to expedite the PI and stay the PI pending appeal.

- H1 2018 SUBLOCADE™ net revenues were \$2m. Initial net revenue levels reflect challenges with the duration and success rate of the prescription journey as well as the rate of HCP trial. FY 2018 SUBLOCADE™ net revenues are forecasted to be in the range of \$25m to \$50m. Strengths of the launch performance to date include: anecdotal reports of patient experience and satisfaction, payor coverage (67% lives covered as of July 14th) and ease and efficiency of the refill process for 2nd and 3rd prescriptions. The Company remains confident of peak SUBLOCADE™ annual net revenue of \$1 billion-plus.
- Indivior has launched a cost saving initiative, initially targeting at least \$25m in savings in 2018, to partially offset the financial impact of recent adverse U.S. market developments. The savings will be captured primarily through reductions in non-critical SG&A, including global support functions and external services.
- Launch preparations for RBP-7000 continue, contingent upon FDA approval (PDUFA date 28th July). While the launch is currently targeted for Q4 2018, the launch date will be reviewed if DRL is successful in gaining an expedited appeal on the PI ruling.
- The Group is in advanced discussions with the U.S. Department of Justice (DOJ) about a possible resolution to its investigations. Please see pages 6 to 9 for a complete Litigation Update.

FY 2018 Financial Guidance withdrawn July 11th

- Indivior withdrew its FY 2018 guidance on July 11th.
- In light of the current uncertainties over the depth of DRL's market entry prior to the District Court's granting of Indivior's request for a TRO, Indivior is unable to issue new guidance.
- The Company commits to providing updated guidance as soon as reasonably practicable, but no later than its Q3 2018 results currently scheduled for November 1st.

Shaun Thaxter, CEO of Indivior, Comment

"While our base U.S. business has recently been impacted by known risks that have materialized, we remain committed to our vision to ensure that patients around the world have access to evidence-based treatment for their addiction and its co-occurring disorders. Our primary focus is to ensure the successful progression of SUBLOCADE™ as it begins its transformation of the treatment of opioid use disorder. Despite the reality that initial revenues were below our financial plan as patients and healthcare providers (HCPs) continue to adjust to a new and unfamiliar specialty distribution and reimbursement model, we are encouraged by the early success of the fundamental drivers of long term product success: anecdotal reports of patient experience and satisfaction, quantity and quality of payor coverage, number of prescription journeys initiated per physician, patient adherence to treatment, ease and efficiency of refill process, and safety profile of reported events being consistent with transmucosal buprenorphine and Phase 3 study outcomes. We remain confident in our SUBLOCADE™ \$1 billion+ annual net revenue goal."

Half Year Operating Review

U.S. Market Update

The market for buprenorphine products continued to grow strongly in Q2 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 legislation that has expanded federal funding and increased OUD treatment capacity. Additionally, overall public awareness of the opioid epidemic continues to grow. As a result, growth in both the number of healthcare providers waived to administer medication-assisted treatment and those able to treat to the new permitted level of 275 patients (from 100 patients) continued in Q2 2018. The number of waived nurse practitioners and physician assistants also continued to grow in Q2 2018.

Overall commercial formulary access remains solid for SUBOXONE® Film. The list price of SUBOXONE® Film in the U.S. increased modestly in January 2018, but this continues to be more than offset by tactical rebating in connection with maintaining formulary access and by the adverse channel mix impact arising from the accelerating number of U.S. Medicaid patients seeking treatment.

The Company has focused on the following areas as key for improving the rate of net revenue growth for SUBLOCADE™:

- Increasing formulary access - 56% (67% as of July 14th) of lives covered, of these fewer than 8% have prior authorization restrictions that go beyond the need for the diagnosis and patient to comply with the product labeling.
- Reducing the time taken from prescription initiation to injection (Prescription Journey) from a range of 43 to 62 days at launch down to 27 to 36 days, currently.
- Increasing the success rate of the prescription journey from 12% at launch to 36% at the end of Q2.

Key performance indicators (KPIs) show a foundation for future growth with: 79% prompted awareness among 'DATA 2000 waived' healthcare practitioners, over 1,300 HCPs initiated prescription journeys, 384 HCPs administered SUBLOCADE™ and 30 HCPs administered SUBLOCADE™ to more than 5 patients. The Company forecasts an acceleration of net revenues in the second half, resulting in FY 2018 net revenues in the range of \$25m to \$50m weighted towards the fourth quarter.

Financial Performance in Half Year 2018

Total net revenue in H1 2018 decreased by 5% to \$524m (H1 2017: \$553m) at actual exchange rates and by 7% at constant exchange rates. Volume gains from continued strong market conditions in the U.S., initial sales of SUBLOCADE™ and growth in Rest of World markets was more than offset by a decline in SUBOXONE® Film market share and unfavorable mix from the increase in Medicaid business. Price improvement was more than offset by tactical rebating activity in the U.S. in connection with formulary access. In Q2 2018, total net revenue decreased 7% at actual exchange rates (8% at constant exchange rates) to \$268m (Q2 2017: \$288m). Total net revenue drivers in the quarter were substantially the same as those for H1 2018.

U.S. net revenue decreased by 9% in H1 2018 to \$411m (H1 2017: \$452m) and by 10% in Q2 2018 to \$214m (Q2 2017: \$237m). During the H1 2018 period, market growth was ahead of last year reflecting benefits from legislation that has increased government funding and treatment capacity. In addition, overall awareness of the opioid epidemic continued to grow. As a result, the number of HCPs qualified to prescribe buprenorphine-based treatments continued to increase. Volume benefits from strong underlying market growth was more than offset by a decline in SUBOXONE® Film market share in price sensitive payors and unfavorable mix from increased Medicaid business. Improved pricing was more than offset by tactical rebating activity in connection with formulary access. Total net revenue drivers in the quarter were substantially the same as those for H1 2018.

In H1 2018, Rest of World net revenue increased by 12% at actual exchange rates (2% at constant exchange rates) to \$113m (H1 2017: \$101m). In Q2 2018, Rest of World net revenue increased 7% at actual exchange rates (1% at constant exchange rates) to \$54m (Q2 2017: \$51m). Volume growth in Australasia and Canada from market share gains drove the overall net revenue improvement.

Gross margin in H1 2018 was 89% (H1 2017: 92%) and 87% in Q2 2018 (Q2 2017: 91%) respectively. The decrease in both periods versus the prior year primarily reflected lower net revenue and the impact of contingency planning for an "at-risk" launch by DRL.

SG&A expenses as reported were \$231m in H1 2018 (H1 2017: \$220m) and \$131m in Q2 2018 (Q2 2017: \$127m). H1 2018 SG&A included a \$17m gain from the out-licensing of the intranasal naloxone opioid overdose patents (recorded in Q1 2018). In the year-ago period, H1 2017 results included exceptional items of \$25m (recorded in Q2 2017) reflecting settlement of the Amneal antitrust matter.

