



February 14, 2019

**FY 2018 Adjusted Financial Results In-Line with Guidance. FY 2019 SUBLOCADE™ Guidance Introduced.**

Period to December 31st	Q4 2018 \$m	Q4 2017 \$m	% Δ Actual FX	% Δ Constant FX	FY 2018 \$m	FY 2017 \$m	% Δ Actual FX	% Δ Constant FX
Net Revenue	236	265	-11	-10	1,005	1,093	-8	-9
Operating Profit/(Loss)	20	(115)	*	*	292	193	+51	+48
Net Income/(Loss)	24	(145)	*	*	275	58	*	*
EPS/(Loss) (cents per share)	3	(20)	*	*	38	8	*	*
Adjusted Operating Profit <sup>1</sup>	78	70	+11	+10	332	403	-18	-19
Adjusted Net Income <sup>1</sup>	67	54	+24	+22	272	270	+1	-
Adjusted EPS <sup>1</sup>	9	7	+29	+22	37	37	-	-

<sup>1</sup>Adjusted basis excludes the impact of exceptional items as referenced in Notes 3 and 4. \* Not meaningful.

This release contains inside information

**Full Year 2018 Financial Highlights**

- Net revenue of \$1,005m, a decrease of 8% versus prior year (-9% at constant exchange). U.S. market growth was more than offset by U.S. SUBOXONE® Film share loss, targeted rebating and mix impact from growth in government channels (Medicaid).
- Operating profit was \$292m (FY 2017: \$193m). On an adjusted basis, FY 2018 operating profit was \$332m, a decrease of 18% (Adj. FY 2017: \$403m). Lower net revenue and higher SUBLOCADE™ and PERSERIS™ launch investments were partially offset by impacts from operating expense reductions.
- Net income was \$275m (FY 2017: \$58m). On an adjusted basis, FY 2018 net income was \$272m +1% (Adj. FY 2017: \$270m). Lower adjusted operating profit was more than offset by lower net financing costs and effective tax rate.
- Cash balance at FY 2018 of \$924m (+\$61m). Net cash of \$681m (+\$305m). Voluntary repayments of \$235m on the Term Loan were made in the period; \$243m remains outstanding.

**Key Operating Developments**

- U.S. SUBOXONE® Film market share averaged and exited FY 2018 at 53%.
- The Court of Appeals for the Federal Circuit (CAFC) has denied Indivior's motion for rehearing and rehearing *en banc* following the CAFC's ruling vacating the preliminary injunction (PI) granted against Dr. Reddy's Laboratories (DRL). The CAFC has also denied Indivior's emergency motions with the CAFC to stay issuance of the mandate pending resolution of Indivior's appeal of the District of Delaware's decision finding DRL does not infringe U.S. Patent No. 8,603,514 ("the '514 patent"), and pending Indivior's forthcoming petition for a writ of certiorari to the Supreme Court of the United States in the PI matter. The CAFC has ordered issuance of the mandate on February 19, 2019. In response, Indivior will file a petition with the Supreme Court of the United States to stay the mandate pending the outcome of the forthcoming petition for certiorari seeking to overturn the CAFC's PI vacatur. If the mandate issues, Indivior assumes that DRL and Alvogen Pine Brook LLC will launch their generic buprenorphine/naloxone sublingual film products on an "at-risk" basis, leading to rapid and material loss of market share for SUBOXONE® Film. It is possible that other companies may also subsequently launch generic buprenorphine/naloxone sublingual film products on an "at-risk" basis. Indivior has been preparing for this eventuality and has implemented certain key elements of its contingency plan in light of these expected generic launches (see details on Page 2).

- SUBLOCADE™ net revenues were \$12m, including \$7m in Q4 2018. Key performance indicators (KPIs) continue to improve (see page 4).
- PERSERIS™ was made available in the U.S. in late November 2018. Commercial launch will take place the week of February 18, 2019 with a field force of 50 representatives.
- Reached a definitive agreement (February 4, 2019) to divest rights related to SUBOXONE® Sublingual Tablets (Sai Bo Song™) in the Peoples Republic of China to Zhejiang Pukang Biotechnology Co., Ltd. (Pukang) for total potential consideration of up to \$122.5m based on achieving certain milestones. The agreement is subject to various closing conditions and is anticipated to close in Q4 2019.
- Termination of Arbaclofen Placabil and ADDEX lead compound due to challenges in their Phase 1 and preclinical studies, respectively, reducing their probability of success below hurdle rates for further investment. This decision does not change our reason to believe in the molecular target (GABAB receptor) and plans are currently being put in place to accelerate our backup program (new lead identification and optimization) in partnership with ADDEX.
- The Group continues in advanced discussions with the U.S. Department of Justice (DOJ) about a possible resolution to its investigations. Please see Notes 8, 9 and 10 beginning on page 22 for further details on provisions and legal proceeding.

### Contingency Plan

Indivior has implemented key elements of its contingency plan to help offset the substantial and material near-term impact to net revenue that is expected to result from the “at-risk” launch of generic versions of SUBOXONE® film. The overriding objectives of the contingency plan are to provide for the commercial success of SUBLOCADE™ and PERSERIS™ while ensuring a minimum cash balance of \$250m to remain in compliance with the Group’s debt covenants. Key actions include:

- Reducing outstanding principal on the Term Loan by \$235m in FY 2018 to \$243m;
- Cash conservation measures resulting in FY 2018 ending cash balance of \$924m;
- Initiatives to reduce structural operating expenses, including headcount reductions, R&D reprioritization and other committed savings; and,
- Additionally, Indivior expects to launch an Authorized Generic of SUBOXONE® Film upon confirmation of the launch of generic buprenorphine/naloxone sublingual film products. The launch is expected to capture share of the generic segment and generate an amount of net revenue in the range of tens of U.S.\$ millions.

### FY 2019 Guidance

Given uncertainties surrounding how the U.S. market for both SUBOXONE® Film and generic alternatives will ultimately develop, Indivior is unable to provide FY 2019 net revenue and net income guidance at this time.

However, Indivior is providing guidance on the following elements of its business for FY 2019:

- SUBLOCADE net revenue of \$50m to \$70m; and,
- Operating expenses (SG&A and R&D combined) of approximately \$440m to \$460m, excluding exceptional items.

As discussed above, Indivior has executed key elements of its contingency plan. Its overriding objectives are to ensure a minimum cash balance of \$250m to remain in compliance with its debt covenants and to help provide resources to cover the transition period of expected material and rapid loss of SUBOXONE® film net revenue in the U.S. until combined net revenue from SUBLOCADE™ and PERSERIS™, along with continued net revenue from the rest of world (ROW), is able to return the Group to profitable growth.

Indivior intends to provide FY 2019 Group net revenue and net income guidance (before exceptionals and currency) once the total U.S. buprenorphine/naloxone sublingual film market dynamics are clearer, which is anticipated to be at its Q1 2019 results release scheduled for May 2, 2019.

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

“FY 2018 brought a series of market challenges which resulted in Indivior delivering lower net revenue and only slightly higher adjusted net income compared to the prior year. As we enter FY 2019, we assume we face the imminent “at-risk” launch of generic rivals to SUBOXONE® Film in the U.S. We have prudently prepared for this event, planning and taking the required actions to help ensure we can deliver on our strategic priorities despite the near-term top-line pressures that generic competition to SUBOXONE® Film will bring. Specifically, we have:

- Maintained our focus on cash generation and preserved our balance sheet;
- Continued to assert our IP against the ANDA filers;
- Completed steps that have appropriately adjusted our operating structure;
- Repaid \$235m of outstanding Term Loan balance to lower the outstanding balance to \$243m; and,
- Prepared the launch of an authorized generic of buprenorphine/naloxone sublingual film to participate in the rapidly forming generic market for buprenorphine/naloxone sublingual film.

Together, these actions are designed to help us remain compliant with our borrowing covenants and help the Group to leverage the profitable long-term growth we expect from our new transformational depot technologies.

