



November 1, 2018

**Nine Month Financial Results – Company On Track to Achieve FY 2018 Revised Guidance**

Period to September 30th	Q3 2018 \$m	Q3 2017 \$m	% Δ Actual FX	% Δ Constant FX	YTD 2018 \$m	YTD 2017 \$m	% Δ Actual FX	% Δ Constant FX
Net Revenue	245	275	-11	-11	768	828	-7	-8
Operating Profit	71	63	13	13	271	308	-12	-13
Net Income	89	50	79	78	251	203	24	22
EPS (cents per share)	12	7	71	78	35	28	24	22
Adjusted Operating Profit*	71	63	13	13	254	333	-24	-25
Adjusted Net Income*	58	47	23	22	205	216	-5	-7
Adjusted EPS*	8	7	14	22	28	30	-7	-7

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

**YTD 2018 Financial Results**

- YTD 2018 net revenue of \$768m (YTD 2017: \$828m) decreased 7% on a reported basis and by 8% at constant FX; strong U.S. market growth was more than offset by SUBOXONE® film share loss in the U.S. and continued rapid growth in the most price sensitive channel (Medicaid), which negatively impacted mix. YTD 2018 SUBLOCADE™ net revenues were \$5m, including \$3m in Q3 2018.
- YTD 2018 adjusted operating profit decreased 24% to \$254m (YTD 2017 adj: \$333m), excluding \$17m of exceptional benefit and \$25m of exceptional cost in the year-ago period; lower net revenue, launch costs behind SUBLOCADE™ and the establishment of the Behavioural Health unit to launch PERSERIS™ were partially offset by lower legal and R&D expenses and initial savings from the Company’s cost initiative launched in July.
- YTD 2018 adjusted net income decreased 5% to \$205m (YTD 2017 adj: \$216m), reflecting the impact of the items listed above partially offset by lower interest costs following the replacement of the term loan facilities in December 2017, higher interest income and a lower effective tax rate.
- Cash balance at the end of Q3 2018 was \$901m (FY 2017: \$863m); net cash was \$569m (FY 2017: \$376m).
- \$150 million of loan principal was voluntarily repaid; outstanding loan balance is \$329m (FY 2017: \$482m).
- On track to achieve FY 2018 revised guidance of net revenue in the range of \$990-\$1,020m and adjusted net income in the range of \$230-\$255m; guidance assumes no material change in U.S. market conditions, (no generic film entry), and excludes exceptional items and assumes constant FX.

**YTD 2018 Operating Highlights**

- U.S. market volume growth continued at low double-digit percentage levels primarily driven by Medicaid channel.
- SUBOXONE® Film market share averaged 54% YTD 2018 (YTD 2017: 58%), exiting Q3 2018 at 52%. During Q3, SUBOXONE® Film share declined to a low of 50%, reflecting the market impact of Dr. Reddy’s Laboratories Ltd.’s (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 preliminary injunction (PI) on July 13th. Subsequently SUBOXONE® Film share has largely recovered and most recently (as of October 19th) stood at 53%. Indivior expects the adverse impact of DRL’s “at-risk” launch on its FY

2018 net revenue to be between \$12m and \$18m. Under the PI granted by the District Court on July 13th, 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 appealed the PI and the bond amount to the CAFC, and asked for an expedited briefing. DRL was granted an expedited briefing by the CAFC, which took place October 4th. The ruling is pending, timing is unknown.

- The Company confirms that FY 2018 SUBLOCADE™ net revenues are expected in the range of \$8m to \$10m. Indivior continued in the third quarter to work diligently to break down the barriers to accelerate SUBLOCADE™ uptake. As a result, payor formulary access and the prescription journey timeline approached targeted levels, the prescription dispense yield rate continued to improve and healthcare provider (HCP) adoption grew. In addition, anecdotal feedback from patients and HCPs remains very encouraging. The Company remains confident in its goal of peak SUBLOCADE™ net revenue of \$1 billion-plus. Please see page 4 for a discussion of SUBLOCADE key performance indicators (KPI).
- Indivior is making good progress against its previously-announced cost savings initiative that targets at least \$55m in pre-tax savings in 2018 and \$25m to \$45m of additional pre-tax savings in FY 2019. Combined, the Company's initiative is expected to generate annual pre-tax savings between \$80m to \$100m in FY 2019. The cost savings initiative is designed to help mitigate against potential impacts to Indivior's profitability and cash flow from a potential generic film entrant in the U.S. Savings from these actions of \$21m were realized in Q3 2018.
- Indivior is preparing a full promotional launch for PERSERIS™ (risperidone) with a field force of 40 to 60 representatives, contingent upon the PI against DRL being upheld by the CAFC. However, the Company will be making PERSERIS™ available in the U.S. in Q4 2018 to begin generating product awareness and trial.
- The Group is in advanced discussions with the U.S. Department of Justice (DOJ) about a possible resolution to its investigations. Please see pages 9 to 12 for a complete Litigation Update.

#### **FY 2018 Guidance**

Indivior is on track to achieve its FY 2018 revised guidance of net revenue of \$990-\$1,020 million and net income in a range of \$230-\$255 million, excluding exceptional items and at constant FX.

- FY 2018 net revenue guidance assumes the following:
  - No material changes in current market conditions in the U.S., chiefly that the CAFC upholds the PI granted by the District Court whereby DRL remains prohibited from selling, offering to sell, or importing its generic buprenorphine/naloxone sublingual film product and/or generally an 'at risk' launch of a generic buprenorphine/naloxone film product will not take place;
  - Intensifying competitive pressure in the Rest of World (ROW) due to continued healthcare austerity measures and increased competition in Europe, partially offset by continued growth in the Australasia region;
  - Net revenue for SUBLOCADE™, which is expected to be between \$8 to \$10 million; and
  - Immaterial net revenue from PERSERIS™ pre-promotional launch availability.
- FY 2018 net income guidance assumes the above and the following:
  - Pre-tax savings of \$55 million from cost actions the Group is taking to streamline the organization;
  - Continued investments to drive progression of SUBLOCADE™ and PERSERIS™, increase access to treatment for opioid use disorder (OUD) patients and to support continued compliance enhancements; and,
  - A mid-teens effective tax rate from the recently enacted tax law change in the U.S., along with the Group's existing tax position.

### [Shaun Thaxter, CEO of Indivior, Comment](#)

“Following a set of new market challenges in Q3, triggered by DRL’s “at-risk” launch and further erosion in generic tablet pricing, Indivior has moved swiftly to streamline the organization in a way that preserves our ability to continue executing against our strategy of global leadership in the treatment of addiction and its co-occurrences.

“I am proud of how our global teams have responded and adapted to the new operating structure we have put in place. With our streamlined business we have maintained SUBOXONE® Film’s leadership position in the U.S., provided for continued strong support for the near-term drivers of Indivior’s future – SUBLOCADE™ and PERSERIS™ – while also providing the Company further flexibility to mitigate against a potential generic entrant in the U.S.

