

February 18, 2021



FY 2020 Financial Results Announced. FY 2021 Guidance Introduced.

Period to Dec. 31st	Q4 2020 \$m	Q4 2019 \$m	% Change		FY 2020 \$m	FY 2019 \$m	% Change
Net Revenue	185	133	39		647	785	-18
Operating (Loss)/Profit	(9)	(42)	-79		(156)	178	NM
Net (Loss)/Income	(13)	(55)	-76		(148)	134	NM
Basic (LPS)/EPS (cents/share)	(2)	(8)	-75		(20)	18	NM
Adj. Basis							
Adj. Operating Profit/(Loss)*	32	(46)	NM		88	202	-56
Adj. Net Income/(Loss)*	26	(37)	NM		59	176	-66
Adj. Basic EPS/(LPS)*	4	(5)	NM		8	24	-67

* *Adjusted (Adj.) basis excludes the impact of exceptional items as referenced in Notes 3 and 4. NM: Not Meaningful.*

FY 2020 Highlights

- Net revenue (NR) of \$647m (-18% vs. FY 2019) mainly reflected SUBOXONE® (buprenorphine and naloxone) Film share loss, partly offset by higher NR from SUBLOCADE® (buprenorphine extended-release) injection.
- Reported operating loss of \$156m. Exceptional costs of \$244m primarily relate to litigation settlements - see Notes 3 and 4. Adj. operating profit of \$88m (-56% vs. adj. FY 2019) mainly due to lower NR and higher SG&A expense from growth investments in SUBLOCADE and legal defense costs primarily due to resolving the Department of Justice (DOJ) matter.
- Reported net loss of \$148m. Adj. net income of \$59m (-66% vs. adj. FY 2019), reflecting lower operating profit and net finance expense (versus net finance income in FY 2019).
- Cash of \$858m (-\$202m vs. FY 2019), following \$103m payment, including interest, related to DOJ resolution. Net cash of \$623m (-\$198m vs. FY 2019).

Operating Highlights

- FY 2020 SUBLOCADE NR of \$130m (+81% vs. FY 2019) and Q4 2020 NR of \$39m (+18% vs. Q3 2020); strong growth from the Organized Health Systems (OHS) channel, despite COVID-19 impact on new patient enrolments. FY 2020 units dispensed were approx. 127,000* (+115% vs. FY 2019); Q4 2020 units dispensed were approx. 40,100* (+14% vs. Q3 2020).
- PERSERIS® (risperidone) extended-release injection NR of \$14m (+133% vs. FY 2019).
- SUBOXONE® Film share averaged 21% in FY 2020 (FY 2019: 32%) and exited FY 2020 at 21% (FY 2019 exit share: 24%).
- Completed strategic alignment which is expected to reduce the Group's underlying operating expense base (SG&A + R&D) by \$60m to \$70m (before reinvestment), while accelerating its growth strategy for SUBLOCADE with increased investment behind further penetrating Organized Health Systems (OHS) and supporting its strong commitment to integrity and compliance.

FY 2021 Guidance Highlights

Base case NR guidance assumes the operating backdrop will improve in H2 2021, as COVID-19 pandemic restrictions impacting in-person healthcare practitioner access subside and healthcare systems approach normality. Detailed guidance, including potential risks are provided on Page 2.

- Total base case FY 2021 NR up to \$625m; SUBLOCADE NR of \$185m to \$210m; PERSERIS NR of \$17m to \$20m.
 - Downside case if COVID-19 pandemic restrictions persist in H2 2021: Total NR of \$565m; SUBLOCADE NR of \$170m; PERSERIS NR of \$15m.
- Mid- to high-single digit percentage point decline in FY 2021 adj. gross margin; recovery to mid-80's rate in 2022.
- Adj. OPEX (SG&A+R&D) of \$420m to \$440m, mainly reflecting incremental investment in US long-acting injectables.
- Positive adj. pre-tax income.

Comment by Mark Crossley, CEO of Indivior PLC

"Given the challenges of the COVID-19 pandemic, I am delighted both with the solid results that Indivior delivered in FY 2020 and with the dedication to patients displayed by each and every one of our employees. Critically, we materially de-risked the business with resolution of the DOJ and RB matters and we took decisive strategic alignment actions which place Indivior on a clear path towards realizing the transformational potential of SUBLOCADE. We are convinced this important new treatment paradigm represents a significant untapped asset to help patients and society address the desperate condition and widespread epidemic of OUD. Accelerating the growth of SUBLOCADE remains the biggest potential driver of value creation. We are committed to delivering clear, measurable progress in FY 2021 against our SUBLOCADE peak annual net revenue goal of \$1 billion+ and organic revenue diversification strategies."

*Includes shipments in ROW geographies

Detailed FY 2021 Guidance

Guidance assumes the operating backdrop, chiefly the ability to accelerate in-person promotion and seek in-patient care, will improve in H2 2021 as COVID-19 pandemic restrictions subside and healthcare systems approach normality.

- Total base case FY 2021 NR up to \$625m; SUBLOCADE NR of \$185m to \$210m; PERSERIS NR of \$17m to \$20m
- In a downside scenario in which the operating backdrop continues to be adversely impacted by pandemic restrictions through H2 2021, Indivior believes total net revenue for FY 2021 could be adversely impacted by up to \$60m. On this basis, total net revenue could be approximately \$565m with SUBLOCADE and PERSERIS net revenue of approximately \$170m and \$15m, respectively.
- Mid- to high-single digit decline in FY 2021 adj. gross margin primarily due to current product and regional mix; adj. GM expected to return to mid-80's in 2022 as more profitable SUBLOCADE is expected to grow as a proportion of total NR.
- Adj. OPEX (SG&A+R&D) of \$420m to \$440m reflecting benefits from completed strategic alignment, partially offset by:
 - incremental investments for US long-acting injectables (LAIs), fueled by the relative strength in US SUBOXONE Film (the Group may make further LAI growth investments based on continued relative US Film strength); and,
 - COVID-delayed supply-related projects.
- Positive adj. pre-tax income.

Operating Review

U.S. Opioid Use Disorder (OUD) Market Update

In FY 2020, growth of the U.S. buprenorphine medication-assisted treatment (BMAT) market was sustained at a low teens percentage rate, underpinned by continued growth in the number of patients receiving treatment and by increased access to treatment. The increased market growth followed implementation of new federal and state government actions in light of the COVID-19 pandemic to facilitate access to medication-assisted treatment (MAT), including counselling, for patients suffering from OUD. For example, the Drug Enforcement Administration (DEA), jointly with the Substance Abuse and Mental Health Services Administration (SAMHSA), is continuing to allow healthcare providers to initiate and continue buprenorphine treatment by telemedicine.

Underlying market growth has also benefited from increased overall public awareness of the opioid epidemic and approved treatments, as well as from regulatory and legislative changes introduced prior to the COVID-19 pandemic that have expanded OUD treatment funding and treatment capacity. States increasingly acknowledge that providing treatment brings substantial value to both patients and society and that BMAT is under-utilized.⁽¹⁾

In response, the number of physicians, nurse practitioners and physician assistants who have received a waiver to administer MAT and those able to treat up to the permitted level of 275 patients continued to grow in FY 2020. As a result, there is increasing patient access to treatment. Indivior supports efforts to encourage more eligible HCPs to provide treatment, and the Group continues to resource its compliance capabilities for the growing number of BMAT prescribers and patients.

The Group is uncertain how long the elevated underlying BMAT growth rate will continue, but longer term it believes the growth rate will revert to the previously observed high single-digit to low double-digit percentage growth rate. The Group's focus is to continue to expand access of SUBLOCADE amongst core healthcare practitioners (HCPs) and Organized Health Systems (OHS), in order to ensure availability of this potentially important new treatment option to the estimated 1 million+ patients per month who are prescribed BMAT by HCPs.

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

Financial Performance: FY 2020 & Q4 2020

Total net revenue in FY 2020 decreased 18% to \$647m (FY 2019: \$785m). In Q4 2020, total net revenue increased 39% to \$185m (Q4 2019: \$133m).