- In SUBLOCADE™, we are making progress toward a truly new treatment paradigm for OUD patients and the opioid crisis, and the coming year will see us further strengthen our execution in pursuit of our \$1bn-plus net revenue target. With PERSERIS™ we believe we have a differentiated long-acting injectable treatment for schizophrenia, a common co-occurrence of substance use disorders, and the long-sought strategic opportunity we have created to diversify our revenue base. We are confident these products will be the future value drivers of Indivior and our focus in 2019 will be on their successful commercial execution.
- Of course, we could not drive these new launches, together with our base film and tablet business, without our talented and committed global workforce. We are truly grateful that – despite the recent period of disruption and uncertainty – the new organization that has emerged this year is energized and optimistic.
- Finally, in everything we do we think first and foremost about the patient. Our inspiration is to improve the lives of the many patients across all walks of society who suffer from the chronic relapsing conditions of addiction and its co-occurring disorders. This relentless patient-centricity, along with maintaining the highest regulatory and compliance standards, provides the foundational elements of Indivior’s long-term success.”

### FY Operating Review

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

In 2018, market volume for buprenorphine products continued to grow at low-teen percentage rates, in line with Indivior’s expectations. This volume growth was driven by benefits from legislation and regulatory changes that have increased federal and state funding to expand OUD treatment, as well as from broader 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 of the SUPPORT for Patients and Communities Act of 2018, which expands access to buprenorphine medication-assisted treatment (BMAT). These regulatory and legislative initiatives are supporting greater treatment capacity for those in most need and are likely to be manifested in continued growth in lower-priced government channels, such as Medicaid.

As the leader and innovator in the OUD category, Indivior has launched its new monthly buprenorphine depot SUBLOCADE™. The Group is making good progress in the following KPIs that it believes will drive accelerated net revenue growth for SUBLOCADE™ in pursuit of its \$1 billion-plus peak net revenue goal:

SUBLOCADE™ Prescription Journey Timeline KPIs (12/31/18 vs. 9/30/18):

- Formulary Access – reached targeted levels, exiting FY 2018 at 83%.
- The Prescription Journey – reached targeted levels, exiting FY 2018 at 15 to 22 days.
- The Dispensing Yield Rate – increased to 41% from 38%.

SUBLOCADE™ Demand KPIs (12/31/18 vs. 9/30/18):

- HCPs Initiating a Prescription Journey – increased to 2,430 versus 1,870.
- HCPs Administered SUBLOCADE™ – increased to 1,325 versus 824.
- HCPs Administered SUBLOCADE™ to 5-plus patients increased to 232 versus 108.

**FY 2018 & Q4 2018 Financial Performance**

Total net revenue in FY 2018 decreased 8% to \$1,005m (FY 2017: \$1,093m) at actual exchange rates (-9% at constant exchange rates). In FY 2018, volume improvement from underlying market expansion in the U.S. and net revenue contribution from SUBLOCADE™ (FY 2018: \$12m) were more than offset by the combined impacts of unfavorable mix from the increase in government channels (Medicaid) in the U.S., targeted rebating to maintain formulary access and a decline in SUBOXONE® Film market share. In Q4 2018, total net revenue decreased 11% at actual and 10% at constant exchange rates to \$236m (Q4 2017: \$265m). Along with higher SUBOXONE® Film stocking levels in the U.S. versus Q4 2017, Q4 2018 total net revenue drivers were substantially the same as those for FY 2018. Q4 2018 SUBLOCADE™ net revenue was \$7m.

FY 2018 U.S. net revenue decreased 10% to \$790m (FY 2017: \$877m) and declined 12% in Q4 2018 to \$182m (Q4 2017: \$207m). For both comparative periods, volume benefits from underlying market growth were more than offset by the combined impacts of unfavorable mix from the continued disproportionate growth in government channels (Medicaid), targeted rebating to maintain formulary access and the decline in SUBOXONE® Film market share as a result of competitive pricing pressure from generic buprenorphine/naloxone tablet providers. Improved SUBOXONE® Film pricing was more than offset by tactical rebating activity in connection with formulary access. In Q4 2018, there was higher SUBOXONE® Film stocking levels in the U.S. versus Q4 2017 due to increased anticipation by distributor partners of an “at-risk” generic launch after the CAFC’s decision on November 20, 2018, to vacate the preliminary injunction (PI) previously granted Indivior against DRL. This increase was more than offset by unfavorable mix and higher rebate rates as discussed for the full year.

FY 2018 ROW net revenue decreased 1% at actual exchange rates (3% at constant exchange rates) to \$215m (FY 2017: \$216m). In Q4 2018, ROW net revenue decreased 7% at actual exchange rates (1% at constant exchange rates) to \$54m (Q4 2017: \$58m). For both comparative periods, continued growth in Australasia and Canada were more than offset by impacts in certain European markets from ongoing austerity measures.

FY 2018 gross margin was 87% (FY 2017: 90%) and the gross margin was also 85% in Q4 2018 (Q4 2017: 88%). The decrease in both periods versus the prior year primarily reflects lower net revenue driven by higher rebate rates and unfavorable mix and the impact of contingency planning for an “at-risk” launch of a generic buprenorphine/naloxone sublingual film product.

FY 2018 SG&A expenses as reported were \$494m (FY 2017: \$707m) and \$140m in Q4 2018 (Q4 2017: \$326m). FY 2018 SG&A included net exceptional costs of \$16m. The exceptional costs comprised \$13m related to restructuring and \$40m related primarily to potential redress for ongoing intellectual property related litigation, partially offset by a \$37m gain from the out-licensing of the intranasal naloxone opioid overdose patents. FY 2017 results included exceptional items of \$210m for an increased legal provision related to investigative and antitrust litigation matters and the legal settlement of the Amneal antitrust matter, partially offset by the release of a legacy litigation reserve.

Q4 2018 SG&A included net exceptional costs of \$34m. The exceptional costs comprised \$13m related to restructuring and \$40m related primarily to potential redress for ongoing intellectual property related litigation,

partially offset by an exceptional gain of \$19m related to a further payment for the intranasal naloxone opioid overdose patents as discussed above. Q4 2017 SG&A included total exceptional costs of \$185m for the increased legal provision partially offset by the release of a legacy litigation reserve as described above.

On an adjusted basis, FY 2018 SG&A expenses decreased 4% to \$478m (Adj. FY 2017: \$497m) and in Q4 2018 SG&A expenses decreased by 25% to \$106m (Adj. Q4 2017: \$141m). The decrease in both periods largely reflects benefits from cost savings actions partially offset by the planned investments for launching SUBLOCADE™ and PERSERIS™.

Reported FY 2018 and Q4 2018 R&D expenses were \$91m and \$41m, respectively (FY 2017: \$89m; Q4 2017: \$22m). The increase was primarily driven by the Q4 2018 impairment of the Arbaclofen Placarbil and ADDEX lead compounds in development, which have been classified as exceptional items. Excluding exceptionals, FY 2018 and Q4 2018 R&D expenses decreased by 25% to \$67m and by 23% to \$17m, respectively (Adj. FY 2017: \$89m; Adj. Q4 2017: \$22m). The decreases in both periods primarily reflect lower clinical activity and the reprioritization of R&D activities primarily to support SUBLOCADE™ Health Economics and Outcomes Research (HEOR) and post-marketing study commitments.

FY 2018 operating profit was \$292m (FY 2017: \$193m) and Q4 2018 operating profit was \$20m (Q4 2017 operating loss: \$115m). Exceptional costs of \$40m and \$210m are included in the FY 2018 and FY 2017 results, respectively. Exceptional costs of \$58m and \$185m are included in Q4 2018 and Q4 2017, respectively.

On an adjusted basis, FY 2018 operating profit was \$332m (33% margin), an 18% decrease versus \$403m (37% margin) in FY 2017. The decrease reflects lower net revenue, launch investments for SUBLOCADE™ and PERSERIS™, partly offset by a reduction in operating expenses (SG&A and R&D) from cost savings initiatives. On an adjusted basis, Q4 2018 operating profit was \$78m (33% margin), an 11% increase versus \$70m (26% margin) in Q4 2017. The increase reflects benefits from cost savings initiatives that more than offset lower net revenue.