“Our primary strategic focus is to accelerate the performance of SUBLOCADE™ towards its long-term potential, which we remain confident will exceed \$1bn in annual net revenues in a large and growing market. I am pleased to say that we are making progress across key prescription journey and treatment adoption metrics, and anecdotal feedback from patients and HCPs remains very encouraging.

“This quarter we will make PERSERIS™ available without salesforce promotion in the U.S. We believe this differentiated long-acting treatment for schizophrenia will create a new opportunity to serve patients in a closely-related market that offers Indivior scale and growth. We will make a decision on full commercial launch post the PI ruling.

“Underscoring our operational activities will be an unwavering focus on maintaining the highest regulatory and compliance standards. We continue to look to the future with confidence.”

### [YTD Operating Review](#)

#### **U.S. Market Update**

In 2018, market volume for buprenorphine products has continued to grow at low double-digit percentage rates, in line with Indivior’s expectations. This volume growth is being driven by benefits from legislation and regulatory changes that have expanded federal funding and permanently increased OUD treatment capacity, as well as from increased general awareness of the opioid epidemic.

Indivior supports the swift actions the U.S. government has taken to combat the opioid epidemic, including the recent enactment on October 24th of the SUPPORT for Patients and Communities Act of 2018 which expands access to buprenorphine medication-assisted treatment (BMAT) by:

- Making the buprenorphine prescribing authority permanent for nurse practitioners and physician assistants;
- Specifically allowing for specialty pharmacy distribution of injectable medications to treat OUD;
- Allowing for administration of OUD injectable treatments by non-waivered healthcare practitioners;
- Allowing waived practitioners to immediately treat 100 patients at a time if the practitioner is board certified in addiction medicine or addiction psychiatry, or in a qualified practice setting;
- Putting into law the regulation expanding the patient limit to 275 for certain qualified physicians;
- Authorizing additional funding for State Targeted Response Grants to support programs that help reduce opioid-related overdoses and addiction; and
- Embedding substance use disorder training into medical school curricula with a goal of expanding the number of physicians able to treat OUD.

These initiatives, while supporting greater treatment capacity for those at most need, are likely to be manifested in continued growth in lower-priced government channels. Furthermore, generic buprenorphine/naloxone tablet pricing is now at commodity floor price levels of over 80% below list price. This level of pricing has the

greatest impact in the most price-sensitive payors and also exerts downward price pressure across all channels. As a result of these factors, Indivior continues to expect pressure on its U.S. SUBOXONE® Film net revenue base.

As the leader and innovator in the OUD category, Indivior has chosen to respond by continuing to drive adoption of its new ground-breaking monthly buprenorphine depot SUBLOCADE™.

Indivior is making good progress in the following KPIs that it believes will drive accelerated net revenue growth for SUBLOCADE™ towards its \$1 billion-plus peak net revenue goal:

SUBLOCADE™ Prescription Journey Timeline KPIs (9/30/18 vs. 6/30/18):

- Formulary Access – increased to 82% of lives covered versus 56%.
- The Prescription Journey – declined to a range of 16 to 22 days from 27 to 37 days.
- The Dispense Conversion Rate – increased to 35% from 29% (data is based on new methodology<sup>1</sup>).

SUBLOCADE™ Demand KPIs (9/30/18 vs. 6/30/18):

- Continued positive anecdotal HCP and patient feedback post-trial; prompted awareness was 91% versus 79%.
- HCPs Initiating a Prescription Journey – increased to 1,870+ versus 1,300+.
- HCPs Administered SUBLOCADE™ – increased to 824 versus 384.
- HCPs Administered SUBLOCADE™ to 5-plus patients increased to 108 versus 30.

**Financial Performance: YTD 2018 & Q3 2018**

YTD 2018 total net revenue decreased by 7% to \$768m (YTD 2017: \$828m) at actual exchange rates and by 8% at constant exchange rates. Volume gains from underlying market growth in the U.S. and initial sales of SUBLOCADE™ (YTD 2018: \$5m) were more than offset primarily by the combined impacts of a decline in SUBOXONE® Film market share and unfavorable mix from the increase in Medicaid business in the U.S. Price improvement was also more than offset by tactical rebating activity in the U.S. in connection with formulary access.

In Q3 2018, total net revenue decreased 11% at actual and constant exchange rates to \$245m (Q3 2017: \$275m). While total net revenue drivers in the quarter were substantially the same as those for YTD 2018, Q3 2018 revenue was further impacted by DRL's initial "at-risk" launch of its FDA-approved generic buprenorphine/naloxone sublingual film, which resulted in a rapid but temporary decline in SUBOXONE® Film's U.S. market share and loss of net revenue. Indivior's U.S. market share has since recovered to near pre-DRL entry levels.

YTD 2018 U.S. net revenue decreased by 9% to \$609m (YTD 2017: \$670m) and by 10% in Q3 2018 to \$198m (Q3 2017: \$219m). Volume benefits from strong underlying market growth were more than offset by the combined impacts of a decline in SUBOXONE® Film market share and unfavorable mix from the continued disproportionate growth in the Medicaid channel. Improved pricing was more than offset by tactical rebating activity in connection with formulary access. Total U.S. net revenue drivers in Q3 2018 were substantially the same as those for YTD 2018, with the greater decline in net revenue due to DRL's "at-risk" launch of its generic buprenorphine/naloxone sublingual film, which resulted in a rapid but temporary decline in SUBOXONE® Film's U.S. market share and loss of net revenue.

In YTD 2018, ROW net revenue increased by 1% at actual exchange rates (decreased 4% at constant exchange rates) to \$159m (YTD 2017: \$158m). In Q3 2018, ROW net revenue decreased 16% at actual exchange rates (15% at constant exchange rates) to \$47m (Q3 2017: \$56m). In Q3, continued growth in Canada and Australasia

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<sup>1</sup> Based on closed cases unique to month of enrollment. See Investor Supplement dated November 1, 2018; slide 6, note 2.

was more than offset by declines in certain EU markets from intensified competition, timing of shipments and one-time benefits included in the year-ago period.

Gross margin in YTD 2018 was 88% (YTD 2017: 91%) and 86% in Q3 2018 (Q3 2017: 90%). The decrease in both periods versus the prior year primarily reflects lower net revenue and the impact of contingency planning for an “at-risk” launch by DRL.

SG&A expenses as reported were \$354m in YTD 2018 (YTD 2017: \$381m) and \$123m in Q3 2018 (Q3 2017: \$162m). YTD 2018 SG&A included a \$17m exceptional gain from the out-licensing of the intranasal naloxone opioid overdose patents (recorded in Q1 2018). In the year-ago period, YTD 2017 results included exceptional costs of \$25m (recorded in Q2 2017) reflecting settlement of the Amneal antitrust matter.