FY 2020 U.S. net revenue decreased 23% to \$456m (FY 2019: \$589m). Growth in the overall U.S. BMAT market was sustained at a low teens percentage rate as discussed above (“U.S. Opioid Use Disorder (OUD) Market Update”), primarily due to strength in government channels. Underlying market strength and SUBLOCADE net revenue growth of 75% to \$126m (FY 2019: \$72m) were more than offset by SUBOXONE Film share loss and the absence of net revenue contribution from the AGx film program, which was terminated at the end of FY 2019.

In Q4 2020, U.S. net revenue increased 68% to \$134m (Q4 2019: \$80m). While Q4 2020 net revenue dynamics were substantially the same as those for FY 2020, the comparable year-ago quarter had one-time items that impacted net revenue, chiefly the negative effect of the federal law change enacted October 2019 (HR 4378), which modified the impact of authorized generics (AGx) in determining the mandated rebate amount in government channels for branded SUBOXONE Film. This negatively impacted Q4 2019 net revenue by approximately \$47m and the Group subsequently terminated its AGx buprenorphine/naloxone sublingual film program at the end of 2019.

FY 2020 Rest of World (ROW) net revenue decreased 3% to \$191m (FY 2019: \$196m). In Q4 2020, ROW net revenue decreased 4% to \$51m (Q4 2019: \$53m). Contribution from SUBLOCADE to ROW net revenue of \$4m and \$2m are included in the FY 2020 and Q4 2020 periods, respectively. These benefits were more than offset primarily by continued austerity measures in Western European markets.

FY 2020 and Q4 2020 gross margin as reported was 85% and 88%, respectively (FY 2019: 82%; Q4 2019: 68%). Excluding \$5m of net exceptional costs of sales related to inventory provisions due to the adverse impact of COVID-19, FY 2020 adjusted gross margin was 86%. The FY 2020 gross margin improvement was primarily due to improved revenue mix from the absence of net revenue from the AGx buprenorphine/naloxone sublingual film program in 2020. The Q4 2020 gross margin increase reflects the impact of federal legislation (HR 4378) discussed above that adversely impacted Q4 2019 gross margin.

FY 2020 SG&A expense as reported were \$666m (FY 2019: \$414m). FY 2020 SG&A expenses included exceptional costs of \$239m, primarily related to resolution of litigation matters. Q4 2020 SG&A expenses as reported were \$158m (Q4 2019: \$115m). The exceptional costs recorded in Q4 2020 totalled \$47m (Q4 2019: exceptional benefit \$4m). See Notes 3 and 4 for details on exceptional costs.

On an adjusted basis, FY 2020 SG&A expenses increased 10% to \$427m (Adj. FY 2019: \$390m). The increase reflects stepped up SUBLOCADE marketing expenses, principally the direct-to-consumer (DTC) campaign, higher legal expenses related to DOJ resolution, partially offset by reduced travel and entertainment due to COVID-19 restrictions. On an adjusted basis, Q4 2020 SG&A expenses declined 7% to \$111m (Q4 2019: \$119m). The decline in the quarter largely reflects lower marketing expenses, reduced travel and entertainment and impact from completed strategic alignment actions.

FY 2020 and Q4 2020 R&D expenses were \$40m and \$13m, respectively (FY 2019: \$53m; Q4 2019: \$17m). The decreases in both periods primarily reflect lower clinical activity and the reprioritization of R&D activities as part of the completed strategic alignment to principally support SUBLOCADE Health Economics and Outcomes Research (HEOR) and post-marketing study commitments for SUBLOCADE and PERSERIS, as well as lower than expected investments for supply-related projects.

FY 2020 operating loss as reported was \$156m (FY 2019 op. profit: \$178m). Exceptional costs of \$244m and \$24m are included in the FY 2020 and FY 2019 reported results, respectively. On an adjusted basis, FY 2020 operating profit was \$88m (FY 2019 adj. op. profit: \$202m). The decline on an adjusted basis primarily reflects

lower net revenue and increases in marketing and legal defense costs as detailed above. These items were partially offset by lower R&D and general and administrative expenses.

Q4 2020 operating loss as reported was \$9m (Q4 2019 op. loss: \$42m). Exceptional costs of \$41m and a \$4m benefit are included in the Q4 2020 and Q4 2019 reported results, respectively. On an adjusted basis, Q4 2020 operating profit was \$32m (Q4 2019: adj. op. loss: \$46m). The increase on an unadjusted and adjusted basis primarily reflects the gross profit impact in the year-ago quarter related to legislation that modified the calculation for determining the rebate amount in government channels for SUBOXONE Film.

FY 2020 net finance expense was \$17m (FY 2019 income: \$2m). The net expense primarily reflects lower interest income on the Group's cash balance due to lower interest rates versus the year-ago period and increased finance expense incurred related to the DOJ liability.

FY 2020 reported total tax benefit was \$25m, an effective tax rate of 14% (FY 2019 tax charge: \$46m, 26% rate). Excluding the \$37m tax benefit on exceptional items in FY 2020, total tax expense was \$12m, an effective tax rate of 17% (FY 2019: \$28m, 14% rate). Q4 2020 reported total tax benefit was \$1m, representing an effective tax rate of 7% (Q4 2019 tax charge: \$13m, 31% rate). Excluding the \$2m tax benefit on exceptional items in Q4 2020, the effective tax rate was 4% (Q4 2019 tax benefit \$9m, 20%).

FY 2020 reported net loss was \$148m (FY 2019 net income: \$134m). Excluding the \$207m after-tax impact from exceptional items, FY 2020 adjusted net income was \$59m (Adj. FY 2019: \$176m). The decline in net income on an adjusted basis primarily reflects lower net revenue, increased operating expenses (primarily marketing and legal defense costs) and net finance expense (versus FY 2019 net finance income).

Reported Q4 2020 net loss on a reported basis was \$13m. (Q4 2019 reported net loss: \$55m). Excluding the \$39m after-tax benefit from exceptional items, Q4 2020 adjusted net income was \$26m. Q4 2019 net loss was \$55m and adjusted net loss was \$37m, reflecting the increased gross profit versus the year-ago quarter related to legislation that modified the calculation for determining the rebate amount in government channels for SUBOXONE Film.

Loss per share on a diluted basis was 20 cents in FY 2020 and earnings per share of 8 cents on an adjusted diluted basis (FY 2019: earnings per share of 18 cents on a diluted and 23 cents on adjusted diluted basis). In Q4 2020, loss per share on a diluted basis was 2 cent and earnings per share of 3 cents on an adjusted diluted basis (Q4 2019: loss per share of 8 cents on a diluted and 5 cents on an adjusted diluted basis).

Balance Sheet & Cash Flow

FY 2020 December 31, 2020 cash and cash equivalents were \$858m, a decrease of \$202m versus the \$1,060m at year-end 2019. Borrowings, including issuance costs, were \$235m at December 31, 2020 (FY 2019: \$239m). As a result, net cash was \$623m at the end of Q4 2020 (FY 2019: \$821m), a \$198m decrease over the twelve-month period. The change was primarily driven by a payment to the DOJ for \$103m (including interest) and the change in net working capital.

Net working capital (inventory, trade receivables and other current assets, less trade and other payables) was negative \$202m at the end of 2020 versus negative \$323m at the end of 2019. The \$121m change over the period was primarily driven by a decrease in sales returns and rebates in the U.S. within payables and a reduction in accrual levels.

Cash used by operating activities in FY 2020 was \$148m (FY 2019 cash generated: \$128m), representing an increased use of cash of \$276m primarily due to lower revenues, timing of payments of sales rebates/other payables and payment to the DOJ for \$103m (including interest). Net cash outflow from operating activities was \$193m in FY 2020 (FY 2019 net cash inflow: \$151m) reflecting the lower cash from operating activities and cash tax payments in FY 2020 versus cash tax received in FY 2019.

FY 2020 cash outflow from investing activities was \$4m (FY 2019: \$2m). The current year outflows related to the purchase of property, plant and equipment and the prior year outflows relate to the purchase of property, plant and equipment offset by proceeds from the disposal of intangible assets.

FY 2020 cash outflow from financing activities was \$10m (FY 2019: \$13m), reflecting the principal portion of lease payments and the quarterly repayment on the term loan facility partially offset by proceeds from issuance of shares to satisfy the vesting of options under an employee stock purchase plan.

