

February 13, 2020



**FY 2019 Adjusted  
Financial Results In-Line with Guidance. FY 2020 Guidance Introduced.**

Period to Dec. 31st	Q4 2019 \$m	Q4 2018 \$m	% Δ Actual FX	% Δ Constant FX	FY 2019 \$m	FY 2018 \$m	% Δ Actual FX	% Δ Constant FX
Net Revenue	133	236	-44	-43	785	1,005	-22	-21
Op. (Loss)/Profit	(42)	20	NM	NM	178	292	-39	-36
Net (Loss)/ Income	(55)	24	NM	NM	134	275	-51	-47
EPS (cents/share)	(8)	3	NM	NM	18	38	-53	-46
Adj. Op. (Loss)/Profit*	(46)	78	NM	NM	202	332	-39	-36
Adj. Net (Loss)/ Income *	(37)	67	NM	NM	176	272	-35	-31
Adj. Basic EPS*	(5)	9	NM	NM	24	37	-35	-31

\* *Adjusted basis excludes the impact of exceptional items as referenced in Notes 3 and 4 on pages 20 and 21.*

*NM: not meaningful*

**This Release Contains Inside Information.**

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

“2019 was a challenging year for Indivior but I am proud that it brought out the very best in our people as we focused our efforts on improving the lives of patients suffering from addiction and its co-occurring disorders. Our solid operating performance allowed us to raise our full-year financial guidance twice, helped by the resilience of SUBOXONE® (buprenorphine and naloxone) Film in the face of buprenorphine/naloxone film generics and by our strict financial discipline and cash conservation. At the same time, we were able to lay the foundations for the future success of our key growth drivers, SUBLOCADE® (buprenorphine extended-release) injection and PERSERIS® (risperidone) extended-release injection, while also further extending our scientific leadership in opioid use disorder (OUD).

Looking to 2020, I am inspired by the opportunity we have in front of us to profoundly impact patient lives in a more meaningful way: our groundbreaking direct-to-consumer (DTC) campaign is focused on helping more patients connect to treatment and our publication of new science is building a strong evidence base supporting SUBLOCADE®’s differentiated product profile. Supported by our enhanced compliance capabilities to meet the growing number of buprenorphine medication-assisted treatment (BMAT) patients and prescribers, we expect these efforts to help us make marked progress toward our peak net revenue goal of \$1bn for SUBLOCADE®. With our new schizophrenia depot PERSERIS® also set to deliver a greater net revenue contribution, 2020 is shaping up to be a pivotal year for Indivior.

Although we are optimistic about delivering on our strategic priorities in 2020, we of course recognise the legal uncertainties we face. We are proactively working to manage these risks while our teams remain focused on leveraging the strategic and operational accomplishments of the past year to further our leadership position in addiction science and diversification into behavioral health.”

### FY 2019 Financial Highlights

- Total net revenue of \$785m declined 22% (-21% at constant currency). U.S. net revenue declined 25% primarily due to SUBOXONE® Film share loss to generic competitors, albeit at a lower rate than suggested by historical industry analogues<sup>(1)</sup>. The impact of share loss was partially offset by good underlying market growth for BMAT, net revenue from SUBLOCADE® of \$72m (FY 2018: \$12m) and net revenue contribution from the authorized generic buprenorphine/naloxone film program. Rest of World net revenue declined 9%, primarily due to continued austerity measures in certain EU markets.
- Reported operating profit was \$178m (FY 2018: \$292m). On an adjusted basis operating profit decreased 39% to \$202m (Adj. FY 2018: \$332m), primarily due to lower overall net revenue and gross profit, partially offset by the significant decrease in operating expenses (SG&A and R&D combined).
- Reported net income was \$134m (FY 2018: \$275m). On an adjusted basis, net income decreased 35% to \$176m (Adj. FY 2018: \$272m), primarily reflecting lower operating profit partially offset by net finance income (versus net finance expense in FY 2018).
- Ending FY 2019 cash balance grew to \$1,060m (FY 2018: \$924m). Net cash was \$821m (FY 2018: \$681m) as outlined in note 9 on page 23.

### FY 2019 Operating Highlights

- U.S. BMAT market growth continued at low double-digit levels; growth continues to be driven primarily by government channels.
- SUBOXONE® Film market share averaged 32% (FY 2018: 53%) and exited FY 2019 at 24% (FY 2018: 53%). Share erosion since the “at-risk” launch of generic buprenorphine/naloxone film products in February 2019 has been lower than suggested by historical industry analogues<sup>(1)</sup>.
- Indivior notified partner Sandoz Inc. of its intention to cease its authorized generic buprenorphine/naloxone sublingual film program in response to the passage of H.R. 4378 (see pg. 3, “U.S. Market Update”). Final shipments of Indivior-produced authorized generic buprenorphine/naloxone film were made in Q4 2019.
- SUBLOCADE® key performance indicators (KPIs) continued to improve; dispense yield consistently over 60%, while healthcare professional (HCP) initiations and administrations also increased during the year.
- U.S. DTC advertising campaign launched to increase patient and HCP awareness of BMAT and SUBLOCADE®.
- PERSERIS® (risperidone) extended-release injection net revenue was in-line with the Group’s expectations.

### FY 2020 Guidance Introduced

- Net revenue is expected to be in the range of \$525m to \$585m and a net loss in the range of (\$50m) to (\$20m) (excluding exceptional items and at constant exchange rates).
- Net revenue guidance assumes continued share erosion of SUBOXONE® Film toward historical industry analogues<sup>(1)</sup>.
- SUBLOCADE® net revenue of between \$150m-\$200m; PERSERIS® net revenue of between \$15-\$25m.
- Guidance reflects increased investments in promotion, channel development and treatment advocacy, including direct to consumer (DTC) advertising through the first quarter. As the Group continues to advance SUBLOCADE® toward a sustainable \$1bn franchise, it will continue to evaluate opportunities to deploy any net revenue overdelivery toward furthering treatment and SUBLOCADE® penetration.
- A modest tax benefit.

### Department of Justice Action

- On April 9, 2019, a federal grand jury in the Western District of Virginia indicted Indivior PLC and Indivior Inc. on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE® Film and/or SUBOXONE® Tablet by certain physicians. DOJ is seeking to recover \$3 billion in monetary forfeitures and all

(1) IMS Institute Report, January 2016, “Price Declines after Branded Medicines Lose Exclusivity in the U.S.”

assets derived from the commission of the alleged offenses. Indivior believes it has strong defenses to the government's charges and will vigorously defend itself. On August 14, 2019, in response to Indivior's Motion to Dismiss the original indictment, DOJ obtained a Superseding Indictment that did not add to or change the charges, but changed certain factual allegations. On November 14, 2019, the Court denied the Motion to Dismiss the original indictment, and on December 19, 2019, Indivior filed a Motion to Dismiss the superseding indictment, which is pending before the Court.

- The Group's legal strategy remains unchanged. In concert with its legal and other technical advisers, the Group is diligently preparing for trial in May 2020. It is not possible to predict with any certainty the potential impact of this litigation or to quantify the ultimate cost of a verdict or resolution, but it could have a material impact on the Group.
- Please see Notes 10, 11 and 12 beginning on page 24 for further details on Provisions, Contingent Liabilities and Legal Proceedings.

## Operating Review

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

The market for BMAT products continued to grow at low double-digit rates in 2019 versus the comparable period in 2018. Market volume growth benefited both from increased overall public awareness of the opioid epidemic and approved treatments, and from regulatory and legislative changes that have expanded opioid use disorder (OUD) treatment funding and treatment capacity. States are also realizing that providing treatment brings substantial value to both patients and society, but BMAT remains underutilized<sup>(1)</sup>.

In response, both the number of physicians who have received a waiver to administer medication-assisted treatment and those able to treat to the permitted level of 275 patients continued to grow in 2019. The number of nurse practitioners and physician assistants who have received a waiver also continued to grow in 2019. Indivior supports efforts to encourage more eligible healthcare practitioners to provide treatment, and the Group continues to invest in expanding its compliance program to meet the growing number of BMAT prescribers and patients.