On an adjusted basis, YTD 2018 SG&A expenses increased 4% to \$371m (Adj. YTD 2017: \$356m) and in Q3 2018 SG&A expenses decreased by 24% to \$123m (Q3 2017 adj.: \$162m). The underlying increase in the YTD period mainly reflects planned investments for launching SUBLOCADE™ and establishment of the new Behavioral Health unit to launch PERSERIS™. The decrease in Q3 2018 primarily reflects the timing of prior year legal costs relating to ANDA defense as well as initial benefits from the Company’s cost savings initiative as announced in July. Realized savings in Q3 2018 were \$21m.

YTD 2018 and Q3 2018 R&D expenses decreased by 25% to \$50m and by 30% to \$16m, respectively (YTD 2017: \$67m; Q3 2017: \$23m). The decreases in both periods primarily reflect lower clinical activity and the reprioritization of R&D activities primarily to supporting SUBLOCADE™ and commitments under early-stage asset agreements.

YTD 2018 operating profit was \$271m (YTD 2017: \$308m) and Q3 2018 operating profit was \$71m (Q3 2017: \$63m). 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, YTD 2018 operating profit was \$254m (33% margin), a 24% decrease versus \$333m (40% margin) in the year-ago period. The decrease reflects lower net revenue, launch investments for SUBLOCADE™ and establishment of the Behavioral Health unit to launch PERSERIS™, partly offset by lower legal and R&D expenses, and initial benefits from cost savings initiatives.

On an adjusted basis, Q3 2018 operating profit was \$71m (29% margin), a 13% increase versus \$63m (23% margin) in the year-ago quarter. The increase in the period reflects the impact of lower legal and R&D expenses in the quarter, as well as initial benefits from cost savings initiatives.

YTD 2018 net finance expense was \$14m (YTD 2017: \$34m) and \$3m in Q3 2018 (Q3 2017: \$9m). The reduction in each period reflects lower interest and amortization of financing costs associated with the replacement of the Group’s term loan borrowing facility in December 2017 and higher interest income.

The YTD 2018 total tax charge was \$6m (YTD 2017: \$71m), a rate of 2% (YTD 2017: 26%). The YTD tax charge included a \$29m exceptional tax credit, comprising a \$2m tax charge on exceptional income offset by a one-time claim for U.S. orphan drug credits of \$31m. The YTD tax charge excluding the tax credit on exceptional items was \$35m (YTD 2017: \$83m), a rate of 15% (YTD 2017: 28%). The Q3 2018 tax credit was \$21m (Q3 2017: \$4m tax charge), a rate of 31% (YTD 2017: 7%). The Q3 2018 adjusted tax charge excluding the tax credit on exceptional items was \$10m (Q3 2017: \$7m), a rate of 15% (Q3 2017: 13%).

The decrease in the adjusted effective tax rate was primarily driven by changes in the relative contribution to pre-tax income by tax jurisdiction, along with the impacts of U.S. tax reform rate reduction and reduced UK rate due to patent box benefit.

YTD 2018 net income was \$251m (YTD 2017: \$203m) as reported. The current and year-ago periods included \$46m benefits and \$13m costs of exceptional items, respectively, net of tax. Excluding exceptional items, YTD

2018 net income decreased 5% to \$205m (YTD 2017 adj.: \$216m). In Q3 2018, net income was \$89m (Q3 2017 net income: \$50m); or \$58m (Q3 2018: \$47m) excluding exceptional items.

YTD 2018 basic EPS were 35 cents (YTD 2017: 28 cents) and 33 cents on a diluted basis (YTD 2017: 27 cents). Q3 2018 basic EPS were 12 cents (Q3 2017: 7 cents) and 12 cents on a diluted basis (Q3 2017: 7 cents). On an adjusted basis, YTD 2018 basic EPS were 28 cents (YTD 2017: 30 cents) and diluted EPS were 27 cents (YTD 2017: 29 cents). On an adjusted basis, Q3 2018 basic EPS were 8 cents (Q3 2017: 7 cents) and diluted EPS were 8 cents (Q3 2017: 6 cents).

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

Cash and cash equivalents at end September 2018 were \$901m, reflecting a YTD increase of \$38m in 2018 (FY 2017: \$863m). Borrowings, net of issuance costs, were \$329m at end September 2018 (FY 2017: \$482m), reflecting the voluntary repayment of \$150m of outstanding loan principal in Q3 2018. As a result, net cash stood at \$569m at end September 2018 (FY 2017: \$376), a \$193m improvement since the start of 2018.

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative \$321m at end September 2018, an increase of \$14m from negative \$335m since the end of FY 2017 primarily driven by an increase in inventory due in part to the launch of SUBLOCADE™ partially offset by lower receivables.

Cash generated from operations in YTD 2018 was \$238m (YTD 2017: \$274m), a decrease of \$36m. The reduction in cash generated versus the year-ago period was primarily due to lower operating profit in the period, increased inventory and a reduction in payables compared to FY 2017 partially offset by lower receivables.

YTD 2018 net cash inflow from operating activities was \$214m (YTD 2017: \$233m), reflecting lower cash from operations partially offset by lower net interest payments in the period of \$8m vs. \$22m in the prior period.

YTD 2018 cash outflow from investing activities was \$24m (YTD 2017: \$38m), reflecting upfront payments for the licensing arrangements with Addex and C4X, capitalized development costs, and ongoing investments in facilities offset by the proceeds received from the disposal of the nasal naloxone intangible asset.

YTD 2018 cash outflow from financing activities increased to \$151m vs. \$84m in YTD 2017, primarily reflecting the impact of the voluntary repayment of \$150m of outstanding loan principal in Q3 2018.

### **R&D / Pipeline Update**

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

- **SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE INJECTION) FOR SUBCUTANEOUS USE CIII:**
  - All Post Marketing Requirement (PMR) and Commitment (PMC) studies are on track.
  - Lifecycle Evidence Generation & Optimization (LEGO) Studies: Buprenorphine Abuse, Misuse, Diversion (AMD) Epidemiology VAS Craving project, Emergency Room Study, Fentanyl Study and Real World HEOR Study –on track.
  - 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 31st, 2018; 24-month last patient out scheduled for March 5th, 2019.
  - SUBLOCADE™ ex-US regulatory filings:
    - Canada: Submission to Health Canada April 19th, 2018; Priority Review status granted by Health Canada. NDS accepted for review May 25th, 2018.
    - Australia: Submission to Australia’s Therapeutic Goods Administration (TGA) on May 25th, 2018.
    - Europe: Submissions being prepared for Q4-2018.