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 Update

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 below are what the Group considers to be the principal risks that could cause the Group's business model, future performance, and solvency or liquidity to differ materially from expected and historical results. Additional risks, not listed here, that the Group cannot presently 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 and compliance processes and systems as well as to retain and/or recruit 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.

COVID-19 Pandemic - The persistence of the COVID-19 pandemic and the ongoing government measures to address the global pandemic continue to create a very challenging business environment for companies across industries worldwide and therefore related risks to the Group's business and operations. In response to COVID-19, the Group has established an agile cross-functional response structure; and implemented a number of mitigation and contingency actions to help maintain the functioning of operations across the organization, supply of all products to our patients, and the welfare of our employees. The Group continuously monitors the potential impact on the health and well-being of our employees as well as the workforce of our key third parties, which ultimately may impact our operations. Furthermore, given the remote working environment, the Group continues to closely monitor cybersecurity threats and the overall operating effectiveness of the monitoring and control activities. Given the evolving and dynamic nature of the COVID-19 pandemic, and uncertainty surrounding the duration of measures designed to mitigate its spread, including the vaccination of the population or attainment of herd immunity, the impact on the Group's operations and financial position is highly uncertain and cannot be predicted with confidence. COVID-19 related developments are under constant review to ensure our mitigation and contingency actions are appropriate, proportionate, and as effective as possible. However, despite the measures the Group has taken, if the pandemic adversely affects Indivior's operations and/or performance, it will have a heightened effect on many of the risks impacting the Group, including its business operations.

The manufacturing of our SUBOXONE and SUBUTEX tablets for all of our European markets is performed by a third-party contract manufacturer located in the UK. The Group has been proactive in taking appropriate actions

since the Brexit referendum, including changes to logistics, shipping, and quality testing and release processes, as well as transfer of regulatory licenses and additional inventory builds. Uncertainties due to the operational impact of the recently signed Trade and Cooperation Agreement between the UK and the European Union (EU) remain a risk closely monitored as it impacts various areas of the Group, including Operations, Regulatory, Supply Chain, and Quality.

Product Pipeline, Regulatory and Safety

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

COVID-19 Pandemic – The COVID-19 pandemic has negatively impacted our R&D operations, specifically trial patient enrolments and limited chemistry, manufacturing & controls (CMC) operations, and therefore caused certain delays in conducting clinical and/or CMC studies internally and/or at our third-party partners.

Commercialization

Successful commercialization of our products is a critical factor for the Group's sustained growth and robust financial position. Launch of a new product involves substantial investment in marketing, market access and sales activities, product stocks, and other investments. Certain factors, if different than anticipated, can significantly impact the Group's performance and position. These factors include: HCP/Patient adoption and adherence; 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; and political and socioeconomic factors.

COVID-19 Pandemic - The pandemic has resulted in overall fewer patient visits to healthcare provider offices for non-COVID-19 reasons or essential treatments, as patients become unable or unwilling to make visits due to overburdened healthcare systems or elect to have remote consultations (telehealth) with their providers. As a result, in Q2 2020, the Group observed a rapid decline in new US patient enrolments followed by a modest improvement in Q3 compared to Q2, and continued growth in Q4 compared to Q3. The pandemic has also resulted in safety concerns, quarantines, or other travel restrictions for patients. Furthermore, even though the Group has developed remote (digital) meeting capability with healthcare providers, the Group's commercial organization is still only able to engage in-person with a limited number of healthcare professionals (HCPs) and Organized Health Systems (OHS). Although COVID-19 has not significantly impacted the Group's overall operating results and financial position to date, a potential enduring and/or significant decline in patient enrolments and on the patient journey, and the inability to effectively engage with HCPs and OHS would have a negative impact on the Group's financial results in future periods.

Governments across the world are considering and taking actions to lower drug prices. In the US, there is bipartisan support for drug pricing reforms at both federal and state levels, which include potential legislative and regulatory actions to encourage the import of drugs, to price drugs according to a defined international pricing reference, to encourage more competition, and to undertake other initiatives. These, together with federal and state government fiscal constraints resulting from the COVID-19 pandemic which constrain public benefit health programs, pose direct and indirect downward pressure risk on drug prices. The Group continues to monitor potential legislative and regulatory changes and their impacts, advocating for the Group's products based on scientific studies and patient-centered outcomes. However, certain potential legislative and regulatory drug pricing changes could have an adverse impact on the Group's financial performance and results in the future.

Economic and Financial

The pharmaceutical business includes inherent risks and uncertainties, requiring the Group to make significant financial investments to develop and support the success of our product portfolio. Generating cash flow from our approved products, together with external financing, sustains our financial position, allows development of new products, and funds business growth. Realizing value on those investments is dependent upon regulatory approvals, market acceptance (including pricing reimbursement levels), strategic partnerships, competition, and legal developments. Unfavorable outcome from resolutions of legal proceedings, impacts from the COVID-19 pandemic, and/or changes in government pricing regulations could negatively impact our operating results and financial position. Together with potential pressure on our level of net working capital, our ability to comply with our debt covenants could be negatively impacted. As a global business, we are also subject to political, economic, and capital markets changes.

Supply

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 uses third parties, including contract manufacturing organizations (CMOs), to manufacture, package and distribute our products. The manufacturing of oral solid dose, film products and aseptically filled injectables 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 and lead to product recalls and/or potential regulatory actions against the Group along with potential reputational damages.

COVID-19 Pandemic - The pandemic could adversely impact our broad supply chain (i.e., "supply to patient delivery" process) if we experience a significant absence of our employees and/or employees at our CMOs and vendors due to infection and/or government containment measures. Through on-going management and risk mitigation, internally and with CMOs, the Group has not experienced any significant COVID-19 related disruptions to its supply to patient delivery process through this date.

Legal and Intellectual Property

Our pharmaceutical operations, which include controlled substances, are subject to a wide range of laws and regulations. Perceived or actual noncompliance with these applicable laws and regulations by a pharmaceutical company can result in investigations or proceedings leading to civil or criminal sanctions, 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.

In connection with the agreements to resolve criminal charges and civil complaints related to SUBOXONE Film (see Note 11, Legal Proceedings, to the condensed consolidated financial statements), the Group has specific requirements that are in addition to the Group's pre-existing obligations to comply with applicable laws and regulations associated with its US pharmaceutical operations. The Group is subject to penalties if it fails to fulfill the requirements within the agreements.

The Group is also a party to several civil lawsuits, including ongoing litigation in the Federal FCA Qui Tam suits, and civil antitrust and state claims filed by various plaintiffs. Many of the civil claims concern the same conduct at issue in the Superseding Indictment filed by the DOJ.

The Group is also a defendant in fewer than 400 civil lawsuits brought by various plaintiffs as part of the opioid class action litigation. These cases are at an early stage and are currently stayed.

Unfavorable outcomes from resolutions of these legal proceedings could have a material adverse impact on the Group's business, financial condition and/or operating results.

See Note 11, Legal Proceedings, to the condensed consolidated financial statements for additional information.

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 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.

As part of the Group's resolution of federal criminal and civil charges related to its legacy products (see Note 11, Legal Proceedings, to the condensed consolidated financial statements for additional information.), the Group has also entered into a Corporate Integrity Agreement (CIA) with HHS-OIG. The five-year CIA requires, among other things, that the Group implement measures designed to ensure compliance with the statutes, regulations, and written directives of U.S. Medicare, U.S. Medicaid, and all other U.S. Federal health care programs, as well as with the statutes, regulations, and written directives of the U.S. Food and Drug Administration. Furthermore, the Group is subject to additional periodic reporting and monitoring requirements related to the Agreements. In addition, the CIA requires reviews by an independent review organization, compliance-related certifications from the Group's executives and certain Board members, and the implementation of a risk assessment and mitigation process. The CIA sets forth specified monetary penalties that may be imposed on a per day basis for failure to comply with the obligations specified in the CIA. The CIA also includes specific procedures under which the Group must notify HHS-OIG if it fails to meet the requirements under the CIA. In the event that HHS-OIG determines the Group to be in material breach of certain requirements of the CIA (including, repeated violations or any flagrant obligations under the CIA, a failure by the Group to report a reportable event and/or take corrective action, a failure to engage and use an independent review organization, a failure to respond to certain requests from HHS-OIG), the Group may be subject to exclusion from participation in the U.S. Federal health care programs, which would have a severe impact on the Group's ability to comply with the financial covenants in the Group's debt facility, maintain sufficient liquidity to fund its operations, pay off its debt in 2022, generate future revenue and ultimately impact the Group's viability.