On February 19, 2019, the market for generic buprenorphine/naloxone film products began to form rapidly after the Court of Appeals for the Federal Circuit (CAFC) vacated the preliminary injunction (PI) granted to Indivior against Dr. Reddy's Laboratories (DRL) and Alvogen Pine Brook LLC (Alvogen).

As a result of the launch of generic buprenorphine/naloxone film products, branded SUBOXONE® Film experienced significant market share loss in 2019, albeit at a lower rate than suggested by historical industry analogues<sup>(2)</sup>. SUBOXONE® Film market share exiting 2019 was 24% compared to 2018 exit share of 53%. Overall formulary access for SUBOXONE® Film remains above expectations at this point in its lifecycle. However, Indivior prudently assumes the pace of market share loss will intensify for SUBOXONE® Film, ultimately resulting in a branded market share position in-line with industry analogues<sup>(2)</sup>. However, the timing for reaching this level is uncertain at this point.

On October 15, 2019, Indivior notified partner Sandoz Inc. of its intention to cease its authorized generic buprenorphine/naloxone sublingual film program in response to the passage of H.R. 4378 – Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (the "legislation"). The legislation, which came into effect on October 1, 2019, included changes to the methodology for calculating the average manufacturer price (AMP) for branded drugs that prohibit including the Group's authorized generic offering in its AMP calculation, but maintaining the Group's authorized generic offering as the "best price" for calculating mandatory rebates.

(1) JAMA Network Open. 2019;2(6):e196373. Doi:10.1001/jamanetworkopen.2019.6373

(2) IMS Institute Report, January 2016, "Price Declines after Branded Medicines Lose Exclusivity in the U.S."

As a consequence of this change, mandatory rebating in U.S. government channels increased. Based on the current business dynamics and material discounting already provided to U.S. government accounts and managed Medicaid entities, this legislative change would have resulted in negative gross profit on SUBOXONE® Film in the majority of U.S. government channels. The Group's decision to terminate the authorized generic buprenorphine/naloxone film program has not affected availability of branded or generic buprenorphine/naloxone film, but enables Indivior's ability to resource SUBLOCADE®, its once-monthly depot buprenorphine for opioid use disorder patients.

Final shipments of Indivior-produced authorized generic buprenorphine/naloxone film were made in Q4 2019 and, as such, the Group does not expect any further impact to its U.S. business from the legislation discussed above.

Indivior made 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 KPIs as of December 31, 2019:

- Formulary Access is at 89% of covered U.S. lives.
- The Prescription Journey is at or above target (12 to 17 days).
- The Dispensing Yield Rate is consistently over 60%.

SUBLOCADE® Demand KPIs (December 31, 2019 vs. December 31, 2018):

- HCPs Initiating a Prescription increased to 4,338 versus 2,430.
- HCPs Administered SUBLOCADE® increased to 3,083 versus 1,325.
- HCPs Administered SUBLOCADE® to 5-plus patients increased to 924 versus 232.

### **Financial Performance FY & Q4 2019**

Total net revenue FY 2019 decreased 22% to \$785m (FY 2018: \$1,005m) at actual exchange rates (-21% at constant exchange rates). In Q4 2019, total net revenue decreased 44% at actual exchange rates (-43% at constant exchange rates) to \$133m (Q4 2018: \$236m).

FY 2019 U.S. net revenue decreased 25% to \$589m (FY 2018: \$790m) and by 56% in Q4 2019 to \$80m (Q4 2018: \$182m). The U.S. BMAT market continued to grow at low double-digit rates, primarily from strength in government channels. Underlying market strength, net revenue contribution from the authorized generic buprenorphine/naloxone film program until termination in Q4 2019 (see pg. 3, "U.S. Market Update") and SUBLOCADE® net revenue of \$72m (2018: \$12m) were more than offset by SUBOXONE® Film share loss due to the introduction of generic buprenorphine/naloxone film alternatives in Q1 2019.

Q4 2019 U.S. net revenue dynamics were substantially the same as those in FY 2019, with SUBOXONE® Film net revenue further adversely impacted by \$47m due to the enactment of new legislation that included new methodology for calculating a branded drug's "best price" for U.S. government channels (see pg. 3, "U.S. Market Update"). The net revenue benefits from authorized generic buprenorphine/naloxone film volume was more than offset by a one-time accrual adjustment for higher Medicaid-related sales by Sandoz.

FY 2019 Rest of World net revenue decreased 9% at actual exchange rates to \$196m (FY 2018: \$215m) (-3% at constant exchange rates). In Q4 2019, Rest of World net revenue decreased 2% at actual exchange rates to \$53m (Q4 2018: \$54m) (nil at constant exchange rates). In FY 2019, expected volume and pricing impacts from ongoing austerity measures in certain European markets were partially offset by continued growth in Australasia. The Rest of World net revenue dynamics in Q4 2019 were substantially the same as those as FY 2019, with Q4 2019 volume benefitting from generic stock outages in the Canadian market.

FY 2019 gross profit was \$645m, or 82% of net revenue (FY 2018: \$877m; margin 87%). Q4 2019 gross profit was \$90m, or 68% of net revenue (Q4 2018: \$201m; margin 85%). The decline in gross profit in both periods was principally due to lower overall net revenue from branded SUBOXONE® Film together with impacts from legislation that included new methodology for calculating SUBOXONE Film's mandated rebate within U.S. government channels (see pg. 3, "U.S. Market Update"), unfavourable product mix related to the Group's authorized generic buprenorphine/naloxone film and inventory adjustments. Q4 2019 gross profit was disproportionately impacted by all of these factors as the mandated rebate impacts and higher authorized generic volumes occurred in the period. With the termination of the authorized generic program, the Group expects SUBOXONE® Film to generate positive gross margin contribution from government channels going forward.

FY 2019 SG&A expenses as reported were \$414m (FY 2018: \$494m) and \$115m as reported in Q4 2019 (Q4 2018: \$140m). FY 2019 SG&A expenses included exceptional costs of \$24m. The exceptional costs comprised of \$20m primarily related to redundancy costs and supply chain restructuring, \$8m related to potential redress for ongoing intellectual property related litigation, and \$4m of income from the 2018 out-licensing agreement related to the Group's intranasal naloxone opioid overdose patents. 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 related to the Group's intranasal naloxone opioid overdose patents.

Q4 2019 SG&A included exceptional income of \$4m from the 2017 out-licensing agreement related to the Group's intranasal naloxone opioid overdose patents. 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.

On an adjusted basis FY 2019 SG&A expenses declined 18% to \$390m (Adj. FY 2018: \$478m). The decline largely reflects savings from streamlining actions, including significant headcount reduction actions completed in Q1 2019. In Q4 2019 SG&A expenses on an adjusted basis increased by 12% to \$119m (Adj. Q4 2018: \$106m). The increase in Q4 2019 reflects increased SUBLOCADE® marketing expenses, chiefly the development and launch of the national DTC television advertising campaign.

FY 2019 and Q4 2019 R&D expenses as reported decreased by 42% to \$53m and by 59% to \$17m, respectively (FY 2018: \$91m; Q4 2018: \$41m). Excluding exceptional items of \$24m in FY 2018 and Q4 2018 related to the impairment of the Arbaclofen Placarbil and ADDEX lead compounds, FY 2019 and Q4 2019 R&D expenses decreased by 21% and by nil respectively (Adj. FY 2018: \$67m; Adj. Q4 2018: \$17m). This primarily reflects lower clinical activity and the reprioritization of R&D activities principally to support SUBLOCADE® Health Economics and Outcomes Research (HEOR), the generation of scientific evidence supporting SUBLOCADE®'s differentiated product profile, as well as post-marketing study requirements and commitments for SUBLOCADE® and PERSERIS®.