- **SUBOXONE® Tablet:**
  - China's CDE (Center for Drug Evaluation), which performs the technical evaluation of the Marketing Application (equivalent to NDA) has completed the technical review of Indivior's Marketing Application and sent an "approval for import" recommendation to the Chinese National Medical Products Administration (NMPA) on August 29<sup>th</sup>, 2018.
  - On September 11<sup>th</sup>, 2018, NMPA approved SUBOXONE® Sublingual Tablets for the treatment of opioid use disorder.
  - Next Steps: (1) *Scheduling*: Chinese government will complete its narcotic scheduling determination for SUBOXONE® Sublingual Tablets. (2) *Import Permit*: Indivior can apply for the import permit or transfer the Import Drug License (IDL) to a qualified third party.
- **SUBOXONE® Film:**
  - Israel: Successful submission on September 3<sup>rd</sup>, 2018.
  - Canada: Activities ongoing to supply SUBOXONE® Film to the Canadian Federal Correction Institutions in Q3 2018. Supplemental New Drug Submission (SNDS) anticipated in Q1 2019; Pre-Submission meeting held with Health Canada on October 17<sup>th</sup>, 2018.
  - New Zealand: Submission plans ongoing.
  - Europe: Pre-Submission meeting held on October 18<sup>th</sup>, 2018 with BfArM (rapporteur) and HPRA (co-rapporteur).

#### **Treatment of Schizophrenia**

- **PERSERIS™ (formerly RBP-7000), Monthly Long-Acting Risperidone:**
  - FDA approval on July 27<sup>th</sup>, 2018.
  - Two PMC studies under planning phase:
    - Conduct a pharmacokinetic study that will evaluate exposure of PERSERIS™ that approximates daily administration of 6 mg oral risperidone.
    - Revise the drug product manufacturing process to include additional overfill for the 90 mg strength so that the delivered mass meets the labelled strength.
  - Initial availability expected in Q4 2018; Full promotional launch contingent upon PI against DRL being upheld by the CAFC.

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

- Arbaclofen Placabil: Manufacture of clinical trial supplies to support an alcohol interaction study in AUD and an absorption study in Alcohol Liver Disease with Cirrhosis (ALD+C).

#### **Early Stage Asset Development (ESAD)**

- **ADX71441 (GABA<sub>B</sub> positive allosteric modulator):**
  - Second Joint Research Committee (JRC) meeting on August 30<sup>th</sup>, 2018.
  - Dog EEG study to finalize the investigational new drug application (IND) preparation; dosing started September 11<sup>th</sup>, 2018. Four study sessions completed.
  - \$5.3m National Institute on Drug Abuse (NIDA) grant to support Phase 1 studies upon IND approval.
- **C4X3256 (Selective Orexin 1 [OX1] receptor antagonist):**
  - NIDA grant in the amount of \$500,000 awarded on June 29<sup>th</sup>, 2018 to assess the efficacy of C4X3256 in reducing the positive reinforcing effect of cocaine in rats that exhibit robust, stable levels of cocaine self-administration. Self-administration study started on August 15<sup>th</sup>, 2018.
  - Finalization of all preclinical study reports.
  - Formulation development and stability work to support First Time In Human (FTIH) studies.
  - Finalization of FTIH protocol, Investigators Brochure, Investigational Medicinal Product Dossier.
- **APV202701A (Selective dopamine [DA] D3 receptor antagonist):**
  - Initiation of IND dossier preparation.

## **Other Key Events**

### **• Peer-reviewed publications:**

- Ronquest NA, Willson TM, Montejano LB, Nadipelli VR, Wollschlaeger BA (2018) Relationship between buprenorphine adherence and relapse, health care utilization and costs in privately and publicly insured patients with opioid use disorder. *Subst Abuse Rehabil.* 9:1-20.
- Cicero TJ, Ellis MS, Chilcoat HD (2018) Understanding the use of diverted buprenorphine. *Drug and Alcohol Dependence.* In press.
- Haight BR, Learned SM, Laffont CM, Fudala PJ, Zhao Y, Garofalo AS, Greenwald MK, Nadipelli VR, Ling W, Heidbreder C (2018) Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicenter, randomized, double-blind, placebo-controlled trial. In press.
- Andorn A, Graham J, Csernansky J, Newcomer JW, Shinde S, Muma G, Heidbreder C, Fava M (2018) Monthly Extended-release Risperidone (RBP-7000) in the Treatment of Schizophrenia: Results from a Phase 3 Long-term Open-Label Study. Submitted.
- Ling W, Nadipelli V, Ronquest N, Albright V, Aldridge A, Learned S, Mehra V, Heidbreder C (2018) Remission from Chronic Opioid Use—Studying Environmental and Socio-economic Factors on Recovery (RECOVER): study design and participant characteristics. Submitted.
- Ling W, Nadipelli VR, Solem CT, Ronquest NA, Yeh Y-C, Learned SM, Mehra V, Heidbreder C (2018) Life-activity Outcomes in Participants of a Buprenorphine Monthly Depot (BUP-XR) Double-blind, Placebo-controlled, Multicenter, Phase 3 Study. Submitted.
- Dhanda R, Varghese D, Fava M, Solem C, Graham J, Learned SM, Heidbreder C, Nadipelli VR (2018) Health-related quality of life in schizophrenia patients treated with RBP-7000 once monthly risperidone: phase-3 open-label study. Submitted.
- Heidbreder C (2018) Fighting apathy and lack of awareness in the struggle against substance use disorder. Submitted.

### **• Peer-reviewed conference abstracts:**

- Haight, B., Andorn, A., Laffont, C., Young, M., Jones, A., Learned, S., Zhao, S., Heidbreder, C. (2018) RBP-6000 buprenorphine monthly depot demonstrates sustained clinical efficacy and safety in phase III opioid use disorder trials. *Deutscher Suchtkongress: September 17-19, Hamburg, Germany.*
- Haight, B., Andorn, A., Laffont, C., Young, M., Jones, A., Learned, S., Zhao, S., Heidbreder, C. (2018) RBP-6000 buprenorphine monthly depot demonstrates sustained clinical efficacy and safety in phase III opioid use disorder trials. *World Association on Dual Disorders 2nd World Congress (WADD), September 27-28, Florence, Italy.*
- Andorn, A., Haight, B., Greenwald, M.K., Zhao, S., Fox, N.L., Heidbreder, C., Learned, S.M. (2018) Higher Abstinence Rates with Greater Buprenorphine Exposure Among Patients Who Inject Opioids. *American College of Emergency Physicians (ACEP): October 1-4, San Diego, CA.*
- Gray, F., Andorn, A., Laffont, C.M., Young, M., Jones, A., Learned, S., Zhao, Y., Heidbreder, C. (2018) RBP-6000 buprenorphine monthly depot demonstrates sustained clinical efficacy and safety in phase III opioid use disorder (OUD) trials. *Federazione Italiana degli Operatori dei Dipartimenti e dei Servizi delle Dipendenze (FeDerSeD): October 24-26, Roma, Italy.*
- Shinde, S., Andorn, A., Graham, J., Muma, G., Swingle, D., Fava, M., Newcomer, J., Csernansky, J., Heidbreder, C. (2018) Long-Term Safety and Injection Site Tolerability of Monthly Extended-Release Risperidone Injections (RBP-7000) for the Treatment of Schizophrenia. *American Psychiatric Nurses Association (APNA): October 24-27, Columbus, OH.*
- Ling, W., Nadipelli, V.R., Solem, C.T., Ronquest, N., Yeh, Y.-C., Heidbreder, C., Learned, S.M., Mehra, V. (2018) Impact of RBP-6000 Buprenorphine monthly injection on Patient-Reported Outcomes: A long-term safety and tolerability study. *Proceedings of the 6th Annual Meeting of the Colorado Consortium for Prescription Drug Abuse Prevention (CCPDAP), October 25, Aurora, CO.*
- Andorn, A., Haight, B., Laffont, C., Young, M., Jones, A., Learned, S., Zhao, S., Heidbreder, C. (2018) RBP-6000 buprenorphine monthly depot demonstrates sustained clinical efficacy and safety in phase III opioid use disorder trials. *Proceedings of the 6th Annual Meeting of the Colorado Consortium for Prescription Drug Abuse Prevention (CCPDAP), October 25, Aurora, CO.*