On an adjusted basis (ex.-exceptionals), H1 2018 SG&A expenses increased 27% to \$248m (Adj. H1 2017: \$195m) and in Q2 2018 SG&A expenses increased by 28% to \$131m (Adj. Q2 2017: \$102m). The underlying increase in both recent periods mainly reflects planned investments for launching and supporting the growth of

SUBLOCADE™ and the ongoing development of the new Behavioral Health unit to launch RBP-7000 (if approved).

H1 2018 and Q2 2018 R&D expenses decreased by 23% to \$34m and by 5% to \$18m, respectively (H1 2017: \$44m; Q2 2017: \$19m). The decreases in both periods reflect lower clinical activity as key late-stage pipeline assets, SUBLOCADE™ and RBP-7000, completed Phase 3 registrational studies and capitalization of RBP-7000 development costs began in Q2 2018.

H1 2018 operating profit was \$200m (H1 2017: \$244m) and Q2 2018 operating profit was \$84m (Q2 2017: \$117m). An exceptional gain of \$17m and exceptional costs of \$25m are included in the current and year-ago period results, respectively. On an adjusted basis (excluding exceptionals), H1 2018 operating profit was \$183m (35% margin), a 32% decrease versus \$269m (49% margin) in the year-ago period on the same basis. On an adjusted basis, Q2 2018 operating profit was \$84m (31% margin), a 41% decrease versus \$142m (49% margin) in the year-ago quarter on the same basis. The decrease in both periods on an adjusted basis primarily reflects lower net revenue, costs for launching SUBLOCADE™ and RBP-7000 (if approved). These factors were partially offset by lower R&D expenses.

H1 2018 EBITDA (operating profit plus depreciation and amortization) as reported decreased 17% to \$207m (H1 2017: \$248m). Excluding (\$17m) and \$25m of exceptional items in the current and year-ago period results, respectively, H1 2018 EBITDA decreased 31% to \$189m (H1 2017: \$273m).

H1 2018 net finance expense was \$11m (H1 2017: \$25m), representing the interest and amortization of financing costs on the Group's term loan borrowing facility, which was partially offset by interest income. Q2 2018 finance expense was \$6m (Q2 2017: \$14m). The decreased finance expense in both periods reflected the lower interest coupon and amortization of financing costs associated with the replacement of the term loan facilities in December 2017.

H1 2018 tax charge was \$27m, or a rate of 14% (H1 2017 tax charge: \$66m; 30% rate). Excluding the \$2m tax charge on exceptional items in H1 2018, the effective tax rate was 15% (H1 2017 adj. tax charge: \$75m; 31% rate). Q2 2018 tax charge was \$8m, or a rate of 10% (Q2 2017 tax charge: \$30m; 29% rate; Q2 2017 adj. tax charge: \$39m; 30% rate). The decrease in the effective tax rate was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the quarter, along with the impacts of U.S. Tax Reform rate reduction and UK reduced rate due to patent box benefit.

H1 2018 net income was \$162m (H1 2017: \$153m) as reported. The current and year-ago periods include \$15m gain and \$16m costs of exceptionals, respectively, net of tax. Excluding exceptional items, H1 2018 net income decreased 13% to \$147m (H1 2017 adj.: \$169m). In Q2 2018, net income was \$70m (Q2 2017 net income: \$73m; or \$89m excluding exceptional items).

H1 2018 basic EPS were 22 cents (H1 2017: 21 cents) and 22 cents on a diluted basis (H1 2017: 20 cents). Q2 2018 basic EPS were 10 cents (Q2 2017: 10 cents) and 9 cents on a diluted basis (Q2 2017: 10 cents). On an adjusted basis, excluding the effect of exceptional items, H1 2018 basic EPS were 20 cents (H1 2017: 23 cents) and diluted EPS were 20 cents (H1 2017: 23 cents). On an adjusted basis, Q2 2018 basic EPS were 10 cents (Q2 2017: 12 cents) and diluted EPS were 9 cents (Q2 2017: 12 cents).

Balance Sheet & Cash Flow

Cash and cash equivalents at the end of H1 2018 were \$951m, reflecting an increase of \$88m in 2018 year to date (FY 2017: \$863m). Borrowings, net of issuance costs, were \$477m at the end of H1 2018 (FY 2017: \$482m). Consequently, net cash stood at \$469m at the end of H1 2018 (FY 2017: \$376).

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative \$287m at the end of H1 2018, an increase of \$48m from negative \$335m since the end of FY 2017 primarily

driven by a gain on the disposal of the nasal naloxone intangible asset, an increase in inventory due in part to the launch of SUBLOCADE™ and lower accruals due to wholesaler destocking earlier in the half year offset by higher Medicaid payments.

Cash generated from operations in H1 2018 was \$119m (H1 2017: \$205m), a decrease of \$86m. The reduction in cash generated versus the year-ago period was primarily due to lower operating profits in the period, increased inventory and a reduction in payables compared to FY 2017.

H1 2018 net cash inflow from operating activities was \$100m (H1 2017: \$185m), reflecting the lower cash from operations and higher net tax payments of \$15m compared to \$4m in the prior period.

H1 2018 cash outflow from investing activities was \$12m (H1 2017: \$16m), reflecting the proceeds received from the disposal of the nasal naloxone intangible asset offset by upfront payments for the licensing arrangements with Addex and C4X, capitalized development costs, and ongoing investments in facilities.

H1 2018 cash outflow from financing activities reduced to \$1m, vs. \$71m in H1 2017, primarily reflecting the terms of the replacement of the term loan facilities in December 2017.

R&D / Pipeline Update

Treatment of Opioid Use Disorder (OUD)

- **SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE INJECTION) FOR SUBCUTANEOUS USE CIII:**
 - FDA approval November 30th, 2017; Commercial launch initiated week of February 26th, 2018.
 - RECOVER Study (REmission from Chronic Opioid use: studying enVironmental and socioEconomic factors on Recovery): top-line 12-month longitudinal analysis findings will be available by December 31, 2018; 24-month last patient out scheduled for March 5th, 2019.
 - All Post Marketing Requirement (PMR) and Commitment (PMC) studies are on track.
 - SUBLOCADE™ addition to the List of Drugs for an Urgent Public Need for the Canadian correctional service facilities on December 28th, 2017.
 - SUBLOCADE™ New Drug Submission (NDS) made to Health Canada April 19th, 2018; Priority Review status granted by Health Canada. NDS accepted for review May 25th, 2018.
 - SUBLOCADE™ submitted to Australia's Therapeutic Goods Administration (TGA) on May 25th, 2018.
 - SUBLOCADE™ submitted to Israel's Ministry of Health for marketing approval July 2nd, 2018.
 - Regulatory submissions for Europe currently being prepared.
 - FDA Office of Prescription Drug Promotion (OPDP) review of SUBLOCADE™ materials completed; launched patient core visual aid (CVA); Website launch expected in August 2018.
 - Key Lifecycle Evidence Generation & Optimization (LEGO) Studies – VAS Craving Study, Emergency Room Study, Fentanyl Study and Real World HEOR Study – initiated and on track.
- SUBOXONE® Tablet China: Submission of NDA to Chinese FDA (CFDA) on December 27th, 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 12th, 2017. PDUFA date of July 28, 2018.
- LEGO studies under development.