On an adjusted basis, FY 2019 operating expenses (SG&A and R&D expenses combined) were \$443m, consistent with company guidance of \$440m-\$460m, including incremental marketing expenses in Q4 2019 to develop and launch the DTC campaign for SUBLOCADE®. These expenses were partially offset by one-off benefits primarily related to the non-vesting of conditional share awards.

FY 2019 operating profit as reported was \$178m, 39% lower compared to the prior year (FY 2018: \$292m). On an adjusted basis, FY 2019 operating profit was \$202m (26% margin), a decrease of 39% versus \$332m (33% margin) in FY 2018. Q4 2019 operating loss on a reported and adjusted basis were \$42m and \$46m, respectively (Q4 2018 profit: \$20m, Adj. Q4 2018 profit: \$78m). The decrease in FY 2019 adjusted operating profit primarily reflects overall lower SUBOXONE® Film net revenue and lower gross profit that was partially offset by operating

expense reductions (SG&A and R&D combined). The operating loss in Q4 2019 primarily reflects lower overall net revenue as well as the net revenue and gross profit impact from the enactment of new legislation that included new methodology for calculating SUBOXONE® Film's "best price" for U.S. government channels (see pg. 3, "U.S. Market Update") and increased SUBLOCADE® marketing expenses.

FY 2019 net finance income was \$2m (FY 2018: \$14m expense). The net improvement reflects lower interest and amortization of financing costs due to the voluntary debt repayments of \$235m of the principal term loan balance in FY 2018, and higher interest income earned from the Group's increased cash balance.

FY 2019 reported tax expense was \$46m, an effective tax rate of 26% (FY 2018: \$3m, 1%). Excluding the \$18m exceptional tax expense, the adjusted FY 2019 tax expense was \$28m, an effective rate of 14% (FY 2018: 15%). The exceptional tax expense is made up of a \$4m tax benefit on exceptional items and net tax expense of \$22m relating to a reversal of development credits claimed in prior years (see Note 12), partially offset by a benefit from new regulation changes stemming from U.S. Tax Reform. The adjusted FY 2018 tax charge was \$46m, excluding one-time items principally related to development credits recognized, an effective tax rate of 15%. On an adjusted basis, the tax rate year over year is substantially consistent, reflecting the geographic mix of earnings.

Q4 2019 reported total tax expense was \$13m, an effective tax rate of 31% (Q4 2018: \$4m tax benefit). Excluding \$22m of exceptional tax, the adjusted Q4 2019 tax benefit was \$9m, an effective tax rate of 20%. In Q4 2018, the adjusted tax charge was \$11m, an effective rate of 14%. Q4 2019 tax exceptionals are consistent with those described above for the full year. Q4 2018 tax exceptional 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.

FY 2019 net income was \$134m (FY 2018: \$275m), and \$176m on an adjusted basis excluding the net \$28m after-tax impact from exceptional items and \$22m exceptional tax item (Adj. FY 2018: \$272m). Q4 2019 net loss was \$55m and adjusted net loss was \$37m, reflecting the impact of the exceptional items discussed above (Q4 2018: \$24m; Adj. Q4 2018: \$67m). The decrease in FY 2019 adjusted net income was due to the decline in net revenue and gross profit, partially offset by lower operating expenses (SG&A and R&D combined) and net finance income. The adjusted net loss in Q4 2019 was primarily due to lower net revenue and gross profit, as well as an increase in operating expense primarily due to increased marketing investment for SUBLOCADE®.

FY 2019 EPS on a diluted and adjusted diluted basis were 18 cents (FY 2018: 38 cents on a diluted and 37 cents adjusted diluted basis). In Q4 2019, loss per share on a diluted basis was 8 cents and 5 cents on an adjusted diluted basis (Q4 2018: 3 cents on a diluted and 9 adjusted diluted basis).

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

FY 2019 cash and cash equivalents were \$1,060m, an increase of \$136m versus the \$924m position at FY 2018. Borrowings, before issuance costs, were \$239m at the end of FY 2019 (FY 2018: \$243m). As a result, net cash stood at \$821m at the end of FY 2019 (FY 2018: \$681), a \$140m improvement over the prior year.

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative \$323m at year end, a decline of \$33m from negative \$356m at the end of FY 2018 primarily driven by a decrease in sales returns and rebates in the U.S. within payables and a reduction in accrual levels and lower trade and other receivables.



Cash generated from operations in FY 2019 was \$128m (FY 2018: \$327m), a decrease of \$199m. The reduction in cash generated versus the year-ago period was primarily due to lower operating profit along with lower rebates, trade payables, and accrual balances resulting from lower revenues and costs.

FY 2019 net cash inflow from operating activities was \$151m (FY 2018: \$303m), a decrease of \$152m reflecting lower cash from operations slightly offset by higher net interest received of \$5m versus net interest payment of \$8m in the prior year and tax refunds of \$18m versus tax payment of \$16m in 2018.

FY 2019 cash outflow from investing activities was \$2m, with \$7m for the purchase of equipment and building outfits (FY 2018: \$4m) offset by \$4m received relating to the disposal of the nasal naloxone intangible asset. The 2018 balance reflects upfront payments for licensing arrangements with ADDEX Therapeutics and C4X Discovery, capitalized development costs, and ongoing investments in facilities, mostly offset by proceeds received from the disposal of the nasal naloxone intangible asset.

FY 2019 cash outflow from financing activities decreased \$224m to \$13m from \$237m in FY 2018. The current year outflows reflect the new classification of lease payments adopted under IFRS 16 *Leases*, and the quarterly amortisation of the term loan facility. The prior year reflects the impact of the voluntary repayments of \$235m of the outstanding Term Loan balance in H2 2018.

### R&D / Pipeline Update

Indivior's quarterly R&D and pipeline update may be found at: <http://www.indivior.com/research-and-development/>.

### Risk Factors

The Board of Directors oversees the approach to risk management and ensures that the principal risks, including those that would threaten the Group's business model, future performance or viability, are effectively managed and/or mitigated. While the Group aims to identify and manage such risks, no risk management strategy can provide absolute assurance against loss.

Set out 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 predict or does not believe to be equally significant, may also materially and adversely affect the Group's business, results of operations and financial position. The principal risks 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. Uncertainties of the impact of Brexit on our operations remain a risk closely monitored as it impacts various areas of the Group, including Operations, Regulatory, Supply Chain, and Quality.

### **Product Pipeline, Regulatory & 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 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 the 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. 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, 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. Unfavourable outcome from government resolutions and/or from legal proceedings (including the Western District of Virginia Indictment), as well as potential exclusion from participating in US Federal Health Care Programs may negatively impact our financial position and therefore, our ability to comply with our debt covenants. 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 pharmaceutical 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 Group, 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 (including the Western District of Virginia Indictment), expiry and/or loss of IP rights could have a material adverse impact on the Group's prospects, results of operations and financial condition, including potential exclusion from participating in US Federal Health Care Programs. As previously disclosed in the Prospectus dated November 17, 2014, Indivior has indemnification obligations in favor of Reckitt Benckiser (RB) (page 43). Some of these indemnities are unlimited in terms of amount and duration and amounts potentially payable by the Group pursuant to such indemnity obligations could be significant and could have a material adverse effect on the Group's business, financial condition and/or operating results. Requests for indemnification may be subject to legal challenge. Notes 1 and 11 to the condensed financial statements (pages 18 and 24) provide information related to the potential impact of the legal proceedings on the Group's financial position and going concern.

## **Compliance**

- 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 2019 financial year will contain additional details on these principal business risks.



## Exchange Rates

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

	Full Year to December 31, 2019	Full Year to December 31, 2018
GB £ period end	1.3263	1.2746
GB £ average rate	1.2768	1.3362
€ Euro period end	1.1228	1.1451
€ Euro average	1.1198	1.1819

## Presentation / Webcast Details

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

Webcast link: <https://edge.media-server.com/mmc/p/tiukodrn>

**Confirmation Code:** 7975237

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

## Forward-Looking Statements

This announcement contains certain statements that are forward-looking. 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 2020 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 subsequent releases): factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; 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 and in the supply chain; disruptions in or failure of information technology systems; 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; challenges in the commercial execution; 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 indictment by the U.S. Department of Justice, potential exclusion from participating in U.S. Federal Health Care Programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; 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 (i.e., sedatives, tranquilizers, or alcohol). It is extremely dangerous to take nonprescribed benzodiazepines or other medications that act on the nervous system while taking SUBOXONE® Film.