- Graham, J., Andorn, A., Shinde, S., Muma, G., Swingle, D., Fava, M., Newcomer, J., Csernansky, J., Heidbreder, C. (2018) Efficacy and Safety of Monthly Extended-Release Risperidone Injection (RBP-7000) for the Treatment of Schizophrenia. American Psychiatric Nurses Association (APNA): October 24-27, Columbus, OH.
- Kaempf, G., Andorn, A., Shinde, S., Haight, B., Zhao, S., Heidbreder, C., Learned, S. (2018) Efficacy, Safety and Injection Site Tolerability of RBP-6000 in the Treatment of Opioid Use Disorder: Results From two Phase III Trials. Canadian Society of Addiction Medicine (CSAM): October 25-27, Vancouver, CN.
- Graham, J., Fava, M., Newcomer, J., Andorn, A., Shinde, S., Muma, G., Heidbreder, C. (2018) RBP-7000 for the Treatment of Schizophrenia: Efficacy and Safety Results from two Phase III Trials. U.S. Psychiatry & Mental Health Congress: October 25-28, Orlando, FL. Shinde, S., Andorn, A., Haight, B., Zhao, Y., Heidbreder, C., Learned, S.M. (2018) Long term Safety and Efficacy with RBP-6000 Monthly Buprenorphine Depot Injection for the Treatment of Opioid Use Disorder. 20th International Society of Addiction Medicine Annual Meeting (ISAM), November 3-6, Busan, South Korea.
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- Haight, B., Andorn, A., Zhao, S., Chilcoat, H., Heidbreder, C., Learned, S. (2018) Long-term Treatment Retention and Abstinence With RBP-6000 Buprenorphine Monthly Depot in Phase 3 OUD Studies American Academy of Addiction Psychiatry (AAAP): December 6-9, Bonita Springs, FL.
- Graham, J., Csernansky, J., Fava, M., Newcomer, J., Andorn, A., Shinde, S., Muma, G., Heidbreder, C. (2018) Long-Term Clinical Effectiveness of a New Monthly Extended-release Formulation of Risperidone (RBP-7000) for the Treatment of Schizophrenia. Am Coll of Neuropsychopharmacology (ACNP), December 9-13, Hollywood, 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 believes that it has strong defences in the antitrust and other litigations and is 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.
- 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. Fact discovery is closed. Expert discovery is set to begin in November, and motions for class certification are being briefed.
- 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. The Federal Circuit granted Dr. Reddy's motion to expedite the appeal of the preliminary injunction but denied Dr. Reddy's motion to stay the PI pending appeal. Indivior filed its reply brief on August 16, 2018. On October 4, 2018, the Federal Circuit heard oral argument on the PI appeal. The outcome of the PI appeal remains pending.

- 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.

- 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.
- On October 4, 2018, the USPTO declined to institute an IPR on the challenged claims of the '512 patent.
- Indivior believes this claim is without merit and will continue to vigorously defend this action.

#### **Estate of John Bradley Allen**

- On December 27th, 2016, the Estate of John Bradley Allen filed a civil complaint against Indivior, among other parties, in the Northern District of New York seeking relief under Connecticut's products liability and unfair trade practices statutes for damages allegedly caused by SUBOXONE®. Following a hearing on Indivior's motions to dismiss the lawsuit, the trial court exercised its discretion to dismiss the lawsuit without prejudice on the basis that the action is barred by the applicable statute of limitations. The time period for plaintiffs to file an appeal of this dismissal expired on September 10, 2018 without plaintiffs having filed an appeal.

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*.

On September 26<sup>th</sup>, the Group provided revised FY 2018 net revenue and adjusted net income guidance. The revised guidance chiefly assumes Dr. Reddy's Laboratories Ltd. (DRL) will continue to be prohibited from relaunching its FDA-approved generic buprenorphine/naloxone sublingual film product in the United States under the preliminary injunction (PI) that was granted to the Group by the U.S. District Court for the District of New Jersey (District Court) on July 13, 2018. Under the PI, DRL is enjoined by from using, engaging in the use, 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 the '305 Patent litigation has not yet been set, but analogs indicate a ruling could be expected sometime between H2 2019 and H2 2020. DRL appealed the grant of the PI and the bond amount to the U.S. Court of Appeals for the Federal Circuit (CAFC) and filed an Emergency Motion for a Stay of Injunction Pending Appeal and an Emergency Motion to Expedite Proceedings. On July 24th, Indivior filed its opposition to the two emergency motions. The CAFC granted DRL's motion to expedite the appeal of the preliminary injunction but denied their motion to stay the PI pending the appeal. On October 4, 2018, the Federal Circuit heard oral argument on the PI appeal. The outcome of the PI appeal remains pending. If the CAFC grants DRL's appeal and lifts the PI, DRL would likely relaunch its FDA-approved generic buprenorphine/naloxone sublingual film product at-risk in the United States. Based on

industry analogs, this would likely result in the Group's branded SUBOXONE® Film product rapidly losing market share, which would materially impact net revenue and net income. In addition, the Group may be liable to DRL for damages during the period of the injunction. In worst-case scenarios these combined effects could adversely impact the Group's ability to operate, require significant change to the structure of the business and recapitalization.

Other than in respect to the revised guidance for the full year 2018 explained above 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 Group's 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 anticipated 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 10 to 11 referring to the current status of Abbreviated New Drug Application (ANDA) litigation

and to the going concern statement on page 23 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 26 to 28.

- 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 pages 9 to 10 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 26 to 28.
- 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 OUD 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 pages 9 to 10 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 26 to 28.