Treatment of Alcohol Use Disorder (AUD)

- Arbaclofen Placarbil: Moving forward with the manufacture of Clinical Trial Supplies to support, in parallel, an alcohol interaction study in AUD and an absorption study in Alcohol Liver Disease with Cirrhosis (ALD+C).

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 GABAB receptor.
- Indivior/ADDEX Joint Research Committee (JRC) established and met Q1 2018.

- 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 in Q1 2018.
- Indivior/C4X Strategic alliance launch took place Q2 2018.
- C4X's oral orexin-1 program was awarded a grant by the National Institute on Drug Abuse (NIDA) in the amount of \$500,000 for cocaine addiction.

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.

Key Scientific Congresses

- Fifth Annual Western Canada Addiction Forum (WCAF): May 4-5, Kelowna, British Columbia, Canada.
- American Psychiatry Association (APA): May 5-9, New York, NY.
- American College of Preventive Medicine (ACPM): May 23-26, Chicago, IL.
- Thirteenth European Opiate Addiction Treatment Association (EUROPAD) Conference: May 25-27, Krakow, Poland.
- Douzième 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, CN.
- Australasian Professional Society on Alcohol & other Drugs (APSAD): November 4-7, Auckland, Australia.
- American College of Neuropsychopharmacology (ACNP): December 3-7, Hollywood, FL.
- American Academy of Addiction Psychiatry (AAAP): December 6-9, Bonita Springs, FL.

Litigation Update

The Group carries a provision for investigative and antitrust litigation matters of \$438m. Substantially all of the provision relates to the U.S. Department of Justice investigation. The Group is in advanced discussions with the Department of Justice about a possible resolution to its investigations, although it cannot predict with any certainty whether, when, or at what cost it will reach an ultimate resolution.

The Group reduced other elements of the provision that relate to other litigation matters reflecting the Group's belief that it has strong defences in the antitrust and other litigations and is now actively litigating these matters. Indivior cannot predict with any certainty whether, when, or at what cost it will reach ultimate resolution of the antitrust and other litigation matters.

The final aggregate cost of these matters may be materially higher than the amount provided.

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 has responded to the subpoenas and has otherwise cooperated fully with the Department and prosecutors and will continue to do so. The Group is in advanced discussions with the Department of Justice about a possible resolution to its investigation. However, it is not possible to predict with any certainty the potential impact of this investigation on the Group or to quantify the ultimate cost of a resolution.

State Subpoenas

- On October 12, 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 16, 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 and served a subpoena in 2018 requesting documents relating to the bioavailability / bioequivalency of SUBOXONE® Film, manufacturing records for the product and its components, and the potential to develop dependency on SUBOXONE Film. 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.
- A group of 41 states, 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.
- The Group believes it has strong defences and is vigorously litigating these matters.

ANDA Litigation

- Actavis is currently enjoined from launching a generic buprenorphine/naloxone film product until April 2024 based on a June 3, 2016 District Court ruling finding U.S. Patent No. 8,603,514 (the '514 Patent) valid and infringed. Actavis has appealed this ruling. On October 24, 2017, Actavis received tentative approval from FDA for at least its 8mg/2mg generic product under its Abbreviated New Drug Application (ANDA) No. 204383 and on November 15, 2017, it received tentative approval for its 12mg/3mg generic product under ANDA No. 207087.

- On August 31, 2017 a District Court ruling in a lawsuit that asserted claims of U.S. Patent No. 8,017,150 (the '150 Patent), U.S. Patent No. 8,900,497 (the '497 Patent), and the '514 Patent found that these patents are valid but not infringed by Dr. Reddy's. Indivior has appealed this ruling. Dr. Reddy's received final FDA approval for all four strengths of its generic buprenorphine/naloxone film product on June 14, 2018, and immediately launched its generic buprenorphine/naloxone film product "at-risk." On June 15, 2018, Indivior filed a motion with the District Court of New Jersey seeking a Temporary Restraining Order (TRO) and Preliminary Injunction (PI) pending the outcome of a trial on the merits of U.S. Patent No. 9,931,305 (the '305 Patent). The District Court of New Jersey granted Indivior a two-week TRO, preventing Dr. Reddy's from continuing to sell or offer to sell its generic product. Indivior was required to post an \$18 million surety bond to cover Dr. Reddy's damages in the event of an Indivior loss of its patent case against Dr. Reddy's. On June 28, 2018, the District Court of New Jersey heard oral argument in support of Indivior's motion for a PI against Dr. Reddy's and, at the conclusion of this hearing, the District Court extended the TRO for an additional 14 days in order to rule on the PI motion and required Indivior to post another \$18 million surety bond. On July 13, 2018, the District Court issued its ruling granting Indivior a PI against Dr. Reddy's. On the same day, Dr. Reddy's filed a motion to stay the PI pending appeal with the District Court and a Notice of Appeal with the Federal Circuit. On July 18, 2018, the District Court ordered Indivior to post a surety bond for \$72 million (that total figure being inclusive of the \$36 million surety bond already posted) in connection with the PI. That same day, the District Court also denied Dr. Reddy's motion to stay the PI pending appeal. On July 19, 2018, Dr. Reddy's filed with the CAFC its opening brief for the appeal of the PI, along with emergency motions seeking to expedite the appeal of the PI and stay the PI pending the outcome of the appeal. On July 24th, Indivior filed its opposition to the motions to expedite the PI and stay the PI pending appeal.
- Teva filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of buprenorphine/naloxone film. Indivior, Aquestive Pharmaceuticals (formerly known as MonoSol Rx) and Teva agreed that infringement by Teva's 16mg/4mg dosage strength would be governed by the infringement ruling as to Dr. Reddy's 8mg/2mg dosage strength that was the subject of the trial in November 2016. Accordingly, the non-infringement ruling in the Dr. Reddy's case means that the Teva 16mg/4mg dosage strength has been found not to infringe. Indivior has appealed this November 2016 ruling.
- Trial against Alvogen in the lawsuit involving the '514 and '497 Patents for SUBOXONE® Film took place in September 2017. The 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 has appealed this ruling. Alvogen's 30-month stay of FDA approval expired on October 29, 2017. So far as Indivior is aware, FDA to date has not granted tentative or final marketing authorization to Alvogen's generic buprenorphine/naloxone film product. If FDA were to grant final approval to Alvogen, this would enable Alvogen to market its generic buprenorphine/naloxone film product in the U.S.. However, any market launch by Alvogen before a ruling on appeal would be on an "at risk" basis because Indivior would have a claim for damages against Alvogen if Indivior ultimately prevails on appeal. Moreover, if Alvogen does launch "at risk", Indivior would seek a PI with the District Court to enjoin the launch of Alvogen's generic buprenorphine/naloxone film product pending the outcome of the lawsuit against Alvogen for infringement of the '305 Patent.
- By a Court order dated August 22, 2016, Indivior's SUBOXONE® Film patent litigation against Sandoz was dismissed without prejudice because Sandoz is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE® Film.
- On September 25, 2017, Indivior settled its SUBOXONE® Film patent litigation in District Court against Mylan, the terms of which are confidential. Mylan received final FDA approval for its generic version of the 8mg buprenorphine/naloxone film product on June 14, 2018.