FY 2018 EBITDA (operating profit plus depreciation and amortization) was \$308m (FY 2017: \$206m). Excluding \$40m and \$210m of exceptional items in the current and year-ago results, respectively, FY 2018 adjusted EBITDA was \$348m (Adj. FY 2017: \$416m).

FY 2018 net finance expense was \$14m (FY 2017: \$56m) and nil in Q4 2018 (Q4 2017: \$22m). 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 the voluntary repayments of \$235m of the principal balance in the year (\$85m in Q4 2018), and higher interest income.

FY 2018 total tax expense was \$3m, or a rate of 1% (FY 2017 tax charge: \$79m; 58% rate). FY 2018 tax charge included one-time items related to development credits for SUBLOCADE™ of \$34m, including \$1m interest. FY 2017 full-year tax charge also assumed non-deductibility for tax purposes of the exceptional legal provisions and included \$9m related to the release of provisions for unresolved tax matters, partially offset by the impact of the remeasurement of certain deferred tax assets. Excluding exceptional items in FY 2018 pre-tax income and taxation of \$46m (FY 2017: \$91m), the adjusted rate was 15% (Adj. FY 2017: 25%). The decrease in the adjusted rate was due to changes in the geographic mix of earnings, with increased earnings in the UK under the reduced rate for Patent Box, along with a reduction in the U.S. corporate income tax rate from 35% to 21%. Q4 2018 tax credit was \$4m (Q4 2017 charge: \$8m), or a rate of -20% (Q4 2017: 6%). Q4 2018 included a \$10m tax impact on exceptional items and \$5m of exceptional tax items; \$2m relating to finalization of prior year US rate change and \$3m to the finalization of prior year development credits for SUBLOCADE™ (Q4 2017: \$6m release of provisions for unresolved tax matters fully offset by \$6m of taxes on exceptional items). The adjusted tax rate for the quarter was 14% (Q4 2017: 13%)

FY 2018 net income was \$275m (FY 2017: \$58m) as reported. Excluding exceptional costs, FY 2018 net income was broadly unchanged at \$272m (Adj. FY 2017: \$270m). The current and year-ago annual periods include a net

amount of \$3m and \$212m of exceptional items, respectively. In Q4 2018, net income was \$24m (Q4 2017 net loss: \$145m). Excluding exceptional costs, net income for the Q4 was \$67m (Adj. Q4 2017: \$54m). Q4 2018 and Q4 2017 include a net \$43m and \$199m of exceptional items, respectively.

FY 2018 basic EPS was 38 cents (FY 2017: 8 cents) and 37 cents on a diluted basis (FY 2017: 8 cents). On an adjusted basis, excluding the effect of exceptional items, FY 2017 basic EPS was 37 cents (FY 2017: 37 cents) and diluted EPS was 36 cents (FY 2017: 36 cents).

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

Cash and cash equivalents at the end of FY 2018 were \$924m, an increase of \$61m versus FY 2017 of \$863m. Borrowings, net of issuance costs, were \$241m at the end of the year (FY 2017: \$482m), primarily reflecting the impact of the voluntary repayments of \$235m of outstanding Term Loan principal in H2 2018. As a result, net cash stood at \$681m at year end (FY 2017: \$376), a \$305m improvement in the year.

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative \$356m at year end, an increase of \$21m from negative \$335m since the end of FY 2017 primarily driven by an increase in sales returns and rebates in the U.S. within payables, partially offset by increased inventories due in part to the launch of SUBLOCADE™.

Cash generated from operations in FY 2018 was \$327m (FY 2017: \$369m), a decrease of \$42m. The reduction in cash generated versus the year-ago period was primarily due to higher operating profit more than offset by a lower increase in legal provisions versus the prior year, net of other working capital changes.

FY 2018 net cash inflow from operating activities was \$303m (FY 2017: \$295m), an increase of \$8m reflecting lower cash from operations more than offset by lower net interest payments of \$8m vs. \$36m in the prior year and reduced tax payments of \$16m vs. \$33m in 2017.

FY 2018 cash outflow from investing activities was \$4m (FY 2017: \$43m), reflecting upfront payments for licensing arrangements with ADDEX and C4X, capitalized development costs, and ongoing investments in facilities, mostly offset by proceeds received from the disposal of the nasal naloxone intangible asset.

FY 2018 cash outflow from financing activities increased to \$237m vs. \$84m in FY 2017, primarily reflecting the impact of the voluntary repayments of \$235m of the outstanding Term Loan balance in H2 2018.

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

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

- **SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE INJECTION) FOR SUBCUTANEOUS USE CIII:**
  - SUBLOCADE™ approval in Canada on November 21, 2018.
  - In the US, all Post Marketing Requirement (PMR) and Commitment (PMC) studies are on track.
  - Lifecycle Evidence Generation & Optimization (LEGO) Studies: These studies are dedicated to understand the use of diverted buprenorphine (see our publication list), to demonstrate that craving can be used as an endpoint to predict illicit opioid use, to study the effects of SUBLOCADE™ in the emergency room environment to prevent repeated opioid overdoses and potentially change standards of care, and to investigate how SUBLOCADE™ could potentially block the effects of respiratory depression produced by fentanyl that has been increasingly and directly related to drug overdose deaths in the United States. All studies are on track.
  - RECOVER Study (REmission from Chronic Opioid use: studying enVironmental and socioEconomic factors on Recovery): This is a study collecting up to 24-month longitudinal data encompassing demographics, drug use, drug treatment, family relationships, quality of life, mental and physical health, health-care utilization, crime, housing, employment, and urine drug screening (see our publication list). The 12-month longitudinal analysis top line findings were made available in December 2018; the 24-month last patient out is currently scheduled for March 5, 2019.
  - SUBLOCADE™ ex-US regulatory filings: Filings were made in Australia (May 2018), Israel (July 2018), New Zealand (September 2018) and Europe (November 2018).



- **SUBOXONE® Tablet:**
  - On September 11, 2018, the Chinese National Medical Products Administration (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.
  - On February 4, 2019, announced a definitive agreement to divest the rights related to SUBOXONE® Sublingual Tablets (Sai Bo Song™) in China to Zhejiang Pukang Biotechnology Co., Ltd. (Pukang) for total potential consideration of up to \$122.5m based on achieving certain development and commercial milestones. The agreement is subject to various closing conditions and is anticipated to close in Q4 2019.
- **SUBOXONE® Film:**
  - Israel: Submission on September 3, 2018.
  - Canada: Activities ongoing to supply SUBOXONE® Film to the Canadian Federal Correction Institutions in Q3 2018. Supplemental New Drug Submission (SNDS) anticipated in Q2 2019; Pre-Submission meeting held with Health Canada on October 17, 2018.
  - Europe: Pre-Submission meeting held on October 18, 2018 with BfArM (rapporteur) and HPRA (co-rapporteur); Planned MAA submission in the EU in March 2019.

#### Treatment of Schizophrenia

- **PERSERIS™ (formerly RBP-7000), Monthly Long-Acting Risperidone Injection:**
  - FDA approval on July 27, 2018.
  - Initiation of planning and execution of post-marketing and lifecycle management strategies in support of PERSERIS™.

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

- **Arbaclofen Placabil (AP):** Although the overall profile of AP was significantly improved as a result of INDIVIOR'S clinical development and reformulation plans, risks related to variability in absorption and enzyme polymorphism still remain and would have to be addressed unequivocally before committing to further development.
- Decision to stop any further development of AP and rather focus on the development of the GABA<sub>B</sub> positive allosteric modulator family of molecules through our partnership with ADDEX Therapeutics.

#### Early Stage Asset Development (ESAD)

- **ADX71441 (GABA<sub>B</sub> positive allosteric modulator):**
  - Dog EEG study to finalize IND preparation revealed risks narrowing the potential therapeutic window.
  - Decision to stop the development of the lead molecule ADX71441. This decision does not change our reason to believe in the molecular target (GABA<sub>B</sub> receptor) and plans are currently being put in place to accelerate our backup program (new lead identification & optimization) in partnership with ADDEX Therapeutics.
  - **Continuing partnership** covers \$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, 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, 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.