### 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 Group 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:

	9 Months to September 30, 2018	9 Months to September 30, 2017
GB £ period end	1.3167	1.3387
GB £ average rate	1.3526	1.2748
€ Euro period end	1.1739	1.1748
€ Euro average	1.1953	1.1124

### Webcast Details

There will be a presentation at 8:00 a.m. US Eastern / 12:00 pm UK time hosted by Shaun Thaxter, CEO. This presentation will also be webcast live. The details are below and are available on the Company’s website at [www.indivior.com](http://www.indivior.com).

Webcast link: <https://edge.media-server.com/m6/p/bqwwyn7f>

**Confirmation Code:** **4593067**

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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 900 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit [www.indivior.com](http://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](http://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  $\geq 5\%$  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](http://www.sublocade.com).**

#### **ABOUT PERSERIS™**

#### **INDICATION**

PERSERIS™ (risperidone) is indicated for the treatment of schizophrenia in adults.

#### **WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

*See full prescribing information for complete boxed warning.*

- \* **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**
- \* **PERSERIS is not approved for use in patients with dementia-related psychosis.**

#### **CONTRAINDICATIONS**

PERSERIS should not be administered to patients with known hypersensitivity to risperidone, paliperidone, or other components of PERSERIS.

#### **WARNINGS AND PRECAUTIONS**

**Cerebrovascular Adverse Reactions, Including Stroke in Elderly Patients with Dementia-Related Psychosis:** Increased risk of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities. PERSERIS is not approved for use in patients with dementia-related psychosis.

**Neuroleptic Malignant Syndrome (NMS):** Manage with immediate discontinuation and close monitoring.

**Tardive Dyskinesia:** Discontinue treatment if clinically appropriate.

**Metabolic Changes:** Monitor for hyperglycemia, dyslipidemia and weight gain.

**Hyperprolactinemia:** Prolactin elevations occur and persist during chronic administration. Long-standing hyperprolactinemia, when associated with hypogonadism, may lead to decreased bone density in females and males.

**Orthostatic Hypotension:** Monitor heart rate and blood pressure and warn patients with known cardiovascular disease or cerebrovascular disease, and risk of dehydration or syncope.

**Leukopenia, Neutropenia, and Agranulocytosis:** Perform complete blood counts (CBC) in patients with a history of a clinically significant low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing PERSERIS if a clinically significant decline in WBC occurs in absence of other causative factors.

**Potential for Cognitive and Motor Impairment:** Use caution when operating machinery.

**Seizures:** Use caution in patients with a history of seizures or with conditions that lower the seizure threshold.

#### **ADVERSE REACTIONS**

The most common adverse reactions in clinical trials ( $\geq 5\%$  and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions ( $\geq 5\%$ ) were injection site pain and erythema (reddening of the skin).

For more information about PERSERIS™, the full prescribing information, including BOXED Warning, visit <https://www.perseris.com>.

## Condensed consolidated interim income statement

		Unaudited Q3 2018 \$m	Unaudited Q3 2017 \$m	Unaudited YTD 2018 \$m	Unaudited YTD 2017 \$m
<b>For the three and nine months ended September 30</b>	Notes				
<b>Net Revenues</b>	2	<b>245</b>	275	<b>768</b>	828
Cost of Sales		<b>(35)</b>	(27)	<b>(93)</b>	(72)
<b>Gross Profit</b>		<b>210</b>	248	<b>675</b>	756
Selling, general and administrative expenses	3	<b>(123)</b>	(162)	<b>(354)</b>	(381)
Research and development expenses	3	<b>(16)</b>	(23)	<b>(50)</b>	(67)
<b>Operating Profit</b>		<b>71</b>	63	<b>271</b>	308
Operating profit before exceptional items		<b>71</b>	63	<b>254</b>	333
Exceptional items	3	-	-	<b>17</b>	(25)
Finance income		<b>5</b>	2	<b>11</b>	5
Finance expense		<b>(8)</b>	(11)	<b>(25)</b>	(39)
<b>Profit before taxation</b>		<b>68</b>	54	<b>257</b>	274
Income tax benefit/(expense)		<b>21</b>	(4)	<b>(6)</b>	(71)
Taxation before exceptional items	5	<b>(10)</b>	(7)	<b>(35)</b>	(83)
Exceptional items within taxation	5	<b>31</b>	3	<b>29</b>	12
<b>Net income</b>		<b>89</b>	50	<b>251</b>	203

### Earnings per ordinary share (cents)

Basic earnings per share	6	<b>12</b>	7	<b>35</b>	28
Diluted earnings per share	6	<b>12</b>	7	<b>33</b>	27

## Condensed consolidated interim statement of comprehensive income

		Unaudited Q3 2018 \$m	Unaudited Q3 2017 \$m	Unaudited YTD 2018 \$m	Unaudited YTD 2017 \$m
<b>For the three and nine months ended September 30</b>					
Net income		<b>89</b>	50	<b>251</b>	203
<b>Other comprehensive income</b>					
<i>Items that may be reclassified to profit or loss in subsequent years:</i>					
Net exchange adjustments on foreign currency translation		<b>2</b>	3	<b>(8)</b>	6
Other comprehensive income/(loss)		<b>2</b>	3	<b>(8)</b>	6
<b>Total comprehensive income</b>		<b>91</b>	53	<b>243</b>	209

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

## Condensed consolidated interim balance sheet

	Notes	Unaudited Sep 30, 2018 \$m	Audited Dec 31, 2017 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		112	92
Property, plant and equipment		56	54
Deferred tax assets	5	68	58
Other assets		25	15
		<b>261</b>	<b>219</b>
<b>Current assets</b>			
Inventories		76	52
Trade and other receivables		263	278
Current tax receivable		54	32
Cash and cash equivalents	7	901	863
		<b>1,294</b>	<b>1,225</b>
<b>Total assets</b>		<b>1,555</b>	<b>1,444</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	7	(5)	(5)
Provisions	8	(186)	(143)
Trade and other payables	9	(660)	(665)
Current tax liabilities	5	(67)	(41)
		<b>(918)</b>	<b>(854)</b>
<b>Non-current liabilities</b>			
Borrowings	7	(324)	(477)
Provisions	8	(265)	(316)
		<b>(589)</b>	<b>(793)</b>
<b>Total liabilities</b>		<b>(1,507)</b>	<b>(1,647)</b>
<b>Net assets/(liabilities)</b>		<b>48</b>	<b>(203)</b>
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	10	73	72
Share premium		4	2
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(22)	(14)
Retained Earnings		1,288	1,032
<b>Total equity</b>		<b>48</b>	<b>(203)</b>