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

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

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

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

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

Do not take SUBOXONE® Film before the effects of other opioids (e.g., 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 labour.

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 counselling 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 behaviours.

**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	Notes	Unaudited Q4 2019 \$m	Unaudited Q4 2018 \$m	Unaudited FY 2019 \$m	Audited FY 2018 \$m
<b>Net Revenues</b>	2	<b>133</b>	236	<b>785</b>	1,005
Cost of Sales		<b>(43)</b>	(35)	<b>(140)</b>	(128)
<b>Gross Profit</b>		<b>90</b>	201	<b>645</b>	877
Selling, general and administrative expenses	3	<b>(115)</b>	(140)	<b>(414)</b>	(494)
Research and development expenses	3	<b>(17)</b>	(41)	<b>(53)</b>	(91)
<b>Operating (Loss)/Profit</b>		<b>(42)</b>	20	<b>178</b>	292
Operating profit before exceptional items		<b>(46)</b>	78	<b>202</b>	332
Exceptional items	3	<b>4</b>	(58)	<b>(24)</b>	(40)
Finance income		<b>5</b>	6	<b>24</b>	17
Finance expense		<b>(5)</b>	(6)	<b>(22)</b>	(31)
Net finance income/(expense)		-	-	<b>2</b>	(14)
<b>(Loss)/Profit before Taxation</b>		<b>(42)</b>	20	<b>180</b>	278
Income tax (expense)/credit		<b>(13)</b>	4	<b>(46)</b>	(3)
Taxation before exceptional items	5	<b>9</b>	(11)	<b>(28)</b>	(46)
Exceptional items within taxation	3/5	<b>(22)</b>	15	<b>(18)</b>	43
<b>Net (loss)/income</b>		<b>(55)</b>	24	<b>134</b>	275
<b>Earnings per ordinary share (cents)</b>					
Basic (loss)/earnings per share	6	<b>(8)</b>	3	<b>18</b>	38
Diluted (loss)/earnings per share	6	<b>(8)</b>	3	<b>18</b>	37

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

## Condensed consolidated statement of comprehensive income

	Unaudited Q4 2019 \$m	Unaudited Q4 2018 \$m	Unaudited FY 2019 \$m	Audited FY 2018 \$m
<b>For the three and twelve months ended December 31</b>				
Net income	(55)	24	134	275
<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	14	(10)	9	(18)
Other comprehensive income/(loss)	14	(10)	9	(18)
<b>Total comprehensive (loss)/income</b>	<b>(41)</b>	14	<b>143</b>	257

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



## Condensed consolidated balance sheet

	Notes	Unaudited Dec 31, 2019 \$m	Audited Dec 31, 2018 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		72	84
Property, plant and equipment		60	57
Right-of-use assets	1/7	47	-
Deferred tax assets	5	40	44
Other assets	8	73	33
		<b>292</b>	<b>218</b>
<b>Current assets</b>			
Inventories		73	78
Trade and other receivables		227	287
Current tax receivable	5	-	40
Cash and cash equivalents		1,060	924
		<b>1,360</b>	<b>1,329</b>
<b>Total assets</b>		<b>1,652</b>	<b>1,547</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	9	(4)	(4)
Provisions	10	(71)	(69)
Trade and other payables	13	(623)	(721)
Lease liabilities	1/7	(5)	-
Current tax liabilities	5	(39)	(24)
		<b>(742)</b>	<b>(818)</b>
<b>Non-current liabilities</b>			
Borrowings	9	(233)	(237)
Provisions	10	(417)	(424)
Lease liabilities	1/7	(51)	-
Other non-current liabilities		-	(2)
		<b>(701)</b>	<b>(663)</b>
<b>Total liabilities</b>		<b>(1,443)</b>	<b>(1,481)</b>
<b>Net assets</b>		<b>209</b>	<b>66</b>
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	13	73	73
Share premium		5	5
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(23)	(32)
Retained Earnings		1,449	1,315
<b>Total equity</b>		<b>209</b>	<b>66</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, 2019</b>		<b>73</b>	<b>5</b>	<b>(1,295)</b>	<b>(32)</b>	<b>1,315</b>	<b>66</b>
<b>Comprehensive income</b>							
Net income		-	-	-	-	134	134
Other comprehensive income		-	-	-	9	-	9
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>9</b>	<b>134</b>	<b>143</b>
<b>Transactions recognised directly in equity</b>							
IFRS 16 impact (adjustment to opening balance)		-	-	-	-	(2)	(2)
Share-based plans		-	-	-	-	3	3
Deferred taxation on share-based plans and IFRS 16		-	-	-	-	(1)	(1)
<b>Balance at December 31, 2019</b>		<b>73</b>	<b>5</b>	<b>(1,295)</b>	<b>(23)</b>	<b>1,449</b>	<b>209</b>
<b>Audited</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		<b>1</b>	<b>3</b>	<b>-</b>	<b>-</b>	<b>15</b>	<b>19</b>
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>

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

## Condensed consolidated cash flow statement

	Unaudited 2019 \$m	Audited 2018 \$m
<b>For the twelve months ended December 31</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit	178	292
Depreciation, amortization and impairment	20	40
Gain on disposal of intangible assets	(4)	(37)
Depreciation of right-of-use assets	8	-
Share-based payments	3	15
Impact from foreign exchange movements	2	(12)
Decrease/(Increase) in trade and other receivables	62	(33)
Increase in other assets	(39)	-
Decrease/(Increase) in inventories	7	(31)
(Decrease)/Increase in trade and other payables	(101)	58
(Decrease)/Increase in provisions	(8)	35
<b>Cash generated from operations</b>	<b>128</b>	<b>327</b>
Interest paid	(17)	(25)
Interest received	22	17
Taxes refunded/(paid)	18	(16)
<b>Net cash inflow from operating activities</b>	<b>151</b>	<b>303</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(7)	(11)
Proceeds from lease incentives	1	-
Purchase of intangible assets	-	(30)
Proceeds from disposal of intangible assets	4	37
<b>Net cash outflow from investing activities</b>	<b>(2)</b>	<b>(4)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Repayment of borrowings	(4)	(240)
Payment of lease liabilities	(9)	-
Proceeds from the issuance of ordinary shares	-	3
<b>Net cash outflow from financing activities</b>	<b>(13)</b>	<b>(237)</b>
<b>Net increase in cash and cash equivalents</b>	<b>136</b>	<b>62</b>
Cash and cash equivalents at beginning of the period	924	863
<b>Exchange differences</b>	<b>-</b>	<b>(1)</b>
<b>Cash and cash equivalents at end of the period</b>	<b>1,060</b>	<b>924</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, 2018 and should be read in conjunction with those annual accounts, except with regards to IFRS 16 and IFRIC 23 which was implemented in 2019. 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, 2018.

The Condensed Financial Statements reflect the Group's adoption of IFRS 16 *Leases*. On adoption of IFRS 16, the Group recognized lease liabilities in relation to all leases, including those 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 at the net present value of lease payments which are discounted using the lease's incremental borrowing rate. Leases executed prior to adoption were discounted at the January 1, 2019 incremental borrowing rate. The Group applied the modified retrospective approach, which requires recognition of the cumulative effect of initially applying IFRS 16, as of January 1, 2019, to retained earnings.

As at January 1, 2019, the Group recognized \$27 million of right-of-use assets and \$33 million of lease liabilities and an impact to beginning retained earnings of \$2 million. The remaining \$4m related to deferred tax and previously recognized straight-line lease liability. Having adopted IFRS 16, the Group will recognise interest payments and lease liability payments in cashflow from financing activities; both of which are expected to be immaterial.