The Resolution Agreement with the United States Attorney's Office for the Western District of Virginia and Consumer Protection Branch contains certain requirements, such as reporting obligations and that the Group's CEO (a) certify on an annual basis that, to the best of the CEO's knowledge, after a reasonable inquiry, the Group was in compliance with the Federal Food, Drug and Cosmetic Act and has not committed health care fraud, or (b) provide a list of all non-compliant activities and steps taken to remedy the activity. The FTC Stipulated Order contains specific notice and reporting requirements over a ten-year period related to certain activities (e.g., product switching conduct, filing of a Citizen Petition). The Group is subject to contempt prosecution if it fails to comply with any terms of the Resolution Agreement.

The Group's Annual Report for the 2020 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, 2020	Full Year to December 31, 2019
GB £ period end	1.3651	1.3263
GB £ average rate	1.2833	1.2768
€ Euro period end	1.2226	1.1228
€ Euro average	1.1403	1.1198

Webcast Details

There will be a live webcast presentation at 12:00 GM (7:00 am EST) hosted by Mark Crossley, CEO. The details are below. All materials will be available on the Group's website prior to the event at www.indivior.com.

Webcast link: <https://edge.media-server.com/mmc/p/23dqgtiy>

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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, if any, 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 compliance with the Indivior Group's agreements with the U.S. Department of Justice and with the Office of Inspector General of the Department of Health and Human Services, noncompliance with which could result in potential exclusion from 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; risks related to the evolving COVID-19 pandemic and the potential impact of COVID-19 on the Indivior Group's operations and financial condition, which cannot be predicted with confidence; 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 for a complete list.

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

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

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.

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.

Condensed consolidated income statement

		Unaudited Q4 2020 \$m	Unaudited Q4 2019 \$m	Unaudited FY 2020 \$m	Audited FY 2019 \$m
For the three and twelve months ended December	Notes				
Net Revenues	2	185	133	647	785
Cost of Sales		(23)	(43)	(97)	(140)
Gross Profit		162	90	550	645
Gross profit before exceptional items	4	156	90	555	645
Exceptional items	3	6	-	(5)	-
Selling, general and administrative expenses	3	(158)	(115)	(666)	(414)
Research and development expenses	3	(13)	(17)	(40)	(53)
Operating (Loss)/Profit		(9)	(42)	(156)	178
Operating profit/(loss) before exceptional	4	32	(46)	88	202
Exceptional items	3	(41)	4	(244)	(24)
Finance income		3	5	9	24
Finance expense		(8)	(5)	(26)	(22)
Net finance (expense)/income		(5)	-	(17)	2
(Loss)/Profit before Taxation		(14)	(42)	(173)	180
Income tax benefit/(expense)		1	(13)	25	(46)
Taxation before exceptional items	5	(1)	9	(12)	(28)
Exceptional items within taxation	3,5	2	(22)	37	(18)
Net (Loss)/Income		(13)	(55)	(148)	134
(Loss)/Earnings per ordinary share (cents)					
Basic (loss)/earnings per share	6	(2)	(8)	(20)	18
Diluted (loss)/earnings per share	6	(2)	(8)	(20)	18

Condensed consolidated statement of comprehensive income/(loss)

		Unaudited Q4 2020 \$m	Unaudited Q4 2019 \$m	Unaudited FY 2020 \$m	Audited FY 2019 \$m
For the three and twelve months ended December					
Net (loss)/income		(13)	(55)	(148)	134
Other comprehensive income					
<i>Items that may be reclassified to profit or loss in subsequent years:</i>					
Net exchange adjustments on foreign currency translation		15	14	10	9
Other comprehensive income		15	14	10	9
Total comprehensive income/(loss)		2	(41)	(138)	143

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

Condensed consolidated balance sheet

	Notes	Unaudited Dec 31, 2020 \$m	Audited Dec 31, 2019 \$m
ASSETS			
Non-current assets			
Intangible assets		62	72
Property, plant, and equipment		60	60
Right-of-use assets		43	47
Deferred tax assets	5	75	40
Other assets	7	104	73
		344	292
Current assets			
Inventories		93	73
Trade receivables		179	192
Other assets	7	50	35
Current tax receivable	5	7	-
Cash and cash equivalents	8	858	1,060
		1,187	1,360
Total assets		1,531	1,652
LIABILITIES			
Current liabilities			
Borrowings	8	(4)	(4)
Provisions and other liabilities	9	(48)	(71)
Trade and other payables	12	(524)	(623)
Lease liabilities		(8)	(5)
Current tax liabilities	5	(15)	(39)
		(599)	(742)
Non-current liabilities			
Borrowings	8	(230)	(233)
Provisions and other liabilities	9	(577)	(417)
Lease liabilities		(43)	(51)
		(850)	(701)
Total liabilities		(1,449)	(1,443)
Net assets		82	209
EQUITY			
Capital and reserves			
Share capital	13	73	73
Share premium		6	5
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(13)	(23)
Retained Earnings		1,311	1,449
Total equity		82	209

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
Audited							
Balance at January 1, 2019		73	5	(1,295)	(32)	1,315	66
Comprehensive income							
Net income		-	-	-	-	134	134
Other comprehensive income		-	-	-	9	-	9
Total comprehensive income		-	-	-	9	134	143
Transactions recognised directly in equity							
IFRS 16 impact (adjustment to opening balance)		-	-	-	-	(2)	(2)
Share-based payments		-	-	-	-	3	3
Deferred taxation on share-based plans and IFRS 16		-	-	-	-	(1)	(1)
Balance at December 31, 2019		73	5	(1,295)	(23)	1,449	209
Unaudited							
Balance at January 1, 2020		73	5	(1,295)	(23)	1,449	209
Comprehensive loss							
Net (loss)		-	-	-	-	(148)	(148)
Other comprehensive income		-	-	-	10	-	10
Total comprehensive loss		-	-	-	10	(148)	(138)
Transactions recognised directly in equity							
Shares issued		-	1	-	-	-	1
Share-based payments		-	-	-	-	8	8
Deferred taxation on share-based plans		-	-	-	-	2	2
Balance at December 31, 2020		73	6	(1,295)	(13)	1,311	82

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

Condensed consolidated cash flow statement

	Unaudited 2020 \$m	Audited 2019 \$m
For the twelve months ended December 31		
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating (Loss)/Profit	(156)	178
Depreciation and amortization	18	20
Gain on disposal of right-of-use assets	(2)	-
Gain on disposal of intangible asset	-	(4)
Depreciation and impairment of right-of-use assets	8	8
Share-based payments	8	3
Impact from foreign exchange movements	(5)	2
Decrease in trade receivables	15	79
Increase in other assets	(44)	(56)
(Increase)/Decrease in inventories	(16)	7
Decrease in trade and other payables	(103)	(101)
Increase/(Decrease) in provisions and other liabilities ¹	129	(8)
Cash (used in)/generated from operations	(148)	128
Interest paid	(20)	(17)
Interest received	9	22
Taxes (paid)/refunded	(34)	18
Net cash (outflow)/inflow from operating activities	(193)	151
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant, and equipment	(4)	(7)
Proceeds from lease incentives	-	1
Proceeds from disposal of intangible assets	-	4
Net cash outflow from investing activities	(4)	(2)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of borrowings	(4)	(4)
Payment of lease liabilities	(7)	(9)
Proceeds from the issuance of ordinary shares	1	-
Net cash outflow from financing activities	(10)	(13)
Net (decrease)/increase in cash and cash equivalents	(207)	136
Cash and cash equivalents at beginning of the period	1,060	924
Exchange difference	5	-
Cash and cash equivalents at end of the period	858	1,060

¹Changes in provisions and other liabilities line include \$228m of exceptional charges relating to litigation matters offset by the \$100m initial payment under the DOJ resolution in 2020. \$3m of interest on the DOJ resolution has been recorded in the interest paid line item.