- On May 11, 2018, Indivior settled its SUBOXONE® Film patent litigation in the District Court against Par. Under the terms of the settlement agreement, Par can launch its generic buprenorphine/naloxone film product on January 1, 2023, or earlier under certain circumstances. Other terms of the settlement agreement are confidential. So far as Indivior is aware, FDA to date has not granted tentative or final approval for Par's generic buprenorphine/naloxone film product.
- Indivior has filed lawsuits against Alvogen, Dr. Reddy's, and Teva in the District Court of New Jersey, and against Actavis in the District Court of Utah, for infringement of U.S. Patent No. 9,687,454 (the '454 Patent), U.S. Patent No. 9,855,221 (the '221 Patent), and the '305 Patent. The Actavis suit has been transferred to the District Court of Delaware. Motions filed by Alvogen, Dr. Reddy's, and Teva to transfer the lawsuits against them from the District Court of New Jersey to the District Court of Delaware have been denied.

Rhodes Pharmaceuticals

- On December 23, 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 U.S. 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 (IPR) 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 IPR on or about October 6, 2018.
- The District Court case against Indivior has been stayed pending the USPTO's decision whether to institute the IPR.

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. A hearing on Indivior's pending motions to dismiss is scheduled for August 8, 2018.

In the event the final settlement amount of the DOJ matter is materially higher than the provision, and the Group is further adversely impacted should revenues decline (including possible declines from one or more of the generic companies successfully launching generic buprenorphine/naloxone sublingual film product or from further uncertainty in the U.S. buprenorphine/naloxone sublingual film market), or new products fail to meet expectations, the Group would not continue in business without taking necessary measures to reduce its cost base and improve its cash flow. 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.

Risk Factors

The Directors have reviewed the principal risks and uncertainties for the remainder of the 2018 financial year. The principal risks and uncertainties affecting the business activities of the Group are much in line with those detailed on pages 48 to 56 of the Indivior plc Annual Report 2017. The Group utilizes a formal process to identify, evaluate and manage significant risks. During the period, changes to the market environment have occurred, specifically impacting the Principal Risks of *Business Operations and Business Continuity* as well as *Product Liability, Regulation and Litigation*.

Due to the changes in market environment, the Group cannot reliably provide updated FY 2018 net revenue and adjusted net income guidance until the impact of DRL's "at risk" launch of its FDA-approved generic

buprenorphine/naloxone sublingual film product in the United States prior to the granting of the temporary restraining order and subsequent preliminary injunction is better understood. As of July 13, 2018, DRL has been enjoined by the U.S. District Court for the District of New Jersey from using, importing, selling, or offering to sell its FDA-approved generic buprenorphine/naloxone sublingual film product in the United States, pending the outcome of patent infringement litigation brought by Indivior against DRL related to U.S. Patent No. 9,931,305 (the “’305 Patent”). A trial date for this litigation has not yet been set, but analogs indicate a ruling could be expected sometime between H2 2019 and H2 2020. DRL has appealed the grant of the preliminary injunction and the bond amount to the CAFC and asked for expedited briefing. DRL has also asked the CAFC to stay the preliminary injunction pending the appeal. On July 24th, Indivior filed its opposition to the motions to expedite the PI and stay the PI pending appeal. If the Group is unsuccessful in enforcing the validity and establishing infringement of the ‘305 Patent, the Group would be liable for damages for DRL’s lost profits during the period of the injunction, which in the worst-case scenarios could adversely impact the Group’s ability to operate, require significant change to the structure of the business, and recapitalization.

Therefore, other than in respect to the guidance for the full year 2018 and the updates listed below, the Directors consider the principal risks and uncertainties which could have a material impact on the Group’s performance for the rest of the year remain the same as described on pages 48 to 56 of the 2017 Annual Report. These include:

Business operations and business continuity

- The Group’s future revenues are expected to be primarily derived from sales of SUBOXONE® Film and SUBLOCADE™ and any decrease in sales due to competition, supply, or quality issues could significantly affect the groups revenues, financial conditions and results of operations. In addition to customary risks associated with new product launch, complexity in the SUBLOCADE™ specialty distribution and patient access journey may result in initial adoption rates of SUBLOCADE™ being slower than expected and consequently requiring longer than projected to achieve peak net revenues.
- 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 and/or fines.
- The Group has a single source of supply for buprenorphine, an active ingredient in the Group’s products including SUBOXONE® Film and SUBLOCADE™, and any disruption to this source of supply could significantly affect the Group’s revenues, financial conditions and results of operations.
- Indivior utilizes contract manufacturers for SUBOXONE® Film and SUBLOCADE™, and material interruptions could adversely impact the Group's revenues, financial conditions and results of operations.

Product liability, regulation and litigation

- The Group has obtained a preliminary injunction from the U.S. District Court for the District of New Jersey, which prohibits Dr. Reddy’s Laboratories (DRL) from using, importing, selling, or offering to sell its FDA-approved generic buprenorphine/naloxone sublingual film product in the U.S. pending the outcome of patent infringement litigation initiated by the Group related to the Group’s U.S. Patent No. 9,931,305 covering SUBOXONE® Film. A ruling by the District Court in this proceeding is expected in H2 2019-H1 2020. If this ruling is adverse to the Group or if the preliminary injunction is overturned on appeal, the Group would be liable for damages incurred by DRL as a result of its prohibition from using, importing, selling, or offering to sell its generic buprenorphine/naloxone sublingual film product in the market during

the term of the preliminary injunction.