The Group applied practical expedients permitted by the standard on transition, the most significant of which were the reliance on a previous assessment of whether a lease is onerous, the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application, application of a single discount rate to leases with similar characteristics, the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease, and the accounting for operating leases with a remaining lease term of less than 12 months as at January 1, 2019 as short-term leases. Since adoption, the Group continues to apply practical expedients including, the exclusion of initial direct costs for the measurement of the right-of-use asset, application of a single discount rate to leases with similar characteristics. Leases of less than 12 months are not capitalized.

The Group is using one or more practical expedients permitted by the standard on transition and going forward; including the reliance on a previous assessment of whether a lease is onerous, the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application, application of a single discount rate to leases with similar characteristics, the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease, and the accounting for operating leases with a remaining lease term of less than 12 months as at January 1, 2019 as short-term leases.

The Group adopted IFRIC 23 *Uncertainty over Income Tax Treatments* and *Annual Improvements to IFRSs 2015-2017 Cycle* in 2019, however, there was no impact to the financials as a result of this.

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, 2018. These condensed consolidated financial statements have been reviewed and not audited. These condensed consolidated financial statements were approved for issue on February 12, 2020.

As disclosed in Notes 10 and 12, the Group carries a provision of \$438m, substantially all relating to the Department of Justice (DOJ) litigation matters. While the Directors believe the Group has strong defences to the government's charges and will vigorously defend itself, they will still endeavour to pursue a settlement. If a settlement cannot be reached, the final court outcome relating to the DOJ indictment is not expected to impact the Group during the going concern period over the next 12 months. However, an unfavorable outcome from legal proceedings (including the Western District of Virginia Indictment), or potential exclusion from participating in US Federal Health Care Programs would negatively impact the financial position and long-term viability of the Group including the ability to comply with debt covenants. The final resolution of the Group's legal proceedings as disclosed in Note 12 may be materially higher than the amount provided, require payment over a shorter period or could adversely impact the ongoing business operation as noted above which, together with the failure for new products to meet revenue growth expectations and/or lower than forecast revenue of SUBOXONE®, could impact the Group's ability to operate. The Directors have already taken significant steps to reduce the cost base of the business and manage its capital structure to ensure the Group will comply with the Term Loan covenant as specified in Note 9. A combination of the above risks may require additional measures to be taken such as further cost reductions. 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. However, the Directors believe the Group has sufficient liquidity and the ability to carry out any further measures that may be necessary for the Group to continue as a going concern for at least the next twelve months. The Condensed Financial Statements do not include the adjustments that would result if the Group were unable to continue as a going concern.

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, 2018, the auditors issued (1) an emphasis of matter dealing with the outcome of legal proceedings, details of which are included above and in Notes 10 and 12; and (2) a material uncertainty related to going concern. This dealt 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 will be adversely affected by the significant decline in revenue in 2019 and beyond following the "at-risk" launch of generic buprenorphine/naloxone sublingual film products and the potential risk of failure for new products to meet revenue growth expectations. The Group's statutory financial statements for the year ended December 31, 2018 were approved by the Board of Directors on March 1, 2019 and have been 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 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 and non-current assets, net of accumulated depreciation and amortization, by country. Non-current assets for this purpose consist of property, plant and equipment, right-of-use assets, intangible assets, and other receivables. Net revenues for the three and twelve months and non-current assets for the twelve months to December 31, 2019 and 2018 were as follows:

Net revenues from sale of goods:

	Q4 2019	Q4 2018	FY 2019	FY 2018
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
United States	80	182	589	790
ROW	53	54	196	215
<b>Total</b>	<b>133</b>	<b>236</b>	<b>785</b>	<b>1,005</b>

On a disaggregated basis, the Group's net revenue by major product line:

	Q4 2019	Q4 2018	FY 2019	FY 2018
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
SUBLOCADE®	24	6	72	12
Sublingual/Other	109	230	713	993
<b>Total</b>	<b>133</b>	<b>236</b>	<b>785</b>	<b>1,005</b>

Non-current assets:

	Dec 31, 2019 \$m	Dec 31, 2018 \$m
United States	68	62
ROW	184	112
<b>Total</b>	<b>252</b>	<b>174</b>

### 3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

	Q4 2019	Q4 2018	FY 2019	FY 2018
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
Research and development expenses	(17)	(41)	(53)	(91)
Selling and general expenses	(70)	(53)	(199)	(205)
Administrative expenses <sup>1</sup>	(40)	(82)	(196)	(271)
Depreciation and amortization*	(5)	(4)	(19)	(13)
Operating lease rentals <sup>2</sup>	-	(1)	-	(5)
<b>Total</b>	<b>(115)</b>	<b>(140)</b>	<b>(414)</b>	<b>(494)</b>

\* Additional depreciation and amortization of \$9m (2018: \$3n) for intangibles and ROU assets is included within cost of sales.

<sup>1</sup>Administrative expenses include exceptional costs in the current and prior FY period as outlined in table below. Prior year administrative expenses also included non-exceptional expenses of \$4m related to the ongoing protection of the company's intellectual property. These costs were not considered exceptional as they primarily related to non-litigation expenses for the ongoing protection of the Group's prospective revenues.

<sup>2</sup>Following the group's adoption of IFRS 16, *Leases* on January 1, 2019, operating lease rentals have been reclassified to the balance sheet as lease liabilities with a portion being recorded as interest on the P&L.

#### Exceptional Items

Where significant expenses or income that do not reflect the Group's ongoing operations are incurred during the year, these items are disclosed as exceptional items in the income statement. Examples of such items could include restructuring and other expenses relating to the integration of an acquired business and related expenses for the reconfiguration of the Group's activities and/or capital structure, impairment of current and non-current assets, certain costs arising as a result of material and non-recurring regulatory and litigation matters, and certain tax related matters.

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

	Q4 2019	Q4 2018	FY 2019	FY 2018
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
Other operating income <sup>1</sup>	4	19	4	37
Restructuring costs <sup>2</sup>	-	(13)	(20)	(13)
Legal expenses/provision <sup>3</sup>	-	(40)	(8)	(40)
Intangible impairment (R&D) <sup>4</sup>	-	(24)	-	(24)
<b>Total exceptional items before taxes</b>	<b>4</b>	<b>(58)</b>	<b>(24)</b>	<b>(40)</b>
Tax on exceptional items	-	10	4	8
Exceptional items within tax <sup>5</sup>	(22)	5	(22)	35
<b>Total exceptional items</b>	<b>(18)</b>	<b>(43)</b>	<b>(42)</b>	<b>3</b>

<sup>1</sup>Exceptional income in both years 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 in FY 2019 and 2018 as well as Q4 2018 relate to the cost saving initiative to offset the financial impact of recent adverse U.S. market developments. These consist primarily of supply chain restructuring (in 2019), redundancy and related costs (in both years). These are included in SG&A.

<sup>3</sup>Legal expenses in the FY 2019 and FY and Q4 2018 relate to potential redress for ongoing intellectual property related litigation with DRL and Alvogen Pharmaceuticals. These are included within SG&A.

<sup>4</sup>In 2018, Q4 and FY R&D expenses include \$24m of impairment charges related to the Arbaclofen Placabil 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>The tax expense of \$22m for Q4 and FY 2019 primarily consists of \$34m of tax expense relating to a reversal of development credits (relating to orphan drug designation) claimed and reported as exceptional in prior years, offset by a tax benefit of \$11m due to regulation changes stemming from U.S. Tax Reform. Prior year included a benefit of \$34m for the booking of development credits, and \$1m related to the impact of the 2017 US tax reform rate change. (Refer to Notes 5 and 12)



#### 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 Q4/FY 2019 and Q4/FY 2018. Refer to Note 3 for more information on exceptional items.