### **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. doi: <https://dx.doi.org/10.2147%2FSAR.S150253>
- Cicero TJ, Ellis MS, Chilcoat HD (2018) Understanding the use of diverted buprenorphine. *Drug and Alcohol Dependence* 193: 117-123. doi: <https://dx.doi.org/10.1016/j.drugalcdep.2018.09.007>
- Heidbreder C (2018) Fighting apathy and lack of awareness in the struggle against substance use disorder. *Nature Reviews Drug Discovery* 17(11): B8-9. <https://biopharmadealmakers.nature.com/pages/npg-latest-edition-bpdm>
- Wang XY, Jiang H, Zhao M, Li J, Gray F, Sheng L, Li Y, Li X, Ling W, Li W, Hao W. Treatment of opioid dependence with buprenorphine/naloxone sublingual tablets: A phase 3 randomized, double-blind, placebo-controlled trial. *Asia-Pacific Psychiatry.* 2018; e12344. <https://doi.org/10.1111/appy.12344>
- 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. *Contemporary Clinical Trials*, 76: 93-103. <https://doi.org/10.1016/j.cct.2018.11.015>
- 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 multicentre, randomised, double-blind, placebo-controlled trial. *The Lancet* (submitted).

### **Risk Factors**

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

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

#### **Business operations**

- The Group's operations rely on complex processes and systems, strategic partnerships, as well as specially qualified and high performing personnel to develop, manufacture and sell our products. Failure to continuously maintain operational processes and systems as well as to recruit and/or retain qualified personnel could adversely impact products availability and patient health, and ultimately the Group's performance and financials. Additionally, an ever evolving regulatory, political and technological landscape requires that we have the right priorities, capabilities and structures in place to successfully execute on our business strategy and adapt to this changing environment. An example of this evolving landscape is Brexit (decision for the UK to leave the EU), which creates uncertainties and impacts various areas of the Group, including Operations, Regulatory, Supply Chain, and Quality.

#### **Product pipeline, regulatory and safety**

- The development and approval of the Group's products is an inherently risky and lengthy process requiring significant financial, research and development resources, and strategic partnerships. Complex regulations with strict and high safety standards govern the development, manufacturing, and distribution of our products. In addition, strong competition exists for strategic collaboration, licensing arrangements, and acquisition targets. Patient safety depends on our ability to perform robust safety assessment and interpretation to ensure that appropriate decisions are made regarding to the benefit/risk profiles of our products. Deviations from these quality and safety practices can impact patient safety and market access, which can have a material effect on our Group's performance and prospects.

#### **Commercialization**

- Successful commercialization of our products is a critical factor for the Group's sustained growth and robust financial position. Launch of new product involves substantial investment in marketing, market access and sales activities, product stocks, and other investments. If commercialization of a new product is not as successful as anticipated this could have a material impact on the Group's performance and prospects. Generic and brand competition, pricing pressures, private and government reimbursement schemes and systems, negotiations with payors, erosion and/or infringement of



intellectual property (IP) rights, political and socioeconomic factors and HCP/Patient adoption and adherence, if different than anticipated, also can significantly impact the Group's performance and position.

### **Economic & Financial**

- The nature of the pharmaceutical business is inherently risky and uncertain and requires that we make significant financial investments to develop and support the success of our product portfolio. External financing is a key factor in sustaining our financial position and expanding our business growth. Our ability to realize value on those investments is often dependent upon regulatory approvals, market acceptance, strategic partnerships, competition, and legal developments. As a global business, we are also subject to political, economic, and capital markets changes.

### **Supply Chain**

- The manufacturing and supply of our products are highly complex and rely on a combination of internal manufacturing capabilities and third parties for the timely supply of our finished drug and combination drug products. The Group has a single source of supply for buprenorphine, an active product ingredient (API) in the Group's products, and uses contract manufacturing organizations (CMOs) to manufacture, package and distribute our products. The manufacturing of non-sterile pharmaceutical and sterile filled, pharma/combination drug products is subject to stringent global regulatory quality and safety standards, including Good Manufacturing Practice (GMP). Delays or interruptions in our supply chain, and/or product quality failures could significantly disrupt patient access, adversely impact the Group's financial performance; lead to product recalls, and/or potential regulatory actions against the company, along with reputational damages.

### **Legal & Intellectual Property**

- Our pharmaceutical operations, which include controlled substances, are subject to a wide range of laws and regulations from various governmental and non-governmental bodies. Perceived noncompliance with these applicable laws and regulations may result in investigations or proceedings leading the Group to become subject to civil or criminal sanctions and/or pay fines and/or damages, as well as reputational damages.
- Intellectual Property (IP) rights protecting our products may be challenged by external parties, including generic manufacturers. Although we have developed robust patent protection for our products, we are exposed to the risk that courts may decide that our IP rights are invalid and/or that third parties do not infringe our asserted IP rights.
- Unfavorable outcome from government investigations and/or resolutions from legal proceedings, expiry and/or loss of IP rights could have a material adverse impact on the Group's prospects, results of operations and financial condition.
- As previously disclosed in the Prospectus dated November 17, 2014, Indivior has indemnification obligations in favor of Reckitt Benckiser (RB). See further information on legal proceedings in note 10 on pages 23 to 25.

### **Compliance Product Safety**

- Our Group operates on a global basis and the pharmaceutical industry is both highly competitive and regulated. Complying with all applicable laws and regulations, including engaging in commercial activities that are consistent with legal and, industry standards, and our Group's Code of Conduct are core to the Group's mission, culture, and practices. Failure to comply with applicable laws and regulations may subject the Group to civil, criminal and administrative liability, including the imposition of substantial monetary penalties, fines, damages and restructuring the Group's operations through the imposition of compliance or integrity obligations and have a potential adverse impact on the Group's prospects, reputation, results of operations and financial condition.

The Group's annual report for the 2018 financial year will contain additional detail on these principal business risks together with a report on risk appetite.

### **Exchange Rates**

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

	<b>FY 2018</b>	<b>FY 2017</b>
GB £ period end	1.2746	1.3513
GB £ average rate	1.3362	1.2881
€ Euro period end	1.1451	1.2001
€ Euro average rate	1.1819	1.1287

## Webcast Details

There will be a presentation at 11:30 GMT (6:30 am Eastern in the USA) hosted by Shaun Thaxter, CEO. This presentation will also be webcast live. The details are below and are available on the Indivior's website at [www.indivior.com](http://www.indivior.com).

Webcast link: <https://edge.media-server.com/m6/p/at8xatmw>

**Confirmation Code:** **2271449**  
Participants, Local - London, United Kingdom: +44(0)2071 928338  
Participants, Local - New York, United States of America: +1 877 870 9135

## For Further Information

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**Corporate Website** [www.indivior.com](http://www.indivior.com)

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

## Forward-Looking Statements

This announcement contains certain statements that are forward-looking. By their nature, forward-looking statements involve risks and uncertainties 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 2019 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

Various factors may cause differences between Indivior's expectations and actual results, including, among others (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in this release): 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, if at all; 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.

Consequently, forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

## SUBOXONE® (BUPRENORPHINE AND NALOXONE) SUBLINGUAL FILM (CIII)

### Indication

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII) is a prescription medicine indicated for treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

**Treatment should be initiated under the direction of healthcare providers qualified under the Drug Addiction Treatment Act.**

### Important Safety Information

Do not take SUBOXONE® Film if you are allergic to buprenorphine or naloxone as serious negative effects, including anaphylactic shock, have been reported.

SUBOXONE® Film can be abused in a manner similar to other opioids, legal or illicit.

SUBOXONE® Film contains buprenorphine, an opioid that can cause physical dependence with chronic use. Physical dependence is not the same as addiction. Your healthcare provider can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE® Film suddenly without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

SUBOXONE® Film can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other medications that act on the nervous system (ie, sedatives, tranquilizers, or alcohol). It is extremely dangerous to take nonprescribed benzodiazepines or other medications that act on the nervous system while taking SUBOXONE® Film.

You should not drink alcohol while taking SUBOXONE® Film, as this can lead to loss of consciousness or even death.