- 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 within this press release on pages 7 to 8 referring to the current status of Abbreviated New Drug Application (ANDA) litigation and to the going concern statement on page 20 contained within note 1 of these condensed consolidated interim financial statements, which discusses the risks associated with current ANDA litigation, and the contingent liabilities disclosures in Note 8 of these condensed consolidated interim financial statements on pages 23 to 25.
- 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 sale of pharmaceutical products are highly regulated and entail a risk of product liability claims, product recalls, litigation, government investigations and enforcement action, 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 disclosure on page 6 referring to the current status of the DOJ investigation and other investigative and antitrust litigation matters, and the contingent liabilities disclosures in Note 8 of these condensed consolidated interim financial statements on pages 23 to 25.
- As previously disclosed on page 43 of Prospectus dated November 17, 2014, Indivior has indemnification obligations in favor of Reckitt Benckiser (RB). The demerger agreement between Indivior and 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 U.S.
- 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

OUR prescribing healthcare professionals. A significant amount of revenue will be dependent upon HCP offices learning and adopting these new processes so that they are able to prescribe SUBLOCADE.

Compliance with laws 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 disclosure on page 6 referring to the current status of the DOJ investigation and other investigative and antitrust litigation matters, and the contingent liabilities disclosures in Note 8 of these condensed consolidated interim financial statements on pages 23 to 25.

Acquisitions and business development

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

Patient safety

- A 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 Company reports to health authorities across the globe within the required and mandatory timelines. Safety signals are identified and assessed for any changes to the benefit/risk profile. Determination is made if further actions are needed to optimize the safe and effective use of our products, including communicating any relevant changes to key stakeholders.

Exchange Rates

The average and period end exchange rates used for the translation of currencies into U.S. dollars that have most significant impact on the Group’s results were:

	6 Months to June 30, 2018	6 Months to June 30, 2017
GB £ period end	1.3113	1.2926
GB £ average rate	1.3771	1.2584
€ Euro period end	1.1553	1.1379
€ Euro average	1.2115	1.0815

Webcast Details

There will be a presentation at 11:30 am UK time (6:30 am Eastern in the USA) hosted by Shaun Thaxter, CEO. This presentation will also be webcast live. The details are below and are available on the Company’s website at www.indivior.com.

Webcast link: <https://edge.media-server.com/m6/p/9qqtethv>

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This announcement does not constitute an offer to sell, or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

About Indivior

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy and health policy while providing education on evidence-based treatment models that have revolutionized modern addiction treatment. The name is the fusion of the words individual and endeavor, and the tagline “Focus on you” makes the Company’s commitment clear. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of opioid dependence treatments, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic conditions and co-occurring disorders of addiction, including alcohol use disorder and schizophrenia. Headquartered in the United States in Richmond, VA, Indivior employs more than 1000 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

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.

**SUBOXONE (BUPRENORPHINE AND NALOXONE) SUBLINGUAL FILM (CIII)
INDICATION AND HIGHLIGHTED SAFETY INFORMATION**

INDICATION

SUBOXONE Film is indicated for the treatment of opioid dependence.

SUBOXONE Film should be used as part of a complete treatment plan that includes counseling and psychosocial support.

HIGHLIGHTED SAFETY INFORMATION

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

CONTRAINDICATIONS

SUBOXONE Film should not be used by patients who have been shown to be hypersensitive to buprenorphine or naloxone.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: SUBOXONE Film 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. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits.

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

Unintentional Pediatric Exposure: Store SUBOXONE Film safely out of the sight and reach of children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children.

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 is temporarily interrupted or discontinued, monitor patients for withdrawal and treat appropriately.

Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events.

Precipitation of Opioid Withdrawal Signs and Symptoms: An opioid withdrawal syndrome is likely to occur with parenteral misuse of SUBOXONE Film by individuals physically dependent on full opioid agonists, or by sublingual or buccal administration before the agonist effects of other opioids have subsided.

Risk of Overdose in Opioid-Naïve Patients: SUBOXONE Film is not appropriate as an analgesic. There have been reported deaths of opioid naïve individuals who received a 2mg sublingual dose.

ADVERSE REACTIONS

Adverse events commonly observed with the sublingual/buccal administration of the SUBOXONE Film are oral hypoesthesia, glossodynia, oral mucosal erythema, headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.

For more information about SUBOXONE Film, please see the full Prescribing Information and Medication Guide at suboxone.com.

**SUBLOCADE (BUPRENORPHINE EXTENDED-RELEASE) INJECTION FOR SUBCUTANEOUS USE (CIII)
INDICATION AND HIGHLIGHTED SAFETY INFORMATION**

INDICATION

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 dose adjustment for a minimum of 7 days.

SUBLOCADE should be used as part of a complete treatment plan 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.

HIGHLIGHTED 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.

For more information about SUBLOCADE, the full Prescribing Information including BOXED WARNING, and Medication Guide visit www.sublocade.com.

Condensed consolidated interim income statement

		Unaudited Q2 2018 \$m	Unaudited Q2 2017 \$m	Unaudited H1 2018 \$m	Unaudited H1 2017 \$m
For the three months ended June 30					
Net Revenues	Notes 2	268	288	524	553
Cost of Sales		(35)	(25)	(59)	(45)
Gross Profit		233	263	465	508
Selling, general and administrative expenses	3	(131)	(127)	(231)	(220)
Research and development expenses	3	(18)	(19)	(34)	(44)
Operating Profit		84	117	200	244
Operating profit before exceptional items		84	142	183	269
Exceptional items	3	-	(25)	17	(25)
Finance income		4	2	6	3
Finance expense		(10)	(16)	(17)	(28)
Profit before taxation		78	103	189	219
Income tax expense		(8)	(30)	(27)	(66)
Taxation before exceptional items	5	(8)	(39)	(25)	(75)
Exceptional items within taxation	5	-	9	(2)	9
Net income		70	73	162	153

Earnings per ordinary share (cents)

Basic earnings per share	6	10	10	22	21
Diluted earnings per share	6	9	10	22	20

Condensed consolidated interim statement of comprehensive income

		Unaudited Q2 2018 \$m	Unaudited Q2 2017 \$m	Unaudited H1 2018 \$m	Unaudited H1 2017 \$m
For the three months ended June 30					
Net income		70	73	162	153
Other comprehensive income					
<i>Items that may be reclassified to profit or loss in subsequent years:</i>					
Net exchange adjustments on foreign currency translation		(16)	1	(10)	3
Other comprehensive (loss)/income		(16)	1	(10)	3
Total comprehensive income		54	74	152	156