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

	Q4 2019	Q4 2018	FY 2019	FY 2018
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
<b>Operating profit</b>	<b>(42)</b>	<b>20</b>	<b>178</b>	<b>292</b>
Exceptional selling, general and administrative expenses	-	53	28	53
Exceptional research and development expenses	-	24	-	24
Exceptional operating income	(4)	(19)	(4)	(37)
<b>Adjusted operating profit</b>	<b>(46)</b>	<b>78</b>	<b>202</b>	<b>332</b>

##### Reconciliation of profit before taxation to adjusted profit before taxation:

	Q4 2019	Q4 2018	FY 2019	FY 2018
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
<b>(Loss)/Profit before taxation</b>	<b>(42)</b>	<b>20</b>	<b>180</b>	<b>278</b>
Exceptional selling, general and administrative expenses	-	53	28	53
Exceptional research and development expenses	-	24	-	24
Exceptional operating income	(4)	(19)	(4)	(37)
<b>Adjusted (loss)/profit before taxation</b>	<b>(46)</b>	<b>78</b>	<b>204</b>	<b>318</b>

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

	Q4 2019	Q4 2018	FY 2019	FY 2018
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
<b>Net Income</b>	<b>(55)</b>	<b>24</b>	<b>134</b>	<b>275</b>
Exceptional selling, general and administrative expenses	-	53	28	53
Exceptional research and development expenses	-	24	-	24
Exceptional operating income	(4)	(19)	(4)	(37)
Tax on exceptional items	-	(10)	(4)	(8)
Exceptional items within tax	22	(5)	22	(35)
<b>Adjusted net income</b>	<b>(37)</b>	<b>67</b>	<b>176</b>	<b>272</b>

#### 5. TAXATION

In Q4 2019, the tax benefit on adjusted profits amounted to \$9m excluding exceptionals (Q4 2018: \$11m expense) and represented a quarterly effective tax rate of -20% (Q4 2018: 14% excluding exceptionals). The variance was primarily driven by income mix and prior year UK return filings. Exceptional tax expense of \$22m was recognized this quarter; \$34m due to reversal of prior year development tax credits (relating to orphan drug designation), offset by \$11m of tax benefit due to regulation changes stemming from U.S. Tax Reform. In Q4 2018, \$3m of tax credits were recognized, along with \$2m due to finalization of impact of U.S. Tax Reform rate reduction.

In the year ended December 31, 2019, the reported total tax expense was \$46m, or a rate of 26% (FY 2018: \$3m, 1%). The tax expense on adjusted profits was \$28m (FY 2018: \$46m) and represented an adjusted effective tax rate of 14% (2018: 15%).

The Group's balance sheet at December 31, 2019 included a current tax payable of \$39m (FY 2018: \$24m), current tax receivable of \$0m (FY 2018: \$40m), and deferred tax asset of \$40m (FY 2018: \$44m). The current tax asset decreased due the receipt of refunds during the year. The current tax payable increased due to reversal of the exceptional tax credit booked in 2018.

##### Other tax matters

The European Commission issued a press release on April 2, 2019 announcing its conclusion that the United Kingdom ('UK') Finance Company Partial Exemption Rules are partly justified. The UK government has made an annulment application to the General Court against this decision. The UK government is now required to initiate recovery of the alleged State Aid irrespective of any appeal against the decision. The group has responded to the information requested from HMRC following the EU Commission decision regarding the UK Finance Company Exemption. In December 2019, the group received a communication from the CCM attaching a statement regarding EC decision on State Aid and were advised that HMRC will be writing to us shortly. The Group has not received any additional correspondence from HMRC.

The group continues to monitor its position in regard to the potential State Aid challenge and continues to believe there is still significant uncertainty at this stage to quantify any potential future liability that may arise, so no provision has been made at this time. The Group has benefited from the UK controlled foreign company financing exemption and the tax thereon is approximately \$24 million including interest.

The UK's withdrawal from the European Union ('EU') may have a material effect on our taxes. Whilst the UK has left the EU on the 31 January 2020, 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. The UK has entered into a transition period and has until 31 December 2020 to negotiate and conclude additional arrangements. 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 2019 cents	Q4 2018 cents	FY 2019 cents	FY 2018 cents
<b>For the three and twelve months ended December 31</b>				
Basic (loss)/earnings per share	(8)	3	18	38
Diluted (loss)/earnings per share	(8)	3	18	37
Adjusted basic earnings per share	(5)	9	24	37
Adjusted diluted earnings per share	(5)	9	23	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.

<b>Weighted average number of shares</b>	2019 thousands	2018 thousands
On a basic basis	730,235	727,148
Dilution from share awards and options	25,123	23,994
On a diluted basis	755,358	751,142

### 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. ROU ASSETS & LEASE LIABILITY

The following tables summarize the movements of the right-of-use assets and lease liabilities in the year:

<b>Right of Use Assets</b>	Land & Buildings \$m	Plant & Machinery \$m	Total \$m
<b>January 1, 2019</b>	15	12	27
Additions	6	23	29
Lease incentives	(1)		(1)
Depreciation	(3)	(5)	(8)
<b>December 31, 2019</b>	17	30	47

<b>Lease Liabilities</b>	Land & Buildings \$m	Plant & Machinery \$m	Total \$m
<b>January 1, 2019</b>	20	13	33
Additions	6	23	29
Interest expense related to lease liabilities	2	1	3
Repayment of lease liabilities (including interest)	(4)	(5)	(9)
<b>December 31, 2019</b>	24	32	56

## 8. OTHER ASSETS

	Dec 31 2019 \$m	Dec 31 2018 \$m
Long-term prepaid expenses	23	33
Other non-current assets	50	-
<b>Total</b>	<b>73</b>	<b>33</b>

Long-term prepaid expenses relate primarily to payments for contract manufacturing capacity and other non-current assets relate to surety bond funding.

## 9. FINANCIAL LIABILITIES – BORROWINGS

<b>Current</b>	Dec 31 2019 \$m	Dec 31 2018 \$m
Bank loans	(4)	(4)
	<b>(4)</b>	<b>(4)</b>

<b>Non-current</b>	Dec 31 2019 \$m	Dec 31 2018 \$m
Bank loans	(233)	(237)
	<b>(233)</b>	<b>(237)</b>

<b>Analysis of net cash</b>	Dec 31 2019 \$m	Dec 31 2018 \$m
Cash and cash equivalents	1,060	924
Borrowings*	(239)	(243)
	<b>821</b>	<b>681</b>

\*Borrowings reflects the principal amount drawn before debt issuance costs of \$2m (FY 2018: \$2m). These do not include lease liabilities of \$56m.

<b>Reconciliation of net cash</b>	Dec 31 2019 \$m	Dec 31 2018 \$m
The movements in the period were as follows:		
Net cash at beginning of period (January 1)	681	376
Net increase in cash and cash equivalents	136	61
Net repayment of borrowings	4	240
Exchange adjustments	-	4
<b>Net cash at end of period</b>	<b>821</b>	<b>681</b>

Net cash is presented as it is relevant to our Term Loan maximum leverage ratio

The net carrying value of the term loan was trading at approximately 93% of par value. Cash at bank, trade receivables, and trade payables are assumed to approximate their fair values. The terms of the loan in effect at December 31, 2019 are as follows:

	Currency	Nominal interest margin	Maturity	Required annual repayments	Maximum leverage ratio
Term loan facility	USD	Libor* (1%) + 4.5%	2022	\$4m	3.0

\*The Term Loan matures after publication of LIBOR is expected to end. We have engaged with the administrative agent and expect to work with other market participants in the transition to a reasonable substitute base rate. No financial impact is expected in 2020.

- Nominal interest margin is calculated over three-month LIBOR subject to the LIBOR floor.
- The maximum leverage ratio (adjusted aggregated net debt divided by Adjusted EBITDA) is a financial covenant to maintain net secured leverage below 3.0x.
- A \$50m revolving credit facility is available to the Group which remained undrawn at the balance sheet date.

## 10. PROVISIONS

	Dec 31 2019 \$m	Dec 31 2018 \$m
Litigation/Investigative matters	(438)	(438)
Intellectual property related matters	(45)	(44)
Restructuring costs	(2)	(8)
Other	(3)	(3)
Total	(488)	(493)

The Group is involved in legal and intellectual property disputes as described in Note 12, "Legal Proceedings."