Death has been reported in those who are not opioid dependent.

Your healthcare provider may monitor liver function before and during treatment.

SUBOXONE® Film is not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. However, SUBOXONE® Film may be used with caution for maintenance treatment in patients with moderate hepatic impairment who have initiated treatment on a buprenorphine product without naloxone.

Keep SUBOXONE® Film out of the sight and reach of children. Accidental or deliberate ingestion of SUBOXONE® Film by a child can cause severe breathing problems and death.

Do not take SUBOXONE® Film before the effects of other opioids (eg, heroin, hydrocodone, methadone, morphine, oxycodone) have subsided as you may experience withdrawal symptoms.

Injecting the SUBOXONE® Film product may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

Before taking SUBOXONE® Film, tell your healthcare provider if you are pregnant or plan to become pregnant. If you are pregnant, tell your healthcare provider as withdrawal signs and symptoms should be monitored closely and the dose adjusted as necessary. If you are pregnant or become pregnant while taking SUBOXONE® Film, alert your healthcare provider immediately and you should report it using the contact information provided below.

Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor.

Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy, whether that use is medically authorized or illicit. Unlike opioid withdrawal syndrome in adults, NOWS may be life-threatening if not recognized and treated in the neonate. Healthcare professionals should observe newborns for signs of NOWS and manage accordingly.

Before taking SUBOXONE® Film, talk to your healthcare provider if you are breastfeeding or plan to breastfeed your baby. The active ingredients of SUBOXONE® Film can pass into your breast milk. You and your healthcare provider should consider the development and health benefits of breastfeeding along with your clinical need for SUBOXONE® Film and should also consider any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBOXONE® Film affects you. Buprenorphine in SUBOXONE® Film can cause drowsiness and slow reaction times during dose-adjustment periods.

Common side effects of SUBOXONE® Film include nausea, vomiting, drug withdrawal syndrome, headache, sweating, numb mouth, constipation, painful tongue, redness of the mouth, intoxication (feeling lightheaded or drunk), disturbance in attention, irregular heartbeat, decrease in sleep, blurred vision, back pain, fainting, dizziness, and sleepiness.

This is not a complete list of potential adverse events associated with SUBOXONE® Film. Please see [full Prescribing Information www.suboxoneREMS.com](http://www.suboxoneREMS.com) for a complete list.

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

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

## SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE) INJECTION FOR SUBCUTANEOUS USE (CIII)

### INDICATION AND HIGHLIGHTED SAFETY INFORMATION

#### INDICATION

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

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

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

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

#### HIGHLIGHTED SAFETY INFORMATION

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

#### CONTRAINDICATIONS

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

#### WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

#### ADVERSE REACTIONS

Adverse reactions commonly associated with SUBLOCADE (in ≥5% of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.

For more information about SUBLOCADE, the full Prescribing Information including BOXED WARNING, and Medication Guide visit [www.sublocade.com](http://www.sublocade.com).

**PERSERIS™ (risperidone) for extended-release injectable suspension**

**INDICATION AND HIGHLIGHTED SAFETY INFORMATION**

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 (≥ 5% and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions (≥ 5%) were injection site pain and erythema (reddening of the skin).

For more information about PERSERIS, the full Prescribing Information including BOXED WARNING, and Medication Guide visit [www.perseris.com](http://www.perseris.com).

## Condensed consolidated income statement

For the three and twelve months ended December 31	Notes	Unaudited	Unaudited	Unaudited	Audited
		Q4 2018 \$m	Q4 2017 \$m	FY 2018 \$m	FY 2017 \$m
<b>Net Revenues</b>	2	<b>236</b>	265	<b>1,005</b>	1,093
Cost of Sales		<b>(35)</b>	(32)	<b>(128)</b>	(104)
<b>Gross Profit</b>		<b>201</b>	233	<b>877</b>	989
Selling, general and administrative expenses	3	<b>(140)</b>	(326)	<b>(494)</b>	(707)
Research and development expenses	3	<b>(41)</b>	(22)	<b>(91)</b>	(89)
<b>Operating Profit</b>		<b>20</b>	(115)	<b>292</b>	193
Operating profit before exceptional items		<b>78</b>	70	<b>332</b>	403
Exceptional items	3	<b>(58)</b>	(185)	<b>(40)</b>	(210)
Finance income		<b>6</b>	2	<b>17</b>	7
Finance expense		<b>(6)</b>	(24)	<b>(31)</b>	(63)
Net finance expense before exceptional items		-	(8)	<b>(14)</b>	(42)
Exceptional items		-	(14)	-	(14)
<b>Profit before taxation</b>		<b>20</b>	(137)	<b>278</b>	137
Income tax benefit/(expense)		<b>4</b>	(8)	<b>(3)</b>	(79)
Taxation before exceptional items	5	<b>(11)</b>	(8)	(46)	(91)
Exceptional items within taxation	3,5	<b>15</b>	-	<b>43</b>	12
<b>Net income</b>		<b>24</b>	(145)	<b>275</b>	58
<b>Earnings per ordinary share (cents)</b>					
Basic earnings per share	6	<b>3</b>	(20)	<b>38</b>	8
Diluted earnings per share	6	<b>3</b>	(20)	<b>37</b>	8

## Condensed consolidated statement of comprehensive income

For the three and twelve months ended December 31	Unaudited	Unaudited	Unaudited	Audited
	Q4 2018 \$m	Q4 2017 \$m	FY 2018 \$m	FY 2017 \$m
Net income	<b>24</b>	(145)	<b>275</b>	58
<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>(10)</b>	2	<b>(18)</b>	8
Other comprehensive income/(loss)	<b>(10)</b>	2	<b>(18)</b>	8
<b>Total comprehensive income</b>	<b>14</b>	(143)	<b>257</b>	66

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



## Condensed consolidated balance sheet

	Notes	Unaudited Dec 31, 2018 \$m	Audited Dec 31, 2017 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		84	92
Property, plant and equipment		57	54
Deferred tax assets	5	44	58
Other assets		33	15
		<b>218</b>	<b>219</b>
<b>Current assets</b>			
Inventories		78	52
Trade and other receivables		287	278
Current tax receivable		40	32
Cash and cash equivalents		924	863
		<b>1,329</b>	<b>1,225</b>
<b>Total assets</b>		<b>1,547</b>	<b>1,444</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	7	(4)	(5)
Provisions	8	(69)	(143)
Trade and other payables	11	(721)	(665)
Current tax liabilities	5	(24)	(41)
		<b>(818)</b>	<b>(854)</b>
<b>Non-current liabilities</b>			
Borrowings	7	(237)	(477)
Provisions	8	(424)	(316)
Other non-current liabilities		(2)	-
		<b>(663)</b>	<b>(793)</b>
<b>Total liabilities</b>		<b>(1,481)</b>	<b>(1,647)</b>
<b>Net assets/(liabilities)</b>		<b>66</b>	<b>(203)</b>
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	12	73	72
Share premium		5	2
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(32)	(14)
Retained Earnings		1,315	1,032
<b>Total equity</b>		<b>66</b>	<b>(203)</b>

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

## Condensed consolidated statement of changes in equity

	Notes	Share capital	Share Premium	Other reserve	Foreign Currency Translation reserve	Retained earnings	Total equity
		\$m	\$m	\$m	\$m	\$m	\$m
<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		-	-	-	-	275	275
Other comprehensive income		-	-	-	(18)	-	(18)
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>(18)</b>	<b>275</b>	<b>257</b>
<b>Transactions recognised directly in equity</b>							
Share-based plans		1	3	-	-	15	19
Deferred taxation on share-based plans		-	-	-	-	(7)	(7)
<b>Balance at December 31, 2018</b>		<b>73</b>	<b>5</b>	<b>(1,295)</b>	<b>(32)</b>	<b>1,315</b>	<b>66</b>
<b>Audited</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		-	-	-	-	58	58
Other comprehensive income		-	-	-	8	-	8
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>8</b>	<b>58</b>	<b>66</b>
<b>Transactions recognised directly in equity</b>							
Share-based plans		-	2	-	-	16	18
Deferred taxation on share-based plans		-	-	-	-	8	8
<b>Balance at December 31, 2017</b>		<b>72</b>	<b>2</b>	<b>(1,295)</b>	<b>(14)</b>	<b>1,032</b>	<b>(203)</b>