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
<b>Unaudited</b>						
<b>Balance at January 1, 2018</b>	<b>72</b>	<b>2</b>	<b>(1,295)</b>	<b>(14)</b>	<b>1,032</b>	<b>(203)</b>
<b>Comprehensive income</b>						
Net income	-	-	-	-	251	251
Other comprehensive income	-	-	-	(8)	-	(8)
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(8)</b>	<b>251</b>	<b>243</b>
<b>Transactions recognised directly in equity</b>						
Share-based plans	1	2	-	-	10	13
Deferred taxation on share-based plans	-	-	-	-	(5)	(5)
<b>Balance at September 30, 2018</b>	<b>73</b>	<b>4</b>	<b>(1,295)</b>	<b>(22)</b>	<b>1,288</b>	<b>48</b>
<b>Unaudited</b>						
<b>Balance at January 1, 2017</b>	<b>72</b>	<b>-</b>	<b>(1,295)</b>	<b>(22)</b>	<b>950</b>	<b>(295)</b>
<b>Comprehensive income</b>						
Net income	-	-	-	-	203	203
Other comprehensive income	-	-	-	6	-	6
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>6</b>	<b>203</b>	<b>209</b>
<b>Transactions recognised directly in equity</b>						
Share-based plans	-	2	-	-	10	12
Deferred taxation on share-based plans	-	-	-	-	-	-
<b>Balance at September 30, 2017</b>	<b>72</b>	<b>2</b>	<b>(1,295)</b>	<b>(16)</b>	<b>1,163</b>	<b>(74)</b>

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

## Condensed consolidated interim cash flow statement

	Unaudited 2018 \$m	Unaudited 2017 \$m
<b>For the nine months ended September 30</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit	271	308
Depreciation and amortization	11	9
Gain on disposal of intangible asset	(17)	-
Share-based payments	10	10
Impact from foreign exchange movements	1	6
Decrease/(Increase) in trade and other receivables	6	(20)
Increase in inventories	(27)	(5)
Decrease in trade and other payables	(8)	(34)
Decrease in provisions	(9)	-
<b>Cash generated from operations</b>	<b>238</b>	<b>274</b>
Interest paid	(19)	(27)
Interest received	11	5
Taxes paid	(16)	(19)
<b>Net cash inflow from operating activities</b>	<b>214</b>	<b>233</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(7)	(24)
Purchase of intangible assets	(29)	(14)
Proceeds from license of intangible assets	12	-
<b>Net cash outflow from investing activities</b>	<b>(24)</b>	<b>(38)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Repayment of borrowings	(154)	(86)
Proceeds from the issuance of ordinary shares	3	2
<b>Net cash outflow from financing activities</b>	<b>(151)</b>	<b>(84)</b>
<b>Net increase in cash and cash equivalents</b>	<b>39</b>	<b>111</b>
Cash and cash equivalents at beginning of the period	863	692
<b>Exchange differences</b>	<b>(1)</b>	<b>3</b>
<b>Cash and cash equivalents at end of the period</b>	<b>901</b>	<b>806</b>

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

## Notes to the condensed consolidated interim financial statements

### 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

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

These Interim Financial Statements have been prepared in conformity with IAS 34 *Interim Financial Reporting*. The financial information herein has been prepared in the basis of the accounting policies set out in the annual accounts of the Group for the year ended December 31, 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 January 1, 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 finalized.

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 on October 31, 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 loss of the preliminary injunction appeal at the Court of Appeals for the Federal Circuit discussed in Note 8 and 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 materially 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 and if the uptake of SUBLOCADE™ remains slower than expected. 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 revenues from continuing operations attributed to countries based on the country where the sale originates and non-current assets, net of accumulated depreciation and amortization, by country. Non-current assets for this purpose consist of property, plant and equipment, intangible assets, and other receivables. Revenues and non-current assets for the three and nine months to September 30, 2018 and 2017 were as follows:

Revenues from sale of goods:

	Q3 2018	Q3 2017	YTD 2018	YTD 2017
For the three and nine months ended September 30	\$m	\$m	\$m	\$m
United States	198	219	609	670
ROW	47	56	159	158
<b>Total</b>	<b>245</b>	<b>275</b>	<b>768</b>	<b>828</b>

Non-current assets:

	Sep 30, 2018 \$m	Dec 31, 2017 \$m
United States	93	68
ROW	100	93
<b>Total</b>	<b>193</b>	<b>161</b>

## 3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

	Q3 2018	Q3 2017	YTD 2018	YTD 2017
For the three and nine months ended September 30	\$m	\$m	\$m	\$m
Research and development expenses	(16)	(23)	(50)	(67)
Marketing, selling and distribution expenses	(51)	(42)	(151)	(112)
Administrative expenses	(68)	(113)	(188)	(255)
Depreciation and amortization	(3)	(5)	(11)	(9)
Operating lease rentals	(1)	(2)	(4)	(5)
<b>Total</b>	<b>(123)</b>	<b>(162)</b>	<b>(354)</b>	<b>(381)</b>

In 2018, \$8m of development costs relating to PERSERIS™ have been capitalized within intangible assets. Additionally, distribution costs of less than \$3m 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 approximately \$2m, is not material.

## Exceptional Items

	Q3 2018	Q3 2017	YTD 2018	YTD 2017
For the three and nine months ended September 30	\$m	\$m	\$m	\$m
Other operating income	-	-	17	-
Legal Expenses/Provision	-	-	-	(25)
<b>Total exceptional items before taxes</b>	<b>-</b>	<b>-</b>	<b>17</b>	<b>(25)</b>
Tax on exceptional items	-	-	(2)	9
Exceptional items within tax	31	3	31	3
<b>Total exceptional items</b>	<b>31</b>	<b>3</b>	<b>46</b>	<b>(13)</b>

\$17m of exceptional income in the current year to date 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. The tax charge on the exceptional item is \$2m (YTD 2017: \$9m tax benefit). Further, a tax benefit of \$31m has been recognized this quarter relating to a claim for orphan drug credit claimed in US (Q3 2017: \$3m release of provisions for unresolved tax matters).



#### 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 YTD/Q3 2018 and YTD/Q3 2017.

##### Reconciliation of operating profit to adjusted operating profit

	Q3 2018 \$m	Q3 2017 \$m	YTD 2018 \$m	YTD 2017 \$m
<b>For the nine months ended September 30</b>				
<b>Operating profit</b>	<b>71</b>	<b>63</b>	<b>271</b>	<b>308</b>
Exceptional selling, general and administrative expenses	-	-	-	25
Exceptional operating income	-	-	(17)	-
<b>Adjusted operating profit</b>	<b>71</b>	<b>63</b>	<b>254</b>	<b>333</b>

##### Reconciliation of net income to adjusted net income

	Q3 2018 \$m	Q3 2017 \$m	YTD 2018 \$m	YTD 2017 \$m
<b>For the nine months ended September 30</b>				
<b>Net Income</b>	<b>89</b>	<b>50</b>	<b>251</b>	<b>203</b>
Exceptional selling, general and administrative expenses	-	-	-	25
Exceptional operating income	-	-	(17)	-
Exceptional tax items	(31)	(3)	(29)	(12)
<b>Adjusted net income</b>	<b>58</b>	<b>47</b>	<b>205</b>	<b>216</b>

#### 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 Q3 2018, the tax charge on adjusted profits amounted to \$10m excluding exceptionals (Q3 2017: \$7m) and represented a quarterly effective tax rate of 15% (Q3 2017: 13% excluding exceptionals). The Group's balance sheet at September 30, 2018 included current tax payables of \$67m (FY 2017: \$41m), current tax receivables of \$54m (FY 2017: \$32m), and deferred tax assets of \$68m (FY 2017: \$58m). The current tax payable balance is higher due to timing of expenses versus payments and is expected to reduce prior to year-end. The current tax receivable increased due to the booking of the exceptional tax credit and could reduce by year end based on timing of refunds. The deferred tax asset has increased over prior year balances due to current year activity.