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 Group prepared its annual accounts for December 31, 2019 in accordance with International Financial Reporting Standards (IFRS) and IFRS Interpretations Committee (IFRIC) interpretations as adopted by the European Union (EU) and the Companies Act 2006 (the Act) applicable to the companies reporting under IFRS. As a result of the United Kingdom leaving the EU, the Group will be preparing the financial statements for December 31, 2020 in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006, and in accordance with International Financial Reporting Standards adopted pursuant to Regulation (EC) No.1606/2002 as it applies in the European Union (adopted IFRSs). There is no change in the underlying reporting framework applicable for December 31, 2020 and has had no impact on the financial information included herein and therefore the accounting policies set out in the annual accounts of the Group for the year ended December 31, 2019 are applied in preparing this financial information and should be read in conjunction with those annual accounts. In preparing these Condensed Financial Statements, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were applied in a consistent manner to the consolidated financial statements for the year ended December 31, 2019. Additionally, the Group reviewed the impact of COVID-19 on key business practices and further evaluated estimates used in judgmental accounting positions as a result of the pandemic. The Group's review focused on disruptions to the supply chain, inventory obsolescence, impact on cash flows (Going Concern), impairment of finite-lived intangible assets, impairment of fixed assets and expected credit loss provisions for trade receivables. The 2019 balance sheet and statement of cash flow have been expanded to present trade receivables and other assets (current) on separate line items to improve presentation and transparency.

The Group has adopted the following standards as of January 1, 2020, which had no material impact on the Condensed Financial Statements. The IASB issued amendments to IFRS 9 *Financial Instruments*, IAS 39 *Financial Instruments: Recognition and Measurement* and IFRS 7 *Financial Instruments: Disclosures*. These standards relate to the replacement of benchmark interest rates such as LIBOR. The IASB identified two phases of the reform; Phase 1 amendments primarily deal with pre-LIBOR reform where uncertainty could arise in the lead up to transition and Phase 2 amendments relate to post-LIBOR reform, when uncertainty is removed, and new rates adopted. Phase 1 amendments provide relief from applying specific hedge accounting requirements. The Group's adoption of these amendments had no impact on the consolidated financial statements. Phase 2 amendments primarily address potential financial reporting issues that may arise when LIBOR is replaced. For contractual changes or changes to cash flows directly required by LIBOR reform, the effective interest rate (EIR) may be updated without adjusting the carrying amount of the financial asset/liability or the EIR may be used to recalculate the carrying amount, with any modification gain or loss recognized in profit or loss. Phase 2 amendments apply retrospectively from January 1, 2021 with earlier application permitted. As the Group's term loan matures after publication of LIBOR is expected to end, it has engaged with an administrative agent and expects to transition to a reasonable substitute base rate. The Group does not expect the adoption of this standard to have a significant impact on the future consolidated financial statements. Other standards were issued and adopted by the Group on January 1, 2020 which had no impact on the Condensed Financial Statements.

The Condensed 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, 2019. These Condensed Financial Statements have been reviewed and not audited. These Condensed Financial Statements were approved for issue on February 17, 2021.

As disclosed in Notes 9, 10 and 11, the Group has liabilities and provisions totaling \$568m (FY 2019: \$438m) for Department of Justice (DOJ) and related matters and the Reckitt Benckiser (RB) resolution. Although the Group has addressed these risks, various other legal proceedings (as discussed in Note 11) have not been settled and therefore create future financial risk and uncertainty. Ongoing legal proceedings, reasonably possible impacts on the Group from the COVID-19 pandemic, failure of SUBLOCADE® and PERSERIS® to meet revenue growth expectations and/or lower than forecast revenue of SUBOXONE® Film have all been considered as part of the Group's adoption of the going concern basis. Directors of the Group have a reasonable expectation the Group has adequate resources to continue in operational existence for at least one year from the approval of these financial statements. In coming to this conclusion, the Directors considered reasonably possible risks relating to the uptake of SUBLOCADE and PERSERIS, ongoing litigation, and continued competitive pressures on legacy products. These risks were balanced against the Group's working capital position, cost savings actions taken, and timing of the final balloon payment on the Term Loan. The previous material uncertainty relating to the Group's ability to continue as a going concern has been removed in Q4 2020 as a result of the DOJ resolution.

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, 2019, the auditors issued (1) an emphasis of matter dealing with the outcome of litigation matters; and (2) a material uncertainty related to going concern due to the Group's litigation matters, which could have been further adversely affected by the failure of SUBLOCADE and PERSERIS to meet revenue growth expectations and/or lower than forecast revenue of SUBOXONE Film. The Group's statutory financial statements for the year ended December 31, 2019 were approved by the Board of Directors on March 5, 2020 and delivered to the Registrar of Companies House on June 29, 2020.

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 predominantly engaged in a single business activity, which is the development, manufacture, and sale of buprenorphine-based prescription drugs for treatment of opioid dependence and related disorders. The CEO reviews disaggregated net revenue and financial results on a consolidated basis for evaluating financial performance and allocating resources. Accordingly, the Group operates in a single reportable segment.

NET REVENUE & NON-CURRENT ASSETS

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 region. Non-current assets for this purpose consist of intangible assets, property, plant and equipment, right-of-use assets, and other assets. Net revenues and non-current assets for the three and twelve months to December 31, 2020 and 2019 were as follows:

Net revenues from sale of goods:

	Q4 2020	Q4 2019	FY 2020	FY 2019
	\$m	\$m	\$m	\$m
For the three and twelve months ended December 31				
United States	134	80	456	589
Rest of World (ROW)	51	53	191	196
Total	185	133	647	785

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

	Q4 2020	Q4 2019	FY 2020	FY 2019
	\$m	\$m	\$m	\$m
For the three and twelve months ended December 31				
SUBLOCADE	39	24	130	72
PERSERIS	4	3	14	6
Sublingual/Other	142	106	503	707
Total	185	133	647	785

Non-current assets:

	Dec 31, 2020 \$m	Dec 31, 2019 \$m (restated)
United States	141	118
ROW	128	134
Total	269	252

The prior year has been restated to reflect a \$50m reclassification between ROW and United States related to surety bonds. The impact of the change was an increase to United States non-current assets from \$68m to \$118m and a decrease in ROW from \$184m to \$134m.

3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

	Q4 2020	Q4 2019	FY 2020	FY 2019
	\$m	\$m	\$m	\$m
For the three and twelve months ended December 31				
Research and development expenses	(13)	(17)	(40)	(53)
Marketing, selling and general expenses	(53)	(70)	(202)	(199)
Administrative expenses ¹	(102)	(40)	(447)	(196)
Depreciation and amortization	(3)	(5)	(17)	(19)
Total	(158)	(115)	(666)	(414)

¹Administrative expenses include exceptional costs in the current and prior year as outlined in table below.

Exceptional Items

Where significant expenses or income are incurred that do not reflect the Group's ongoing operations, these items are disclosed as exceptional items in the income statement. Examples of such items could include restructuring 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 regulatory and litigation matters/settlements, and certain tax related matters.

The table below sets out exceptional items recorded in the quarter and full year:

	Q4 2020	Q4 2019	FY 2020	FY 2019
For the three and twelve months ended December 31	\$m	\$m	\$m	\$m
Cost of sales credit/(charge) ¹	6	-	(5)	-
Restructuring costs ²	(2)	-	(11)	(20)
Legal settlements/provisions ³	(45)	-	(228)	(8)
Other operating income ⁴	-	4	-	4
Total exceptional items before taxes	(41)	4	(244)	(24)
Tax on exceptional items	2	-	37	4
Exceptional items within taxation ⁵	-	(22)	-	(22)
Total exceptional items	(39)	(18)	(207)	(42)

1. FY 2020 exceptional cost of sales, net, relate to changes in inventory provision estimates due to the adverse impact of COVID-19 on the business. These changes in inventory provision estimates have been considered as exceptional as they are one-off and do not reflect the underlying performance of the business. In Q4 2020 the Group corrected its estimation of inventory consumed from Q3 with the resulting exceptional provision release of \$6m offset the exceptional charge taken in Q3 2020.
2. Restructuring costs incurred in Q4 2020 and YTD 2020 relate to cost saving actions taken by the Group to protect the financial and operational flexibility in response to ongoing challenges posed by COVID-19. Restructuring costs incurred in YTD 2019 were a result of adverse U.S. market developments, more specifically the launch of generic buprenorphine/naloxone film in the U.S. Each of these charges are a result of one-off factors and are therefore non-recurring. Restructuring costs in YTD 2020 consist of termination costs and lease early termination costs. Restructuring costs in YTD 2019 consist of supply chain restructuring and termination costs. These costs are included in SG&A.
3. In January 2021, the Group reached a resolution with RB for \$50m which was recognized in Q4 2020, offset by a reduction in provision for DOJ related matters for \$5m. \$228m of legal settlement related expenses in YTD 2020 relate to resolution with RB and DOJ, \$50m and \$178m, respectively. \$8m of legal expenses in YTD 2019 relate to potential redress for ongoing intellectual property related litigation with Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories Inc. (collectively, "DRL") and Alvogen Pharmaceuticals (Alvogen). These costs are included in SG&A. Refer to Note 9 for more information on legal provisions and other liabilities.
4. Exceptional income in 2019 related to the proceeds received from out-licensing of nasal naloxone opioid overdose patents which are included in SG&A.
5. Exceptional items within taxation of \$22m in 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 \$12m due to regulation changes stemming from US tax reform.