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

Condensed consolidated interim balance sheet

	Notes	Unaudited Jun 30, 2018 \$m	Audited Dec 31, 2017 \$m
ASSETS			
Non-current assets			
Intangible assets		108	92
Property, plant and equipment and other assets		55	54
Deferred tax assets	5	63	58
Other receivables		22	15
		248	219
Current assets			
Inventories		72	52
Trade and other receivables		285	278
Current tax receivable		26	32
Cash and cash equivalents	7	951	863
		1,334	1,225
Total assets		1,582	1,444
LIABILITIES			
Current liabilities			
Borrowings	7	(5)	(5)
Provisions	8	(189)	(143)
Trade and other payables	9	(644)	(665)
Current tax liabilities	5	(51)	(41)
		(889)	(854)
Non-current liabilities			
Borrowings	7	(472)	(477)
Provisions	8	(264)	(316)
		(736)	(793)
Total liabilities		(1,625)	(1,647)
Net liabilities		(43)	(203)
EQUITY			
Capital and reserves			
Share capital	10	73	72
Share premium		4	2
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(24)	(14)
Retained Earnings		1,199	1,032
Total equity		(43)	(203)

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

Condensed consolidated interim statement of changes in equity

	Share capital	Share Premium	Other reserve	Foreign Currency Translation reserve	Retained earnings	Total equity
Notes	\$m	\$m	\$m	\$m	\$m	\$m
Unaudited						
Balance at January 1, 2018	72	2	(1,295)	(14)	1,032	(203)
Comprehensive income						
Net income	-	-	-	-	162	162
Other comprehensive income	-	-	-	(10)	-	(10)
Total comprehensive income	-	-	-	(10)	162	152
Transactions recognised directly in equity						
Share-based plans	1	2	-	-	5	8
Deferred taxation on share-based plans	-	-	-	-	-	-
Balance at June 30, 2018	73	4	(1,295)	(24)	1,199	(43)
Unaudited						
Balance at January 1, 2017	72	-	(1,295)	(22)	950	(295)
Comprehensive income						
Net income	-	-	-	-	153	153
Other comprehensive income	-	-	-	3	-	3
Total comprehensive income	-	-	-	3	153	156
Transactions recognised directly in equity						
Share-based plans	-	1	-	-	5	6
Deferred taxation on share-based plans	-	-	-	-	-	-
Balance at June 30, 2017	72	1	(1,295)	(19)	1,108	(133)

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

Condensed consolidated interim cash flow statement

	Unaudited 2018 \$m	Unaudited 2017 \$m
For the six months ended June 30		
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating Profit	200	244
Depreciation and amortization	7	4
Gain on disposal of intangible asset	(17)	-
Share-based payments	5	5
Impact from foreign exchange movements	(4)	2
Increase in trade and other receivables	(11)	(11)
Increase in inventories	(24)	(5)
Decrease in trade and other payables	(30)	(57)
(Decrease)/increase in provisions	(7)	23
Cash generated from operations	119	205
Interest paid	(10)	(19)
Interest received	6	3
Taxes paid	(15)	(4)
Net cash inflow from operating activities	100	185
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(5)	(15)
Purchase of intangible assets	(20)	(1)
Proceeds from license of intangible assets	13	-
Net cash inflow/(outflow) from investing activities	(12)	(16)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of borrowings	(2)	(71)
Proceeds from the issuance of ordinary shares	3	-
Net cash (outflow) from financing activities	1	(71)
Net increase in cash and cash equivalents	89	98
Cash and cash equivalents at beginning of the period	863	692
Exchange differences	(1)	2
Cash and cash equivalents at end of the period	951	792

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 and legal provision.

These condensed consolidated interim financial statements reflect the Group's adoption of IFRS 15 *Revenue from Contracts with Customers* and IFRS 9 *Financial Instruments* as of January 1, 2018. There were 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 of IFRS 16 on its consolidated financial statements but has not yet completed its detailed assessment. The actual financial statement impact 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 assets and liabilities for operating leases of office facilities; however, the total amount has not been quantified.

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 July 24, 2018.

As disclosed in Note 8, the Group carries a provision of \$438m relating to the Department of Justice investigations. The final settlement amount may be materially higher than this provision. This could impact the Group's ability to operate, which would be further adversely impacted should revenues decline, (including possible declines from one or more of the generic companies successfully launching generic buprenorphine/naloxone sublingual film product or from further uncertainty in the U.S. buprenorphine/naloxone sublingual film market) or new products fail to meet expectations, 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 at least the next twelve months. 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 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 were delivered to the Registrar of Companies.

2. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker ('CODM'). The CODM, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer (CEO). The Indivior Group is engaged in a single business activity, which is the development, manufacture and sale of buprenorphine-based prescription drugs for treatment of opioid dependence. The CEO reviews financial information on a geographic basis for evaluating financial performance and allocating resources. The Group has a single reportable segment.

Revenues

Revenues are attributed to countries based on the country where the sale originates. The following table represents revenue from continuing operations attributed to countries based on the country where the sale originates and non-current assets, net of accumulated depreciation and amortization, by country. Non-current assets for this purpose consist of property, plant and equipment, intangible assets, and other receivables. Revenues and non-currents assets for the six months to June 30, 2018 and 2017 were as follows:

Revenues from sale of goods:

	Q2 2018	Q2 2017	H1 2018	H1 2017
For the six months ended June 30	\$m	\$m	\$m	\$m
United States	214	237	411	452
ROW	54	51	113	101
Total	268	288	524	553

Non-current assets:

	June 30, 2018 \$m	Dec 31, 2017 \$m
United States	65	68
ROW	120	93
Total	185	161

3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

	Q2 2018	Q2 2017	H1 2018	H1 2017
For the six months ended June 30	\$m	\$m	\$m	\$m
Research and development expenses	(18)	(19)	(34)	(44)
Marketing, selling and distribution expenses	(56)	(37)	(102)	(69)
Administrative expenses	(71)	(86)	(121)	(143)
Depreciation and amortization	(3)	(2)	(6)	(4)
Operating lease rentals	(1)	(2)	(2)	(4)
Total	(131)	(127)	(231)	(220)

In 2018, \$7m of development costs relating to RBP-7000 have been capitalized within intangible assets. Additionally, distribution costs of less than \$2m 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 about \$2m, is not material.

Exceptional Items

	Q2 2018	Q2 2017	H1 2018	H1 2017
For the six months ended June 30	\$m	\$m	\$m	\$m
Other operating income	-	-	17	-
Legal Expenses/Provision	-	(25)	-	(25)
Total exceptional items before taxes	-	(25)	17	(25)
Tax on exceptional items	-	9	(2)	9
Total exceptional items	-	(16)	15	(16)

\$17m of exceptional income in the half year relates to the proceeds received from the out-licensing of nasal naloxone opioid overdose patents which are included within SG&A. Exceptional expense in the prior year is for a conclusive legal settlement with Amneal Pharmaceuticals LLC relating to anti-trust litigation.