In YTD 2018, the tax charge on adjusted profits amounted to \$35m (YTD 2017: \$83m) excluding exceptionals and represented a YTD tax rate of 15% (YTD 2017: 28%, excluding exceptionals).

The decrease in the adjusted 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.

In YTD 2018, there was an exceptional tax credit of \$31m in relation to the US orphan drug credit claimed for prior years along with tax on exceptional income of \$2m. Prior YTD tax expense included \$9m of tax related to the tax effects of the exceptional items within operating profit and a release of provisions for unresolved tax matters of \$3m.

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

	Q3 2018 cents	Q3 2017 cents	YTD 2018 cents	YTD 2017 cents
<b>For the three and nine months ended September 30</b>				
Basic earnings per share	<b>12</b>	7	<b>35</b>	28
Diluted earnings per share	<b>12</b>	7	<b>33</b>	27
Adjusted basic earnings per share	<b>8</b>	7	<b>28</b>	30
Adjusted diluted earnings per share	<b>8</b>	6	<b>27</b>	29

##### 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	726,721	720,714
Dilution from share awards and options	23,274	27,930
On a diluted basis	749,995	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

<b>Current</b>	Sep 30 2018 \$m	Dec 31 2017 \$m
Bank loans	(5)	(5)
	(5)	(5)
<b>Non-current</b>	Sep 30 2018 \$m	Dec 31 2017 \$m
Bank loans	(324)	(477)
	(324)	(477)
<b>Analysis of net debt</b>	Sep 30 2018 \$m	Dec 31 2017 \$m
Cash and cash equivalents	901	863
Borrowings*	(332)	(487)
	569	376

\*Borrowings reflects the principal amount drawn before debt issuance costs of \$3m (FY 2017: \$5m).

<b>Reconciliation of net debt</b>	Sep 30 2018 \$m	Dec 31 2017 \$m
The movements in the period were as follows:		
Net cash at beginning of period	376	131
Net increase in cash and cash equivalents	38	171
Repayment of borrowings	154	86
Exchange adjustments	1	(12)
Net cash at end of period	569	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 September 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.

## 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 believes that it has strong defences in the antitrust and other litigations and is 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.
- 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. Fact discovery is closed. Expert discovery is set to begin in November, and motions for class certification are being briefed.
- 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. The Federal Circuit granted Dr. Reddy's motion to expedite the appeal of the preliminary injunction but denied Dr. Reddy's motion to stay the PI pending appeal. Indivior filed its reply brief on August 16, 2018. On October 4, 2018, the Federal Circuit heard oral argument on the PI appeal. The outcome of the PI appeal remains pending.

- 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.
- 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.
- On October 4, 2018, the USPTO declined to institute an IPR on the challenged claims of the '512 patent.
- Indivior believes this claim is without merit and will continue to vigorously defend this action.

#### **Estate of John Bradley Allen**

- On December 27th, 2016, the Estate of John Bradley Allen filed a civil complaint against Indivior, among other parties, in the Northern District of New York seeking relief under Connecticut's products liability and unfair trade practices statutes for damages allegedly caused by SUBOXONE®. Following a hearing on Indivior's motions to dismiss the lawsuit, the trial court exercised its discretion to dismiss the lawsuit without prejudice on the basis that the action is barred by the applicable statute of limitations. The time period for plaintiffs to file an appeal of this dismissal expired on September 10, 2018 without plaintiffs having filed an appeal.

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

	Sep 30 2018 \$m	Dec 31 2017 \$m
Sales returns and rebates	(455)	(433)
Trade payables	(42)	(40)
Accruals	(147)	(179)
Other tax and social security payables	(16)	(13)
<b>Total</b>	<b>(660)</b>	<b>(665)</b>

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			
<b>At January 1, 2018</b>	<b>721,462,733</b>	<b>\$0.10</b>	<b>72</b>
Allotments	6,844,104	\$0.10	1
<b>At September 30, 2018</b>	<b>728,306,837</b>		<b>73</b>

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2017	720,597,566	\$0.10	72
Allotments	865,167	\$0.10	-
At September 30, 2017	721,462,733		72

### Allotment of ordinary shares

During the period, 6,844,104 ordinary shares (2017: 865,167) 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 October 16, 2018, Indivior became entitled to a milestone payment of approximately \$19m relating to the out-licensing of nasal naloxone opioid overdose patents. This will be reflected as exceptional pre-tax income in our 2018 full year results.

In the Half Year 2018 results, the Group announced its intention to implement a program to streamline the Group and reduce certain costs. This resulted in a reduction in headcount of over 150 employees in October 2018. Incremental costs to affect the savings will be reflected as an exceptional charge in Q4 2018.

## 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 nine months and their impact on the condensed set of financial statements, and a description of the principal risks and uncertainties for the remaining three months of the financial year; and
  - material related-party transactions in the first nine 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 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](http://www.indivior.com)

By order of the Board

Shaun Thaxter  
Chief Executive Officer

Mark Crossley  
Chief Financial Officer

October 31, 2018

# Independent review report to Indivior PLC

## Report on the condensed consolidated interim financial statements

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### Our conclusion

We have reviewed Indivior PLC's condensed consolidated interim financial statements (the "interim financial statements") in the Nine Month Financial Results Release of Indivior PLC for the three and nine month periods ended 30 September 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.

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### 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.

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### 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.

The Directors have already started to take the required steps to reduce the cost base. However, any combination of the above events, the most significant impact being the launch of a generic, would require further significant cost savings and 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 further, 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.

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### What we have reviewed

The interim financial statements comprise:

- the Condensed consolidated interim balance sheet as at 30 September 2018;
- the Condensed consolidated interim income statement and Condensed consolidated statement of comprehensive income for the three and nine month periods then ended;
- the Condensed consolidated interim cash flow statement for the nine month period then ended;
- the Condensed consolidated interim statement of changes in equity for the nine month period then ended; and
- the explanatory notes to the interim financial statements.

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

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

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## Responsibilities for the interim financial statements and the review

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### Our responsibilities and those of the directors

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

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

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### 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 Nine Month Financial Results Release and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP  
Chartered Accountants  
London  
31 October 2018