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 gross profit, operating profit and net income for both Q4/FY 2020 and Q4/FY 2019. Refer to Note 3 for more information on exceptional items.

Reconciliation of gross profit to adjusted gross profit

	Q4 2020	Q4 2019	FY 2020	FY 2019
For the three and twelve months ended December 31	\$m	\$m	\$m	\$m
Gross profit	162	90	550	645
Exceptional cost of sales (credit)/charge	(6)	-	5	-
Adjusted gross profit	156	90	555	645

Reconciliation of operating (loss)/profit to adjusted operating profit/(loss)

	Q4 2020 \$m	Q4 2019 \$m	FY 2020 \$m	FY 2019 \$m
For the three and twelve months ended December 31				
Operating (loss)/profit	(9)	(42)	(156)	178
Exceptional cost of sales (credit)/charge	(6)	-	5	-
Exceptional selling, general and administrative expenses	47	-	239	28
Exceptional operating income	-	(4)	-	(4)
Adjusted operating profit/(loss)	32	(46)	88	202

Reconciliation of (loss)/profit before taxation to adjusted profit/(loss) before taxation

	Q4 2020 \$m	Q4 2019 \$m	FY 2020 \$m	FY 2019 \$m
For the three and twelve months ended December 31				
(Loss)/profit before taxation	(14)	(42)	(173)	180
Exceptional cost of sales (credit)/charge	(6)	-	5	-
Exceptional selling, general and administrative expenses	47	-	239	28
Exceptional operating income	-	(4)	-	(4)
Adjusted profit/(loss) before taxation	27	(46)	71	204

Reconciliation of net (loss)/income to adjusted net income/(loss)

	Q4 2020 \$m	Q4 2019 \$m	FY 2020 \$m	FY 2019 \$m
For the three and twelve months ended December 31				
Net (loss)/income	(13)	(55)	(148)	134
Exceptional cost of sales (credit)/charge	(6)	-	5	-
Exceptional selling, general and administrative expenses	47	-	239	28
Exceptional operating income	-	(4)	-	(4)
Tax on exceptional items	(2)	-	(37)	(4)
Exceptional items within taxation	-	22	-	22
Adjusted net income/(loss)	26	(37)	59	176

5. TAXATION

In the twelve months ended December 31, 2020, the reported total tax benefit was \$25m, or a rate of 14% (FY2019 tax charge: \$46m, 26%). The tax expense on adjusted profits amounted to \$12m (FY2019: \$28m) and represented a year to date effective tax rate of 17% (FY2019: 14%).

The current year tax benefit on exceptional items of \$37m includes the portion of future provision payments that are expected to be deductible (\$27m), along with the tax benefit of other exceptional items, using the currently enacted income tax rates for each jurisdiction. The amount of deductibility and possible filing positions for the legal provisions will be clarified as related matters are settled.

The increase in the adjusted effective tax rate was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the quarter.

The Group's balance sheet at December 31, 2020 included a current tax receivable of \$7m (FY 2019: \$nil), current tax payable of \$15m (FY 2019: \$39m), and deferred tax asset of \$75m (FY 2019: \$40m). The increase in the current tax receivable are due to advance payments and decrease in the current tax payable are mainly due to the reduction in the overall profits for the period. The increase in the deferred tax asset is due to current year activity, including the tax benefit on the exceptional provisions.

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 continues to monitor its position regarding the potential State Aid challenge and based upon our fact pattern has determined that no provision is required at this time. The Group has benefited from the UK controlled foreign company financing exemption and the tax thereon is approximately \$25m including interest.

6. (LOSS)/EARNINGS PER SHARE

	Q4 2020 cents	Q4 2019 cents	FY 2020 Cents	FY 2019 cents
For the three and twelve months ended December 31				
Basic (loss)/earnings per share	(2)	(8)	(20)	18
Diluted (loss)/earnings per share	(2)	(8)	(20)	18
Adjusted basic earnings/(loss) per share	4	(5)	8	24
Adjusted diluted earnings/(loss) per share	3	(5)	8	23

Basic

Basic (loss)/earnings per share ("LPS/EPS") is calculated by dividing (loss)/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 (loss)/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.

	2020 thousands	2019 Thousands
Weighted average number of shares		
On a basic basis	732,863	730,235
Dilution from share awards and options	37,132	25,123
On a diluted basis	769,995	755,358

Adjusted Earnings/(Loss)

The Directors believe that diluted earnings/(loss) 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 (loss)/income to adjusted net income is included in Note 4.

7. CURRENT AND NON-CURRENT OTHER ASSETS

	Dec 31 2020 \$m	Dec 31 2019 \$m
Current and non-current other assets		
Short-term prepaid expenses	17	23
Other current assets	33	12
Total other current assets	50	35
Long-term prepaid expenses	22	23
Other non-current assets	82	50
Total other non-current assets	104	73
Total	154	108

Other current assets and other non-current assets primarily relate to surety bonds. The increase in current and non-current assets is due to additional funding provided to the surety bond holders in FY 2020 (see Note 11). \$26m was returned by one of the surety bond holders in January 2021 and therefore classified as current.

Long-term prepaid expenses relate primarily to payments for contract manufacturing capacity.

8. FINANCIAL LIABILITIES – BORROWINGS

	Dec 31 2020 \$m	Dec 31 2019 \$m
Bank loans		
Bank loans – current	(4)	(4)
Bank loans – non-current	(230)	(233)
Total bank loans	(234)	(237)

	Dec 31 2020 \$m	Dec 31 2019 \$m
Analysis of net cash		
Cash and cash equivalents	858	1,060
Borrowings*	(235)	(239)
Total net cash	623	821

*Borrowings reflect the principal amount drawn before debt issuance costs of \$1m (FY 2019: \$2m). These do not include lease liabilities of \$51m (FY 2019: \$56m).

	Dec 31 2020 \$m	Dec 31 2019 \$m
Reconciliation of net cash		
The movements in the period were as follows:		
Net cash at beginning of period	821	681
Net (decrease)/increase in cash and cash equivalents	(202)	136
Net repayment of borrowings	4	4
Net cash at end of period	623	821

Net cash is presented as it is relevant to our term loan maximum leverage ratio. Net cash is not reduced for lease liabilities of \$51m (FY 2019: \$56m), which is in accordance with the term loan ratio calculations.

At December 31, 2020, the term loan was trading at approximately 98% (FY 2019: 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, 2020 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. There was no financial impact in 2020.

- Nominal interest margin is calculated over three-month LIBOR subject to the LIBOR floor of 1%.
- 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.

9. PROVISIONS AND OTHER LIABILITIES

	Dec 31 2020 \$m	Dec 31 2019 \$m
Provisions & other liabilities		
Provisions		
DOJ related matters	(32)	(438)
Intellectual property related matters	(47)	(45)
Restructuring costs	(6)	(2)
Other	(4)	(3)
Total provisions	(89)	(488)
Other liabilities		
DOJ resolution	(486)	-
RB indemnity settlement	(50)	-
Total other liabilities	(536)	-
Total provisions and other liabilities	(625)	(488)

The Group is involved in legal and intellectual property disputes as described in Note 11, "Legal Proceedings."