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

## Condensed consolidated cash flow statement

	Unaudited 2018 \$m	Audited 2017 \$m
<b>For the twelve months ended December 31</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit	292	193
Depreciation, amortization, and impairment	40	13
Gain on disposal of intangible asset	(37)	-
Share-based payments	15	16
Impact from foreign exchange movements	(12)	6
Increase in trade and other receivables	(33)	(59)
Increase in inventories	(31)	(6)
Increase in trade and other payables	58	5
Increase in provisions	35	201
<b>Cash generated from operations</b>	<b>327</b>	<b>369</b>
Interest paid	(25)	(41)
Interest received	17	5
Transaction cost related to loan	-	(5)
Taxes paid	(16)	(33)
<b>Net cash inflow from operating activities</b>	<b>303</b>	<b>295</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(11)	(30)
Purchase of intangible assets	(30)	(13)
Proceeds from license of intangible assets	37	-
<b>Net cash outflow from investing activities</b>	<b>(4)</b>	<b>(43)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from borrowings	-	487
Repayment of borrowings	(240)	(573)
Proceeds from the issuance of ordinary shares	3	2
<b>Net cash outflow from financing activities</b>	<b>(237)</b>	<b>(84)</b>
<b>Net increase in cash and cash equivalents</b>	<b>62</b>	<b>168</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>924</b>	<b>863</b>

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

## Notes to the condensed consolidated financial statements

### 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

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

The financial information herein has been prepared in the basis of the accounting policies set out in the annual accounts of the Group for the year ended December 31, 2017 and should be read in conjunction with those annual accounts, except with regards to IFRS 9 and 15 which were implemented in 2018. No standards or interpretations have been adopted before the required implementation date. The Group prepares its annual accounts in accordance with International Financial Reporting Standards (IFRS) and IFRS Interpretations Committee (IFRIC) interpretations as adopted by the European Union and the Companies Act 2006 (the Act) applicable to companies reporting under IFRS. In preparing these condensed consolidated financial statements, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the consolidated financial statements for the year ended December 31, 2017, with the exception of changes in estimates that are required in determining the provision for income taxes and legal provision.

These consolidated 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. There will be a more detailed disclosure related to this in the 2018 Annual Report.

The Group adopted IFRS 16 on January 1, 2019. On adoption of IFRS 16, the Group recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 Leases. Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of lease payments which are discounted using the group's incremental borrowing rate as of January 1, 2019. The Group applied the modified retrospective approach, which requires the recognition of the cumulative effect of initially applying IFRS 16, as of January 1, 2019, to the retained earnings.

In 2019, the Group will recognize \$29 million of right-of-use assets and \$33 million of lease liabilities and an impact to beginning retained earnings of \$4 million. There will be a more detailed disclosure related to the Group's adoption of IFRS 16 in the 2018 Annual Report.

The condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual financial statements as at December 31, 2017. These condensed consolidated financial Statements have been reviewed and not audited. These condensed consolidated financial statements were approved for issue on February 13, 2019.

As disclosed in Note 8, the Group carries a provision of \$438m substantially all relating to the Department of Justice investigations. The final settlement amount may be materially higher than this provision or require payment over a shorter period, which, together with higher than expected loss of revenue following the 'at-risk' launch of generic buprenorphine/naloxone sublingual film products, or the failure for new products to meet revenue growth expectations, could impact the Group's ability to operate. The Directors have taken significant steps to reduce the cost base of the business and manage its capital structure and believe the Group has sufficient liquidity, influence over near-term litigation outcomes and the ability to carry out further measures that may be necessary for the Group to continue as a going concern for at least the next twelve months. However, a combination of the above risks may require additional measures such as further cost savings or a change to the litigation strategy. As such, 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 Financial Statements do not include the adjustments that would result if the Group were unable to continue as a going concern. The auditors have indicated that, consistent with the prior year, they expect to include "material uncertainty relating to going concern" and "emphasis of matter in relation to the outcome of litigation" sections within their auditors' report for the 31 December 2018 statutory accounts.

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 predominately 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 net revenues to third parties, operating expenses by function, and financial results on a consolidated basis for evaluating financial performance and allocating resources. Accordingly, the Group operates in a single reportable segment.

### Net revenues

Revenues are attributed to countries based on the country where the sale originates. The following table represents net 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. Net revenues and non-current assets for the three and twelve months to December 31, 2018 and 2017 were as follows:

Net revenues from sale of goods:

	Q4 2018	Q4 2017	FY 2018	FY 2017
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
United States	182	207	790	877
ROW	54	58	215	216
<b>Total</b>	<b>236</b>	<b>265</b>	<b>1,005</b>	<b>1,093</b>

Non-current assets:

	Dec 31, 2018	Dec 31, 2017
	\$m	\$m
United States	62	68
ROW	112	93
<b>Total</b>	<b>174</b>	<b>161</b>

### 3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

	Q4 2018	Q4 2017	FY 2018	FY 2017
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
Research and development expenses <sup>1</sup>	(41)	(22)	(91)	(89)
Marketing, selling and general expenses <sup>2</sup>	(53)	(51)	(205)	(163)
Administrative expenses <sup>3</sup>	(82)	(270)	(271)	(525)
Depreciation and amortization	(4)	(4)	(13)	(13)
Operating lease rentals	(1)	(1)	(5)	(6)
<b>Total</b>	<b>(140)</b>	<b>(326)</b>	<b>(494)</b>	<b>(707)</b>

<sup>1</sup> R&D expenses include \$24m of impairment costs that have been classified as exceptional as outlined in the table below.

<sup>2</sup> Distribution costs of \$3m previously included in operating expenses have been classified as 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 \$3m, is not material.

<sup>3</sup> Administrative expenses include exceptional costs in the current and prior year as outlined in table below. Prior year administrative expenses also included non-exceptional expenses of \$36m related to the ongoing protection of the company's intellectual property. These costs were not classified as exceptionals as they primarily related to non-litigation expenses for the ongoing protection of the Group's prospective revenues.

### Exceptional Items

	Q4 2018	Q4 2017	FY 2018	FY 2017
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
Other operating income <sup>1</sup>	19	-	37	-
Restructuring costs <sup>2</sup>	(13)	-	(13)	-
Legal Expenses/Provision <sup>3</sup>	(40)	(185)	(40)	(210)
Intangible impairment (R&D) <sup>4</sup>	(24)	-	(24)	-
Financing costs (debt refinancing) <sup>5</sup>	-	(14)	-	(14)
<b>Total exceptional items before taxes</b>	<b>(58)</b>	<b>(199)</b>	<b>(40)</b>	<b>(224)</b>
Tax on exceptional items	10	(6)	8	3
Exceptional benefits within tax <sup>6</sup>	5	6	35	9
<b>Total exceptional items</b>	<b>(43)</b>	<b>(199)</b>	<b>3</b>	<b>(212)</b>

<sup>1</sup> \$37m of exceptional income in FY 2018 (\$19m in Q4) relates to the proceeds received from the out-licensing of nasal naloxone opioid overdose patents which are included within SG&A.

<sup>2</sup> Restructuring costs relate to the cost savings initiative announced in the HY 2018 results to offset the financial impact of recent adverse U.S. market developments. These consist primarily of redundancy and related costs.

<sup>3</sup> \$40m of legal expenses in the current year and quarter relate to potential redress for ongoing intellectual property related litigation with DRL and Rhodes Pharmaceuticals. Exceptional expense of \$185m in Q4 2017 reflects the increased legal provision related to investigative and antitrust litigation matters,

partially offset by the reversal of a legacy litigation reserve. FY 2017 reflects the \$185m and an additional \$25m for the conclusive legal settlement with Amneal Pharmaceuticals LLC relating to anti-trust litigation.