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 H1/Q2 2018 and H1/Q2 2017.

Reconciliation of operating profit to adjusted operating profit

	Q2 2018 \$m	Q2 2017 \$m	H1 2018 \$m	H1 2017 \$m
For the six months ended June 30				
Operating profit	84	117	200	244
Exceptional selling, general and administrative expenses	-	25	-	25
Exceptional operating income	-	-	(17)	-
Adjusted operating profit	84	142	183	269

Reconciliation of net income to adjusted net income

	Q2 2018 \$m	Q2 2017 \$m	H1 2018 \$m	H1 2017 \$m
For the six months ended June 30				
Net Income	70	73	162	153
Exceptional selling, general and administrative expenses	-	25	-	25
Exceptional operating income	-	-	(17)	-
Tax on exceptional items	-	(9)	2	(9)
Adjusted net income	70	89	147	169

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 Q2 2018, tax on total profits amounted to \$8m excluding the tax effect on exceptionals (Q2 2017: \$39m) and represented a quarterly effective tax rate of 10% (Q2 2017: 30% excluding exceptionals). The Group's balance sheet at June 30, 2018 included a current tax payable of \$51m (FY 2017: \$41m), current tax receivable of \$26m (FY 2017: \$32m), and deferred tax asset of \$63m (FY 2017: \$58m).

In the H1 2018, tax on total profits amounted to \$25m (H1 2017: \$75m) excluding the tax effect on exceptionals and represented a H1 2018 tax rate of 15%, (H1 2017: 31%, excluding exceptionals).

The decrease in the effective tax rate to 15% was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the quarter, along with the impacts of U.S. 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

	Q2 2018 cents	Q2 2017 cents	H1 2018 cents	H1 2017 cents
For the six months ended June 30				
Basic earnings per share	10	10	22	21
Diluted earnings per share	9	10	22	20
Adjusted basic earnings per share	10	12	20	23
Adjusted diluted earnings per share	9	12	20	23

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 thousands	2017 thousands
Weighted average number of shares		
On a basic basis	725,917	720,714
Dilution from share awards and options	24,190	27,930
On a diluted basis	750,107	748,644

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

	June 30 2018 \$m	Dec 31 2017 \$m
Current		
Bank loans	(5)	(5)
	(5)	(5)
Non-current		
Bank loans	(472)	(477)
	(472)	(477)
Analysis of net debt		
Cash and cash equivalents	951	863
Borrowings*	(482)	(487)
	469	376

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

	June 30 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	88	171
Net repayment of borrowings	2	86
Exchange adjustments	3	(12)
Net cash at end of period	469	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 June 30, 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 carries a provision for investigative and antitrust litigation matters of \$438m. Substantially all of the provision relates to the U.S. Department of Justice investigation. The Group is in advanced discussions with the Department of Justice about a possible resolution to its investigations, although it cannot predict with any certainty whether, when, or at what cost it will reach an ultimate resolution.

The Group reduced other elements of the provision that relate to other litigation matters reflecting the Group's belief that it has strong defences in the antitrust and other litigations and is now actively litigating these matters. Indivior cannot predict with any certainty whether, when, or at what cost it will reach ultimate resolution of the antitrust and other litigation matters.

The final aggregate cost of these matters may be materially higher than the amount provided.

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 has responded to the subpoenas and has otherwise cooperated fully with the Department and prosecutors and will continue to do so. The

Group is in advanced discussions with the Department of Justice about a possible resolution to its investigation. However, it is not possible to predict with any certainty the potential impact of this investigation on the Group or to quantify the ultimate cost of a resolution.

State Subpoenas

- On October 12, 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 16, 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 and served a subpoena in 2018 requesting documents relating to the bioavailability / bioequivalency of SUBOXONE® Film, manufacturing records for the product and its components, and the potential to develop dependency on SUBOXONE Film. 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.
- A group of 41 states, 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.
- The Group believes it has strong defences and is vigorously litigating these matters.

ANDA Litigation

- Actavis is currently enjoined from launching a generic buprenorphine/naloxone film product until April 2024 based on a June 3, 2016 District Court ruling finding U.S. Patent No. 8,603,514 (the '514 Patent) valid and infringed. Actavis has appealed this ruling. On October 24, 2017, Actavis received tentative approval from FDA for at least its 8mg/2mg generic product under its Abbreviated New Drug Application (ANDA) No. 204383 and on November 15, 2017, it received tentative approval for its 12mg/3mg generic product under ANDA No. 207087.
- On August 31, 2017 a District Court ruling in a lawsuit that asserted claims of U.S. Patent No. 8,017,150 (the '150 Patent), U.S. Patent No. 8,900,497 (the '497 Patent), and the '514 Patent found that these patents are valid but not infringed by Dr. Reddy's. Indivior has appealed this ruling. Dr. Reddy's received final FDA approval for all four strengths of its generic buprenorphine/naloxone film product on June 14, 2018, and immediately launched its generic buprenorphine/naloxone film product "at-risk." On June 15, 2018, Indivior filed a motion with the District Court of New Jersey seeking a Temporary Restraining Order (TRO) and Preliminary Injunction (PI) pending the outcome of a trial on the merits of U.S. Patent No. 9,931,305 (the '305 Patent). The District Court of New Jersey granted Indivior a two-week TRO, preventing Dr. Reddy's from continuing to sell or offer to sell its generic product. Indivior was required to post an \$18 million surety bond to cover Dr. Reddy's damages in the event of an Indivior loss of its patent case against Dr. Reddy's. On June 28, 2018, the District Court of New Jersey heard oral argument in support of Indivior's motion for a PI against Dr. Reddy's and, at the conclusion of this hearing, the District Court extended the TRO for an additional 14 days in order to rule on the PI motion and required Indivior to post another \$18 million surety bond. On July 13, 2018, the District Court issued its ruling granting Indivior a PI against Dr. Reddy's. On the same day, Dr. Reddy's filed a motion to stay the PI pending appeal with the District Court and a Notice of Appeal with the Federal Circuit. On July 18, 2018, the District Court ordered Indivior to post a surety bond for \$72 million (that total figure being inclusive of the \$36 million surety bond already posted) in connection with the PI. That same day, the District Court also denied Dr. Reddy's motion to stay the PI pending appeal. On July 19, 2018, Dr. Reddy's filed with the CAFC its opening brief for the appeal of the PI, along with emergency motions seeking to expedite the appeal of the PI and stay the PI pending the outcome of the appeal. On July 24th, Indivior filed its opposition to the motions to expedite the PI and stay the PI pending appeal.
- Teva filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of buprenorphine/naloxone film. Indivior, Aquevite Pharmaceuticals (formerly known as MonoSol Rx) and Teva agreed that infringement by Teva's 16mg/4mg dosage strength would be governed by the infringement ruling as to Dr. Reddy's 8mg/2mg dosage strength that was the subject of the trial in November 2016. Accordingly, the non-infringement ruling in the Dr. Reddy's case means that the Teva 16mg/4mg dosage strength has been found not to infringe. Indivior has appealed this November 2016 ruling.
- Trial against Alvogen in the lawsuit involving the '514 and '497 Patents for SUBOXONE® Film took place in September 2017. The 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 has appealed this ruling. Alvogen's 30-month stay of FDA approval expired on October 29, 2017. So far as Indivior is aware, FDA to date has not granted tentative or final marketing authorization to Alvogen's generic buprenorphine/naloxone film product. If