The Group carries a provision for investigative and antitrust litigation matters of \$438m. Substantially all of the provision relates to the DOJ litigation, described in Note 12 under "Western District of Virginia Indictment." The Group remains open to resolving the matter, although it cannot predict with any certainty whether, when, or at what cost it will reach an ultimate resolution.

The final resolution may be materially higher than this provision which, together with lower than forecast revenue of SUBOXONE® or the failure for SUBLOCADE and PERSERIS to meet revenue growth expectations, could impact the Group's ability to operate. The Directors have already taken significant steps to reduce the cost base of the business and manage its capital structure. A combination of the above risks may require additional measures to be taken such as further cost reductions.

The Group also carries provisions totalling \$45m for intellectual property related matters, all of which relate to potential redress for ongoing intellectual property related litigation with DRL and Alvogen, and have been recognized 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.

## 11. CONTINGENT LIABILITIES

Other than the disputes for which provisions have been taken as disclosed in Note 10, '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 12, 'Legal Proceedings.'

## 12. LEGAL PROCEEDINGS

### Litigation/Investigative Matters

#### *Western District of Virginia Indictment*

- On April 9, 2019, a federal grand jury in the Western District of Virginia indicted Indivior PLC and Indivior Inc. on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE® Film and/or SUBOXONE® Tablet by certain physicians. DoJ is seeking to recover \$3 billion in monetary forfeitures and all assets derived from the commission of the alleged offenses. Indivior believes it has strong defenses to the government's charges and will vigorously defend itself. On August 14, 2019, in response to Indivior's Motion to Dismiss the original indictment, DoJ obtained a Superseding Indictment that did not add to or change the charges, but changed certain factual allegations. On November 14, 2019, the Court denied the Motion to Dismiss the original indictment, and on December 19, 2019, Indivior filed a Motion to Dismiss the superseding indictment, which is pending before the Court. On January 29, 2020, DoJ filed an Application For Post-Indictment Protective Order seeking to prevent transactions in the assets sought to be forfeited in the superseding indictment, transactions not in the ordinary course of business and transactions of a value of more than \$1 million without prior court approval, and to require defendants to maintain \$438 million in a financial account, and for other relief. Indivior will oppose this Application. It is not possible to predict with any certainty the potential impact of this litigation or to quantify the ultimate cost of a verdict or resolution, but it could have a material impact on the Group.

#### *State Subpoenas and Civil Investigative Demands*

- 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. The Group has fully cooperated in this civil investigation.
- 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 of California 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 has fully cooperated in this civil investigation and is in discussions aimed toward resolving the matter.

- In June 2019, the Group learned that the State of Illinois Insurance Department is investigating potential violations of its civil Insurance Claims Fraud Prevention Act with respect to sales and marketing activity by the Company. The Group is in discussions aimed toward resolving this matter.
- On July 1, 2019, the Indiana Attorney General issued a Civil Investigative Demand investigating potential violations of Indiana's Civil Deceptive Consumer Sales Act with respect to sales and marketing activity by the Company. The Group is cooperating fully in this civil investigation.

#### ***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 class of direct purchasers, (b) a class of end payor plaintiffs, and (c) 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. These antitrust cases are pending in federal court in the Eastern District of Pennsylvania. Pre-trial proceedings were coordinated. The fact and expert discovery periods have closed. On September 27, 2019, the court certified a class of direct purchasers of branded Suboxone® Tablets. The same day, the court also certified, with respect to specified issues, a class of end-payor plaintiffs. The court denied certification of a putative "nationwide injunctive class" of end-payor plaintiffs. On November 4, 2019, the Court of Appeals for the Third Circuit granted Indivior's petition for permission to appeal the certification of the direct purchaser class; this appeal is pending. The District Court ordered that scheduling for submissions of summary judgment motions and for trial will be set after the Third Circuit's ruling on class certification.

#### ***Opioid Class Action Litigation***

- In February 2019, Indivior, along with other manufacturers of opioid products, was first named but not served in one of the national multi-district litigation cases brought by state and local governments and public health agencies in the Northern District of Ohio, alleging misleading marketing messages. Thereafter, Indivior was named in additional cases brought in both federal and state courts by additional state and local government entities as well as individual plaintiffs. To date, there are 292 lawsuits pending against Indivior. The vast majority of these cases (280) have been consolidated and are pending in the multi-district litigation in the Northern District of Ohio. There is currently one case pending in the Fourth Circuit Court of Appeals on appeal from a decision to remand the case to Virginia state court, where the case originated. An additional seven cases filed in Virginia state courts have been removed to federal district courts by defendants seeking to consolidate those cases in the multi-district litigation. Indivior has also been named in one case in the Commonwealth of Pennsylvania, two cases in the Commonwealth of Virginia and one case in the State of Arizona. All proceedings in the multi-district litigation pending in the Northern District of Ohio and Pennsylvania state court have been stayed. The cases pending in Virginia and Arizona state courts are proceeding with litigation and the Company will be vigorously defending against these complaints..

#### ***Securities Class Action Litigation***

- On April 23, 2019, Michael Van Dorp filed a putative class action lawsuit in the United States District Court for the District of New Jersey on behalf of holders of publicly traded Indivior securities alleging violations of U.S. federal securities laws under the Securities Exchange Act of 1934. The complaint names Indivior PLC, Shaun Thaxter, Mark Crossley and Cary J. Claiborne as defendants. On July 30, 2019, the Court granted Mr. Van Dorp's motion for appointment as lead plaintiff on behalf of the putative class. On September 30, 2019, Mr. Van Dorp filed an amended complaint on behalf of the putative class. On November 29, 2019, the Defendants filed a motion to dismiss the amended complaint. Plaintiff filed its opposition to the motion on January 28, 2020, and Defendants' reply is due on February 27, 2020.

#### **Intellectual property related matters**

##### ***ANDA Litigation***

- On December 18, 2019, Indivior settled its SUBOXONE® Film patent litigation against Aveva Drug Delivery Systems, Inc. ("Aveva"), the terms of which are confidential. So far as Indivior is aware, FDA to date has not granted tentative or final approval for Aveva's generic buprenorphine/naloxone film product.
- On October 24, 2017, Actavis Laboratories UT, Inc. ("Actavis," formerly known as Watson Laboratories Inc.) received tentative approval from FDA for 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. 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. That ruling was affirmed by the Court of Appeals for the Federal Circuit ("CAFC") on July 12, 2019. Litigation against Actavis in the District of Delaware on the '305 and '454 patents was dismissed on September 16, 2019.