Provisions

Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events, an outflow of resources to settle that obligation is more likely than not, and the amount can be reliably estimated. Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the reporting date.

The Group carries a provision of \$32m (FY 2019: \$438m) pertaining to DOJ related matters as discussed in Note 11. The opening balance of \$438m was increased by exceptional charges of \$183m and non-exceptional interest of \$2m. \$586m was reclassified to other liabilities with the DOJ resolution. Negotiations with DOJ related plaintiffs resulted in an exceptional provision release of \$5m in Q4 2020 (see Note 3). The remaining DOJ related matters of \$32m are expected to be settled within the year.

The Group carries provisions totaling \$47m (FY 2019: \$45m) for intellectual property related matters, all of which relate to potential redress for ongoing intellectual property litigation with DRL and Alvogen.

Other liabilities

Other liabilities represent contractual obligations to third parties where the amount and timing of payments is fixed. Where other liabilities are not interest-bearing and the impact of discounting is significant, other liabilities are recorded at their present value, generally using rate approximating the risk-free rate at the time the Group entered into the obligation.

On July 24, 2020, the Group reached a resolution with the DOJ and other litigants described in Note 11 under "DOJ and Related Matters" to resolve the investigation of alleged 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. In November 2020, the Group made a payment of \$103m (including interest) when resolution was approved by a judge. Subsequently, six annual instalments of \$50m will be due every January 15 from 2022 to 2027. A final instalment of \$200m will be due on December 15, 2027. Interest accrues on certain portions of the resolution which will be paid together with the annual instalment payments. For non-interest-bearing portions, the liability has been recorded at the net present value based on timing of the estimated payments. The discount rate and interest rate are 1.25%. In FY 2020, the Group recorded interest expense totalling \$3m (FY 2019: nil).

On January 25, 2021, the Group reached a resolution with Reckitt Benckiser (RB) to resolve claims which RB issued in the Commercial Court in London on November 13, 2020, seeking indemnity under the 2014 Demerger Agreement. Pursuant to the settlement, RB withdrew the US \$1.4b claim to release Indivior from any claim for indemnity under the Demerger Agreement relating to the DOJ and FTC settlements which RB entered into in July 2019, as well as other claims for indemnity arising from those matters. The Group has agreed to pay RB a total of \$50m and has agreed to release RB from any claims to seek damages relating to its settlement with the DOJ and the FTC. The Group made a \$10m payment in February 2021, following the resolution. Subsequently, annual instalment payments of \$8m will be due every January from 2022 to 2026. The Group carries a liability totaling \$50m (FY 2019: \$0m) related to this settlement. The effect of discounting was not material.

10. CONTINGENT LIABILITIES

Except as described in Note 11 under “DOJ and Related Matters” and “Intellectual Property Related Matters”, for which provisions and other liabilities have been recognized, descriptions of the contingent liabilities for State Aid risk are set out in Note 5 and legal and other disputes to which the Group is party are set out in Note 11.

11. LEGAL PROCEEDINGS

DOJ Resolution

Agreement to Resolve Criminal Charges and Civil Complaints Related to SUBOXONE Film

- The Group settled with the United States Department of Justice (Justice Department or DOJ), the U.S. Federal Trade Commission (FTC), and U.S. state attorneys general the criminal and civil liability in connection with a multi-count indictment brought in April 2019 by a grand jury in the Western District of Virginia, a civil lawsuit joined by the Justice Department in 2018, and an FTC investigation. Under the terms of the agreement, Indivior Solutions Inc. (“Solutions Inc.”), a wholly owned subsidiary of Indivior PLC, has pleaded guilty to a single count of making a false statement relating to health care matters in 2012 in violation of 18 U.S.C. Section 1035. Indivior will make payments to federal and state authorities totaling \$600 million (plus applicable interest of 1.25% on a portion of that total amount), has agreed to a stipulated injunction with the FTC, and entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services (HHS). In November 2020, the Court approved the settlement and dismissed all charges returned by the grand jury in April 2019.
- Under the terms of a related agreement with the HHS, Solutions Inc. will be excluded from participating in government health programs. This exclusion will not apply to any other entities within the Group. The Group does not anticipate the exclusion of Solutions Inc. will have any material impact on the Group’s ability to continue to participate in government health programs.
- Under the terms of the five-year Corporate Integrity Agreement with the HHS Office of the Inspector General (HHS-OIG), the Group will continue its commitment to promote compliance with laws and regulations and its ongoing evolution of an effective compliance program, including written standards, training, reporting, and monitoring procedures. The Group will be subject to reporting and monitoring requirements, including annual reports and compliance certifications from key management and the Board Nominating & Governance Committee submitted to HHS-OIG. In addition, the Group will be subject to monitoring by an Independent Review Organization, who will submit audit findings to HHS-OIG, and review by a Board Compliance Expert, who will prepare two compliance assessment reports in the first and third reporting periods of the Corporate Integrity Agreement. See Risk Factors Update Section for further discussion.
- Under the terms of the resolution agreement with the Justice Department, the Group has agreed to compliance terms regarding its sales and marketing practices. Compliance with these terms is subject to annual Board and CEO certifications submitted to the U.S. Attorney’s Office.

In November 2020, the Group made a payment of \$103m (including interest) when the resolution was approved by a judge. Subsequently, six annual instalments of \$50 million will be due every January 15 from 2022 through 2027. The final instalment of \$200 million will be due in December 2027. The Group carries a liability totaling of \$486 million (FY 2019: nil) pertaining to the DOJ resolution.

DOJ Related Matters

Federal FCA Qui Tam Suits

- In August 2018, the United States unsealed three *qui tam* suits pending in the Western District of Virginia that made a variety of allegations under state and federal False Claims Act statutes regarding marketing and promotion practices related to SUBOXONE, and in some instances claiming unlawful retaliation. The suits also seek reasonable attorney’s fees and costs. Many of the civil claims concern the same conduct at issue in the Superseding Indictment filed by the Justice Department. Indivior is aware of additional claims regarding similar allegations about marketing and promotion practices which were resolved along with the three Western District of Virginia *qui tam* suits in the federal civil settlement agreement with the Justice Department; and resolved in principle with the state Attorney Generals and are being formalized in civil settlement agreements with the fifty states. The Group is in discussions with certain relators aimed toward resolving the retaliation claims and claims for attorney’s fees and costs.

State and Local Matters

- In October 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.
- In November 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. Certain of the *qui tam* suits filed in the Western District of Virginia and

the District of New Jersey assert claims under the civil California insurance code. The Group is in discussions toward resolving these claims and claims for associated attorney's fees and costs.

- 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 its sales and marketing activity. Certain of the qui tam suits filed in the Western District of Virginia and the District of New Jersey assert claims under this statute, including claims for associated attorney's fees and costs. The Group is in discussions aimed toward resolving this matter.
- In addition to the federal and state health program claims, claims have been asserted under the city false claims acts of Chicago and New York City regarding the promotion of Suboxone film. The Group has resolved the matter with the City of Chicago.

FTC investigation

- Indivior Inc. and the FTC have agreed to resolve the FTC's pending investigation. In July 2020, the government simultaneously filed a complaint alleging a violation of 15 U.S.C. §45(a), and a joint motion seeking entry of a stipulated order. The US District Court for the Western District of Virginia entered this stipulated order in November 2020 and dismissed the case with prejudice. Pursuant to the stipulated order, the FTC received \$10 million. Furthermore, as detailed in the text of the stipulated order, for a ten-year period Indivior Inc. is required to make specified disclosures to the FTC and is prohibited from certain conduct.

False Claims Act Allegations

- In August 2018, the United States District Court for the Western District of Virginia unsealed a declined qui tam complaint alleging causes of action under the Federal and state False Claims Acts against certain entities within the Group predicated on best price issues and claims of retaliation (United States ex rel. Miller v. Reckitt Benckiser Group PLC et al., Case No. 1:15-cv-00017 (W.D. Va.)). The suit also seeks reasonable attorneys' fees and costs. We understand that all government plaintiffs have declined to intervene. The Group was served with the complaint in January 2021. We are in discussions regarding this matter with the plaintiff-relator.
- In May 2018, Indivior Inc. received an informal request from the Office of the United States Attorney for the Southern District of New York, seeking records relating to the Suboxone manufacturing process. We are in discussions with the government regarding the matter.