FDA were to grant final approval to Alvogen, this would enable Alvogen to market its generic buprenorphine/naloxone film product in the U.S.. However, any market launch by Alvogen before a ruling on appeal would be on an “at risk” basis because Indivior would have a claim for damages against Alvogen if Indivior ultimately prevails on appeal. Moreover, if Alvogen does launch “at risk”, Indivior would seek a PI with the District Court to enjoin the launch of Alvogen’s generic buprenorphine/naloxone film product pending the outcome of the lawsuit against Alvogen for infringement of the ‘305 Patent.

- By a Court order dated August 22, 2016, Indivior’s SUBOXONE® Film patent litigation against Sandoz was dismissed without prejudice because Sandoz is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE® Film.
- On September 25, 2017, Indivior settled its SUBOXONE® Film patent litigation in District Court against Mylan, the terms of which are confidential. Mylan received final FDA approval for its generic version of the 8mg buprenorphine/naloxone film product on June 14, 2018.
- On May 11, 2018, Indivior settled its SUBOXONE® Film patent litigation in the District Court against Par. Under the terms of the settlement agreement, Par can launch its generic buprenorphine/naloxone film product on January 1, 2023, or earlier under certain circumstances. Other terms of the settlement agreement are confidential. So far as Indivior is aware, FDA to date has not granted tentative or final approval for Par’s generic buprenorphine/naloxone film product.
- Indivior has filed lawsuits against Alvogen, Dr. Reddy’s, and Teva in the District Court of New Jersey, and against Actavis in the District Court of Utah, for infringement of U.S. Patent No. 9,687,454 (the ‘454 Patent), U.S. Patent No. 9,855,221 (the ‘221 Patent), and the ‘305 Patent. The Actavis suit has been transferred to the District Court of Delaware. Motions filed by Alvogen, Dr. Reddy’s, and Teva to transfer the lawsuits against them from the District Court of New Jersey to the District Court of Delaware have been denied.

Rhodes Pharmaceuticals

- On December 23, 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 U.S. 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 (IPR) 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 IPR on or about October 6, 2018.
- The District Court case against Indivior has been stayed pending the USPTO’s decision whether to institute the IPR.

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. A hearing on Indivior’s pending motions to dismiss is scheduled for August 8, 2018.

In the event the final settlement amount of the DOJ matter is materially higher than the provision, and the Group is further adversely impacted should revenues decline (including possible declines from one or more of the generic companies successfully launching generic buprenorphine/naloxone sublingual film product or from further uncertainty in the U.S. buprenorphine/naloxone sublingual film market), or new products fail to meet expectations, the Group would not continue in business without taking necessary measures to reduce its cost base and improve its cash flow. 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.

9. TRADE AND OTHER PAYABLES

	June 30 2018 \$m	Dec 31 2017 \$m
Sales returns and rebates	(427)	(433)
Trade payables	(49)	(40)
Accruals	(156)	(179)
Other tax and social security payables	(12)	(13)
Total	(644)	(665)

Sales return and rebate accruals, primarily in the U.S., are provided 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 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 may 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	6,641,420	\$0.10	1
At June 30, 2018	728,104,153	\$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	390,817	\$0.10	-
At June 30, 2017	720,988,383	\$0.10	72

Allotment of ordinary shares

During the period, 6,641,420 ordinary shares (2017: 390,817) were allotted to satisfy vestings/exercises under the Group's Long-Term Incentive Plan and U.S. Employee Stock Purchase Plan.

11. POST BALANCE SHEET EVENTS

On July 13, 2018, the U.S. District Court for the District of New Jersey granted a preliminary injunction (PI) against Dr. Reddy's Laboratories (DRL). The restrictions of the previously entered temporary restraining order remain in place, and DRL is unable to sell, offer to sell, or import its generic buprenorphine/naloxone sublingual film product, pending the outcome of recently filed litigation against DRL related to U.S. Patent No. 9,931,305 (the '305 patent), or a decision of the U.S. Court of Appeals for the Federal Circuit dissolving the injunction. DRL has appealed the grant of the preliminary injunction and the bond amount to the CAFC and asked for expedited briefing. DRL has also asked the CAFC to stay the preliminary injunction pending the appeal. On July 24th, Indivior filed its opposition to the motions to expedite the PI and stay the PI pending appeal.

The U.S. District Court for the District of New Jersey ordered Indivior to post a \$72m bond to provide security to DRL should the court conclude at the end of patent litigation that the '305 patent is invalid and/or not infringed.

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.
 - an indication of important events that have occurred during the first six months and their impact on the condensed set of financial statements, and a description of the principal risks and uncertainties for the remaining six months of the financial year; and
 - material related-party transactions in the first six months and any material changes in the related-party transactions described in the last annual report.

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

July 24, 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 H1 2018 Results of Indivior PLC for the three and six month periods ended 30 June 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, which is not modified, 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 these matters. The final aggregate settlement amount may be materially higher than this provision.

Emphasis of matter – Going Concern

In forming our conclusion on the Interim Financial Statements, which is not modified, we have considered the adequacy of the disclosure made in Note 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 able to successfully launch generic buprenorphine/naloxone sublingual film;
- there is further uncertainty in the U.S. buprenorphine/naloxone sublingual film market; and/or
- the market acceptance of SUBLOCADE™ continues to be slower than expected.

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. 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. 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 30 June 2018;
- the Condensed consolidated interim income statement and Condensed consolidated statement of comprehensive income for the periods 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 periods then ended; and
- the explanatory notes to the interim financial statements.

The Interim Financial Statements included in the H1 2018 Results have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

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

Responsibilities for the Interim Financial Statements and the review

Our responsibilities and those of the directors

The H1 2018 Results, including the Interim Financial Statements, is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the H1 2018 Results in accordance with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express a conclusion on the interim financial statements in the H1 2018 Results based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

What a review of interim financial statements involves

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

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

We have read the other information contained in the H1 2018 Results and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP
Chartered Accountants
London
24 July 2018