<sup>4</sup>In 2018, Q4 and FY R&D expenses include \$24m of impairment charges related to the Arbaclofen Placarbil and lead ADDEX compounds for which development has ceased due to challenges in the Phase 1 and preclinical studies, respectively thereby reduction of their probability of success below hurdle rates for further investment.

<sup>5</sup>Financing costs of \$14m, written off due to the early debt refinancing, were accounted for as a significant modification in accordance with IAS 39 'Financial Instruments: Recognition and Measurement' based on legal release of the debt, the change in currency profile of the overall debt, and the removal and relaxation of financial covenants.

<sup>6</sup>The tax benefit of \$5m for Q4 2018 consists of \$2m relating to finalization of US tax reform change and \$3m to the finalization of prior year development credits for SUBLOCADE™ (Q4 2017: \$6m release of provisions for unresolved tax matters). In FY 2018, there was an exceptional tax credit of \$34m in relation to development credits for SUBLOCADE™ claimed for prior years, rate change impact in the US of \$1m, along with tax on exceptional income and other adjustments of \$8m. Prior year tax exceptionals of \$9m related to the release of provisions for unresolved tax matter partially offset by the impact of the remeasurement of deferred tax asset along with the tax on exceptional income.

#### 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 FY/Q4 2018 and FY/Q4 2017.

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

	Q4 2018 \$m	Q4 2017 \$m	FY 2018 \$m	FY 2017 \$m
<b>For the three and twelve months ended December 31</b>				
<b>Operating profit</b>	<b>20</b>	<b>(115)</b>	<b>292</b>	<b>193</b>
Exceptional selling, general and administrative expenses	34	185	16	210
Exceptional research and development expenses	24	-	24	-
<b>Adjusted operating profit</b>	<b>78</b>	<b>70</b>	<b>332</b>	<b>403</b>

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

	Q4 2018 \$m	Q4 2017 \$m	FY 2018 \$m	FY 2017 \$m
<b>For the three and twelve months ended December 31</b>				
<b>Net Income</b>	<b>24</b>	<b>(145)</b>	<b>275</b>	<b>58</b>
Exceptional selling, general and administrative expenses	34	185	16	210
Exceptional research and development expenses	24	-	24	-
Exceptional financing costs	-	14	-	14
Exceptional tax items	(15)	-	(43)	(12)
<b>Adjusted net income</b>	<b>67</b>	<b>54</b>	<b>272</b>	<b>270</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 Q4 2018, the tax expense on adjusted profits amounted to \$11m excluding exceptionals (Q4 2017: \$8m) and represented a quarterly effective tax rate of 14% (Q4 2017: 13% excluding exceptionals). A tax benefit of \$5m was recognized this quarter; \$2m relating to finalization of prior year US rate change and \$3m to the finalization of prior year development credits for SUBLOCADE™ (Q4 2017: \$6m release of provisions for unresolved tax matters). The tax rates as reported for the quarter was -20% (Q4 2017: 6%)

In FY 2018, the tax charge on adjusted profits amounted to \$46m (FY 2017: \$91m) excluding exceptionals and represented a FY tax rate of 15% (FY 2017: 25%, 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 in the next year.

In FY 2018, there was an exceptional tax credit of \$34m in relation to development credits for SUBLOCADE™ claimed for prior years, rate change impact in the US of \$2m, along with tax on exceptional income and other adjustments of \$8m. Prior FY tax expense included \$9m of tax relating to a release of provisions for unresolved tax matters, netted by the impact of the re-measurement of deferred tax assets, and are exceptional and \$3m related to the tax effects of the exceptional items within operating profit.

The Group's balance sheet at December 31, 2018 included current tax payables of \$24m (FY 2017: \$41m), current tax receivables of \$40m (FY 2017: \$32m), and deferred tax assets of \$44m (FY 2017: \$58m). The current tax receivable increased due to the booking of the



exceptional tax credit. The deferred tax asset has decreased over prior year balances due to current year activity, largely relating the share award vestings and a decline in share price as at the reporting date.

#### Other tax matters

The European Commission has announced their intention to open a State Aid investigation into the UK's controlled foreign company ("CFC") financing exemption. At 31 December 2018, the Group has benefited from the UK controlled foreign company financing exemption by approximately \$24 million; however, at present the Group believes no provision is required in respect of this matter.

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

	Q4 2018	Q4 2017	FY 2018	FY 2017
For the three and twelve months ended December 31	cents	cents	cents	cents
Basic earnings per share	3	(20)	38	8
Diluted earnings per share	3	(20)	37	8
Adjusted basic earnings per share	9	7	37	37
Adjusted diluted earnings per share	9	7	36	36

#### 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	727,148	721,126
Dilution from share awards and options	23,994	27,356
On a diluted basis	751,142	748,482

#### 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

	Dec 31 2018 \$m	Dec 31 2017 \$m
<b>Current</b>		
Bank loans	(4)	(5)
	(4)	(5)
<b>Non-current</b>		
Bank loans	(237)	(477)
	(237)	(477)
<b>Analysis of net debt</b>		
Cash and cash equivalents	924	863
Borrowings*	(243)	(487)
	681	376

\*Borrowings reflects the principal amount drawn before debt issuance costs of \$2m (FY 2017: \$5m).

	Dec 31 2018 \$m	Dec 31 2017 \$m
<b>Reconciliation of net debt</b>		
The movements in the period were as follows:		
Net cash at beginning of period	376	131
Net increase in cash and cash equivalents	61	171
Net repayment of borrowings	240	86
Exchange adjustments	4	(12)
Net cash at end of period	681	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 December 31, 2018 are as follows:

	Currency	Nominal interest margin	Maturity	Required annual repayments	Maximum leverage ratio
Term loan facility	USD	Libor (1%) + 4.5%	2022	1%	3.0*

- Nominal interest margin is calculated over three-month 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 divided by Adjusted EBITDA ratio) which stands at 3.0x.

## 8. PROVISIONS

	Dec 31 2018 \$m	Dec 31 2017 \$m
Litigation matters	(438)	(438)
Intellectual property related matters	(44)	(19)
Restructuring Program	(8)	-
Other	(3)	(2)
Total	(493)	(459)

The Group is involved in legal and intellectual property disputes as described in Note 10, Legal Proceedings.

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.

In the event the final settlement amount of the DOJ matter is materially higher than the provision or is required to be paid over a shorter period of time, and the Group is further adversely impacted by higher than expected loss of revenue following the 'at-risk' launch of generic buprenorphine/naloxone sublingual film products or the failure for new products to meet revenue growth expectations, the

Group would not continue in business without taking further necessary measures to reduce its cost base and improve its cash flow. The Directors have taken significant steps to reduce the cost base of the business and manage its capital structure. However, a combination of the above risks may require additional measures such as further cost savings or a change to the litigation strategy.

The Group also carries provisions totalling \$44m for intellectual property related matters, \$40m of these relate to potential redress for ongoing intellectual property related litigation with DRL and Rhodes Pharmaceuticals and have been classified as exceptional costs (see note 3).

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

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.

## 9. CONTINGENT LIABILITIES

Other than the disputes for which provisions have been taken as disclosed in Note 8, 'Provisions' or as separately disclosed in Note 5, 'Taxation', reliable estimates could not be made of the potential range of cost required to settle legal or intellectual property disputes where the possibility of losses is more than remote. Descriptions of the significant tax, legal and other disputes to which the Group is a party are set out in Note 5, 'Taxation' and Note 10, 'Legal Proceedings.'

## 10. LEGAL PROCEEDINGS

### Litigation Matters

#### *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.
- Civil antitrust claims have been filed by (a) a putative class of direct purchasers, (b) a putative class of end payor purchasers, (c) Amneal Pharmaceuticals LLC (Amneal), a manufacturer of generic buprenorphine / naloxone tablets, and (d) a group of states, now numbering 41, and the District of Columbia. Each set of plaintiffs filed generally similar claims alleging, among other things, that Indivior violated U.S. federal and/or state antitrust and consumer protection laws in attempting to delay generic entry of alternatives to SUBOXONE® tablets. Plaintiffs further allege that Indivior unlawfully acted to lower the market share of these products. The Group has settled the dispute with Amneal, and Amneal has dismissed its claims against the Group with prejudice. The other antitrust cases are pending in federal court in the Eastern District of Pennsylvania. Pre-trial proceedings were coordinated. The fact discovery period has closed; expert discovery and briefing on class certification issues is ongoing. This States' lawsuit relates to the antitrust investigation conducted by various states, as discussed in previous filings.