- On August 31, 2017, the United States District Court for the District of Delaware found that asserted claims of the '150 Patent, U.S. Patent No. 8,900,497 ("the '497 Patent") and the '514 Patent are valid but not infringed by Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories Inc. (collectively, "DRL"). Indivior appealed the rulings as to the '514 and '150 patents, and on July 12, 2019, the CAFC upheld the District Court ruling, finding the patents not invalid but also not infringed by DRL. DRL has requested that the District of Delaware award it attorneys' fees and costs, and Indivior has opposed that request. A hearing on DRL's request has been scheduled for February 12, 2020, and a decision is pending before the court.
- Litigation against DRL is currently pending in the District of New Jersey regarding 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 July 13, 2018, the District Court issued a ruling granting Indivior a Preliminary Injunction (PI) pending the outcome of a trial on the merits of the '305 Patent. Indivior was required to post a surety bond for \$72 million in connection with the PI. On November 20, 2018, the CAFC issued a decision vacating the PI against DRL. Indivior's motion for rehearing and rehearing en banc was denied on February 4, 2019, and the mandate issued on February 19, 2019. DRL is no longer prevented from selling, offering to sell, or importing their generic buprenorphine/naloxone sublingual film products. DRL has re-launched its generic product, and any sales in the U.S. are on an "at-risk" basis, subject to the outcome of the ongoing litigation in the District of New Jersey. On June 18, 2019, DRL filed a motion for leave to file their first amended Answer, Affirmative Defenses, and Counterclaims to add counterclaims for anticompetitive conduct by Indivior in violation of federal antitrust laws and for recovery against Indivior's sureties for damages resulting from the injunction that was issued against DRL. The motion was granted by the Magistrate Judge on November 20, 2019. Indivior appealed that ruling to the District Court Judge on December 4, 2019 and a decision is still pending with the court. The Court held a claim construction hearing in October of 2019, and entered its ruling in November of 2019. In light of the claim construction, the parties filed a Stipulated Order and Judgment of non-infringement on the '305 Patent, which was entered by the Court on January 7, 2020.
- On November 13, 2018, DRL filed two separate petitions for inter partes review ("IPR") of the '454 Patent with the USPTO. The USPTO denied institution of one of the IPR petitions but granted institution for the second IPR petition. Indivior filed its Patent Owner's Response on the granted petition in September 2019. DRL filed its Reply on December 10, 2019. Indivior filed its Patent Owner's Sur-Reply on January 21, 2020. Oral argument is set for March 3, 2020. A final decision on the IPR is expected in or about June of 2020.
- Teva Pharmaceuticals USA, Inc. ("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 of the '514, '497, and '150 patents by Teva's 16mg/4mg dosage strength would be governed by the infringement ruling as to DRL's 8mg/2mg dosage strength that was the subject of the trial in November 2016. Accordingly, the non-infringement ruling by the District of Delaware in the DRL case means that the Teva 16mg/4mg dosage strength has been found not to infringe those patents. Indivior appealed the November 2016 DRL ruling as to the '514 and '150 patents, and on July 12, 2019, the CAFC upheld the District Court finding of noninfringement. Teva received final approval from the FDA for CASSIPA on September 7, 2018 and has agreed to be bound by the decision in the District of New Jersey DRL case for the '454 and '305 Patents. Teva was therefore able to launch CASSIPA at-risk as of February 19, 2019, when the CAFC issued 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 ongoing litigation against Teva and DRL in the District of New Jersey.
- Trial against Alvogen Pine Brook, Inc. ("Alvogen") in the lawsuit involving the '514 and '497 Patents 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 ruled both patents were not infringed by Alvogen. Indivior appealed this ruling, and on July 12, 2019, the CAFC upheld the noninfringement judgments. Alvogen has requested that the District of Delaware award it attorneys' fees and costs, and Indivior has opposed that request. A hearing on Alvogen's request has been scheduled for February 12, 2020, and a decision is pending before the court.
- Litigation against Alvogen is pending in the United States District Court for the District of New Jersey regarding the '454 and '305 Patents. 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. On January 31, 2019, Indivior and Alvogen entered in to an agreement whereby Alvogen was 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 issued a mandate vacating the PI against DRL. The mandate vacating the DRL PI issued on February 19, 2019, and Alvogen launched its generic product. Any sales in the US are on an "at-risk" basis, subject to the ongoing litigation against Alvogen in the District of New Jersey. On June 21, 2019, Alvogen filed a motion for recovery on the bond for improper restraints and asked that the court set a schedule for an accounting of



damages. Indivior filed its opposition on July 15, 2019 and Alvogen filed a reply on July 29, 2019. This motion was denied on November 5, 2019. On August 9, 2019, Alvogen filed a motion for leave to file an amended Answer to Complaint and Separate Defenses and Counterclaims to add counter claims alleging anticompetitive conduct by Indivior in violation of federal and state antitrust laws. The motion was granted by the Magistrate Judge on November 20, 2019. Indivior appealed that ruling to the District Court Judge on December 4, 2019, and a decision is still pending with the court. The Court held a claim construction hearing in October of 2019, and the Court entered its ruling in November of 2019. In light of the claim construction, the parties filed a Stipulated Order and Judgment of non-infringement on the '305 Patent, which was signed by the Court on January 9, 2020.

- 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. Sandoz launched an authorized generic version of SUBOXONE® Film on February 19, 2019.
- On September 25, 2017, Indivior settled its SUBOXONE® Film patent litigation against Mylan Technologies Inc.; Mylan Pharmaceuticals Inc.; and Mylan N.V. ("Mylan"), the terms of which are confidential. Mylan received final FDA approval for its generic version of the 8mg/2mg buprenorphine/naloxone film product on June 14, 2018. Mylan launched its generic version on or about February 22, 2019.
- On May 11, 2018, Indivior settled its SUBOXONE® Film patent litigation against Par Pharmaceutical, Inc. ("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.

#### **Regulatory exclusivity related matters**

##### ***Braeburn Inc. v. FDA and Indivior Inc.***

- On December 21, 2018, Braeburn Inc. received tentative approval for its injectable depot buprenorphine product, Brixadi™. FDA did not grant final approval to Braeburn because it determined that the monthly version of Brixadi™ was blocked until November 30, 2020 by Indivior's three-year exclusivity period for injectable depot buprenorphine products that are approved to treat moderate to severe opioid use disorder.
- On April 9, 2019, Braeburn Inc. sued the FDA in the United States District Court for the District of Columbia, asking the Court for an order holding unlawful, vacating, and setting aside FDA's decision that SUBLOCADE®'s three-year exclusivity period bars approval of its monthly Brixadi product. Indivior moved to intervene on April 11, 2019, and that motion was granted on April 12, 2019. Braeburn moved for summary judgment on May 13, 2019, and both the FDA and Indivior filed cross-motions for summary judgment on June 3, 2019. The court heard oral argument on the parties' cross-motions on July 15, 2019.
- On July 22, 2019, the U.S. District Court for the District of Columbia granted Braeburn's motion for summary judgment, and vacated FDA's initial three-year exclusivity decision. The Court remanded the issue for FDA "to reconsider, with deliberate speed, Braeburn's application for final approval of Brixadi Monthly."
- On November 7, 2019, FDA issued a decision concluding that the 3-year exclusivity recognized for SUBLOCADE® precludes final approval of Brixadi monthly until November 30, 2020.

##### ***Braeburn Citizen Petition***

- On April 5, 2019, Braeburn submitted a Citizen Petition to the FDA asking that FDA revoke the Orphan Drug Designation that previously was granted to Indivior and applied to SUBLOCADE®, and that the FDA further refuse to grant Orphan Drug Exclusivity to SUBLOCADE®. Indivior submitted a response to this Citizen Petition on July 24, 2019. Braeburn submitted two additional supplements on August 27, 2019. Indivior submitted a response to those supplements on October 4, 2019. On October 9, 2019, FDA issued an interim response stating that it was still considering the petition because it raises significant issues requiring extensive review and analysis by Agency officials, and it would respond to the petition as soon as the Agency has reached a decision. Braeburn submitted additional comments on October 11, 2019. A substantive response is still pending with FDA.
- FDA issued a response on November 7, 2019, revoking the orphan drug designation for buprenorphine for "treatment of opiate addiction in opiate users" because the Agency had determined that buprenorphine was not eligible for orphan drug designation at the time it was requested. See Notes 3 and 5 for more information.

### 13. TRADE AND OTHER PAYABLES

	Dec 31 2019 \$m	Dec 31 2018 \$m
Sales returns and rebates	(460)	(510)
Trade payables	(39)	(47)
Accruals	(113)	(149)
Other tax and social security payables	(11)	(15)
<b>Total</b>	<b>(623)</b>	<b>(721)</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.

### 14. SHARE CAPITAL

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
<b>At January 1, 2019</b>	<b>728,441,653</b>	<b>\$0.10</b>	<b>73</b>
Allotments	2,346,066	\$0.10	-
<b>At December 31, 2019</b>	<b>730,787,719</b>		<b>73</b>

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2018	721,462,733	\$0.10	72
Allotments	6,978,920	\$0.10	1
At December 31, 2018	728,441,653		73

#### Allotment of ordinary shares

During the period, 2,346,066 ordinary shares (2018: 6,978,920) were allotted to satisfy vestings/exercises under the Group's Long-Term Incentive Plan and U.S. Employee Stock Purchase Plan.