#### *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®. This lawsuit was dismissed without prejudice on August 9, 2018.

### **Opioid Class Action Litigation**

- In February 2019, Indivior PLC, along with other manufacturers of opioid products, was named in the national civil opioid class action litigation brought by state and local governments, alleging misleading marketing messages. This complaint was filed by several Kentucky public health agencies in the class action consolidated in the federal district court for the Northern District of Ohio. Indivior has not been served with the complaint, but these claims present the potential that the company could be found liable for civil damages in this and other civil opioid class actions.

### **Intellectual property related matters**

#### **ANDA Litigation**

- Actavis is currently enjoined from launching a generic buprenorphine/naloxone film product until April 2024 based on a June 3, 2016 ruling by the United States District Court for the District of Delaware finding the asserted claims of 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. Litigation against Actavis is also pending in the District of Delaware on Indivior's more recently listed Orange Book Patents: U.S. Patent Nos. 9,687,454 (the '454 Patent), and 9,931,305 (the '305 Patent).
- On August 31, 2017, the United States District Court for the District of Delaware found 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 are valid but not infringed DRL. Indivior has appealed this ruling. Litigation against DRL is currently pending in the District of New Jersey on the '454 and '305 patents. DRL 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 United States District Court for the District of New Jersey seeking a Temporary Restraining Order (TRO) and Preliminary Injunction (PI) pending the outcome of a trial on the merits of the '305 Patent. The court granted Indivior a two-week TRO, preventing DRL from continuing to sell or offer to sell its generic product. Indivior was required to post an \$18 million surety bond to cover DRL's damages in the event of an Indivior loss of its patent case against DRL. On June 28, 2018, the court heard oral argument in support of Indivior's motion for a PI against DRL and, at the conclusion of this hearing, 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 DRL. 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. DRL appealed to the United States Court of Appeals for the Federal Circuit (CAFC) on the same day. On November 20, 2018, the CAFC issued a decision vacating the PI against DRL. Indivior filed a timely petition for rehearing and rehearing en banc on December 20, 2018. The CAFC denied the petition on February 4, 2019. On February 5, 2019, Indivior filed an emergency motion to stay the issuance of mandate pending the resolution of the appeal of the District of Delaware decision with respect to the '514 patent, and pending Indivior's forthcoming petition for a writ of certiorari to the Supreme Court of the United States in the PI matter. The CAFC denied that motion on February 11, 2019, and Indivior filed a second emergency motion to stay the mandate pending resolution of its forthcoming application for an administrative stay to the Supreme Court of the United States. The CAFC denied that motion and ordered issuance of the mandate on February 19, 2019. Indivior will file an application to the Supreme Court of the United States requesting a stay of the mandate pending resolution of its forthcoming petition for *certiorari* seeking to overturn the CAFC's PI vacatur. Any DRL generic product sales in the U.S. would be on an "at-risk" basis, subject to the outcome of the appeal of the non-infringement judgment related to U.S. Patent Nos. 8,603,514, as well as the ongoing litigation against DRL in the District of New Jersey. On February 12, 2019, the CAFC granted Indivior's request to expedite the appeal of the non-infringement judgment in the '514 patent case to the extent it will be placed on the next available oral argument calendar.
- On November 13, 2018, DRL filed two separate petitions for *inter partes review* of the '454 Patent with the USPTO. Indivior's preliminary responses are due March 6, 2019 and March 7, 2019.
- Teva filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of buprenorphine/naloxone film (CASSIPA™). 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. Litigation is ongoing against Teva in the District of New Jersey on the '454 patent and '305 patent. Teva received final approval from the FDA for CASSIPA on September 7, 2018 and has agreed to be bound by the decision in the DRL PI case. Teva is therefore enjoined from launching CASSIPA unless and until the CAFC issues a mandate vacating the PI against DRL. Any sales of CASSIPA in the U.S. would be on an "at-risk" basis, subject to the outcome of the appeal of the non-infringement judgment related to the '514 patent, as well as the ongoing litigation against Teva and DRL in the District of New Jersey.
- 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

United States District Court for the District of Delaware issued its ruling finding both patents not infringed by Alvogen. Indivior has appealed this ruling. Litigation against Alvogen is also pending in the United States District Court for the District of New Jersey on the '454 Patent and the '305 Patent. On January 22, 2019, Indivior filed a motion for a temporary restraining order ("TRO") and preliminary injunction in the District of New Jersey, requesting that the Court restrain the launch of Alvogen's generic buprenorphine/naloxone film product until a trial on the merits of the '305 patent. Alvogen received approval for its generic product on January 24, 2019. The same day, the District of New Jersey granted a TRO until February 7, 2019, with a PI hearing scheduled for that day. On January 31, 2019, Indivior and Alvogen entered in to an agreement whereby Alvogen is enjoined from the use, offer to sell, or sale within the United States, or importation into the United States, of its generic buprenorphine and naloxone sublingual film product unless and until the CAFC issues a mandate vacating the PI against DRL. Any Alvogen generic product sales in the U.S. would be on an "at-risk" basis, subject to the outcome of the appeal of the non-infringement judgment related the '514 patent, as well as the ongoing litigation against Alvogen in the District of New Jersey. On February 12, 2019, the CAFC granted Indivior's request to expedite the appeal of the non-infringement judgment in the '514 patent case to the extent it will be placed on the next available oral argument calendar.

- 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 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 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.

#### **Rhodes Pharmaceuticals**

- On December 23, 2016 Rhodes Pharmaceuticals filed a complaint against Indivior in the United States District Court for 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.

#### **11. TRADE AND OTHER PAYABLES**

	Dec 31 2018 \$m	Dec 31 2017 \$m
Sales returns and rebates	(510)	(433)
Trade payables	(47)	(40)
Accruals	(149)	(179)
Other tax and social security payables	(15)	(13)
<b>Total</b>	<b>(721)</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.

## 12. 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	6,978,920	\$0.10	1
<b>At December 31, 2018</b>	<b>728,441,653</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 December 31, 2017	721,462,733		72

### Allotment of ordinary shares

During the period, 6,978,920 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.

## 13. POST BALANCE SHEET EVENTS

On February 4, 2019, the Court of Appeals for the Federal Circuit (CAFC) denied Indivior's motion for rehearing and rehearing en banc following the CAFC's ruling vacating the preliminary injunction (PI) granted against Dr. Reddy's Laboratories (DRL). The CAFC has also denied Indivior's requests to stay issuance of the mandate pending the outcomes of the '514 Patent appeal currently pending with the CAFC and its forthcoming petition for certiorari with the Supreme Court. The CAFC has ordered issuance of the mandate on February 19, 2019. Indivior will file an application to the Supreme Court of the United States requesting a stay of the mandate pending resolution of its forthcoming petition for certiorari seeking to overturn the CAFC's PI vacatur. If the mandate issues, DRL will no longer be prevented from selling, offering to sell, or importing its generic buprenorphine/naloxone sublingual film product in the U.S. We assume that DRL will resume the "at-risk" launch of its generic film product in the U.S. following the issuance of the mandate. Further, pursuant to an agreement reached with Alvogen, we assume that they will also launch their generic product in the U.S. "at-risk" once the mandate issues and DRL is permitted to launch.

Indivior reached a definitive agreement (February 4, 2019) to divest rights related to SUBOXONE® Sublingual Tablets (Sai Bo Song™) in the Peoples Republic of China to Zhejiang Pukang Biotechnology Co., Ltd. (Pukang) for total potential consideration of up to \$122.5m based on achieving certain milestones. The agreement is subject to various closing conditions and is anticipated to close in Q4 2019.

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 further reduction in headcount of over 120 employees in Q1 2019. Incremental costs to affect the savings will be reflected as an exceptional cost in Q1 2019.