Securities Class Action Litigation

- In April 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. In February 2021, the parties reached a settlement agreement. A Motion for Entry of Order Preliminarily Approving Settlement is pending with the court.

Intellectual Property Related Matters

ANDA Litigation

- Litigation against DRL is currently pending in the District of New Jersey regarding U.S. Patent No. 9,687,454 and 9,931,305 ("the '454 and '305 Patents"). DRL received final FDA approval for all four strengths of its generic buprenorphine/naloxone film product in June 2018, and immediately launched its generic buprenorphine/naloxone film product "at-risk." In July 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. In November 2018, the CAFC issued a decision vacating the PI against DRL. DRL launched its product at-risk in February 2019. In June 2019, DRL filed a motion for leave to file their first amended Answer, Affirmative Defenses, and Counterclaims to add various antitrust counterclaims resulting from the injunction that was issued against DRL. The motion was granted in November 2019. No trial date has been set for either the patent claims or the antitrust counterclaims.
- In November 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. The Patent Trial and Appeal Board (USPTO) issued a decision in June 2020, holding that claims 1-5, 7, and 9-14 were unpatentable, but that DRL had not shown that claim 8 is unpatentable. Claim 6 was not challenged and therefore was not addressed in the PTAB decision. Indivior appealed to the Court of Appeals for the Federal Circuit in July 2020. No court date has been set yet.
- 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. In August 2019, Alvogen filed a motion for leave to file an amended Answer to Complaint and Separate Defenses and

Counterclaims to add various antitrust counter claims. The motion was granted in November 2019. No trial date has been set for either the patent claims or the antitrust counterclaims.

Teva Opposition to SUBLOCADE European Patent

- In October 2018, Teva Pharmaceutical Industries Ltd. (“Teva”) filed a Notice of Opposition with the European Patent Office seeking to revoke European Patent No. EP 2579874 (“EP 874”), which relates to the formulation for SUBLOCADE. Due to the ongoing disruptions caused by COVID-19, the European Patent Office has not yet set a hearing date.

Antitrust Litigation and Consumer Protection

Antitrust Class and State Claims

- 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. The court has not set a trial date.
- In 2013, Reckitt Benckiser Pharmaceuticals, Inc. (now known as Indivior Inc.) received notice that it and other companies were defendants in a lawsuit initiated by writ in the Philadelphia County (Pennsylvania) Court of Common Pleas. See *Carefirst of Maryland, Inc. et al. v. Reckitt Benckiser Inc., et al.*, Case No. 2875, December Term 2013. The plaintiffs include approximately 79 entities, most of which appear to be insurance companies or other providers of health benefits plans. The Carefirst Plaintiffs have not served a complaint, but they have indicated that their claims are related to those asserted by the plaintiffs in re Suboxone, MDL No. 2445 (E.D. Pa.). The Carefirst case remains pending.

The Group has evaluated the antitrust class and state claims in light of the DOJ settlement under which a Group subsidiary plead guilty to one count of making a false statement relating to health care matters in one state in 2012. The Group continues to believe in its defenses and continues to vigorously defend itself. Select plaintiffs in these matters have previously made settlement demands (which were not accepted and most of which are not current offers), totaling approximately \$290m, which was used for contingency planning only to model possible downside financial effects. The final aggregate cost of these matters, whether resolved by litigation or by settlement, may be materially different. If the Group were to entertain further settlement discussions, we make no representations as to what amounts, if any, it may agree to pay, nor regarding what amounts the plaintiffs will demand.

Other Antitrust and Consumer Protection Claims

- In July 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.
- In 2020 Group was served with lawsuits from a number of insurance companies, some of whom are proceeding both on their own claims and through the assignment of claims from affiliated companies. Cases filed by (1) Humana Inc. and (2) Centene Corporation, Wellcare Healthcare Plans, Inc., New York Quality Healthcare Corp. (d/b/a Fidelis Care), and Health Net, LLC are pending in the Eastern District of Pennsylvania. Cases filed by (1) Blue Cross and Blue Shield of Massachusetts, Inc., Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., (2) Health Care Service Corp., (3) Blue Cross and Blue Shield of Florida, Inc., Health Options, Inc., (4) BCBSM, Inc. (d/b/a Blue Cross and Blue Shield of Minnesota) and HMO Minnesota (d/b/a Blue Plus), and (5) Molina Healthcare, Inc. are pending in the Circuit Court for the County of Roanoke, Virginia. The allegations in these cases include many allegations made in other litigations, including prior antitrust complaints, indictments, and qui tam complaints. These plaintiffs have asserted claims under federal and state RICO statutes, state antitrust statutes, state statutes prohibiting unfair and deceptive practices, state statutes prohibiting insurance fraud, and common law fraud, negligent misrepresentation, and unjust enrichment. Each of these cases is in its initial stages.

The Group has begun its preliminary evaluation of the claims, believes in its defenses, and intends to vigorously defend itself. Currently, engagement with the claimants has been minimal and the Group’s evaluation of the various claims is in preliminary stages. Accordingly, no estimate of the range of potential loss can be made at this time.

Civil Opioid Litigation

- As of February 16, 2021, Indivior has been named as a defendant in fewer than 400 civil lawsuits brought by state and local governments, public health agencies, and individuals against manufacturers, distributors and retailers of opioids alleging that they engaged in a longstanding practice to market opioids as safe and effective for the treatment of long term chronic pain in order to increase the market for opioids and their own market share. The vast majority of these cases have been consolidated and are pending in a federal multi-district litigation (MDL) in U.S. District Court for the Northern District of Ohio, or are pending before the Joint Panel on Multidistrict Litigation for anticipated transfer to the MDL. At the present time, litigation against Indivior in the MDL is stayed. Other cases of which the Group has been notified but not yet served are expected may also be consolidated with the MDL. There remain three (3) cases against Indivior pending in state courts located in Arizona, Pennsylvania and Virginia. The Group has already filed Motions to Dismiss the complaints in both Arizona and Virginia. The Motions to Dismiss were argued in August and September 2020 and were under advisement until both courts issued stay orders in November 2020 (Arizona) and January 2021 (Virginia). Litigation against Indivior is currently stayed in all three jurisdictions.

Given the status and preliminary stage of litigation in both the MDL and state courts, no estimate of a possible loss in the opioid litigation can be made at this time.

12. TRADE AND OTHER PAYABLES

	Dec 31 2020 \$m	Dec 31 2019 \$m
Trade and other payables		
Sales returns and rebates	(396)	(460)
Trade payables	(20)	(39)
Accruals	(99)	(113)
Other tax and social security payables	(9)	(11)
Total	(524)	(623)

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.

13. SHARE CAPITAL

	Equity Ordinary Shares	Nominal value paid per share	Aggregate nominal value \$m
Issued and fully paid			
At January 1, 2020	730,787,719	\$0.10	73
Allotments	2,847,792	\$0.10	-
At December 31, 2020	733,635,511		73

	Equity Ordinary Shares	Nominal value paid per share	Aggregate nominal value \$m
Issued and fully paid			
At January 1, 2019	728,441,653	\$0.10	73
Allotments	2,346,066	\$0.10	-
At December 31, 2019	730,787,719		73

Allotment of ordinary shares

During the period, 2,847,792 ordinary shares (2019: 2,346,066) were allotted to satisfy vesting/exercises under the Group's Long-Term Incentive Plan and U.S. Employee Stock Purchase Plan.

14. POST BALANCE SHEET EVENTS

On January 25, 2021, the Group reached an agreement with Reckitt Benckiser (RB) to resolve claims which RB issued in the Commercial Court in London on November 13, 2020, seeking indemnity under the 2014 Demerger Agreement. Pursuant to the settlement, RB withdrew the US \$1.4b claim and to release Indivior from any claim for indemnity under the Demerger Agreement relating to the DOJ and FTC settlements which RB entered into in July 2019, as well as other claims for indemnity arising from those matters. Indivior agreed to pay RB a total of \$50m and has agreed to release RB from any claims to seek damages relating to its settlement with the DOJ and the FTC. The Group made a \$10m payment, in February 2021 following the settlement. Subsequently, annual instalment payments of \$8m will be due every January from 2022 to 2026. The Group carries a liability totaling \$50m (FY 2019: \$0m) related to this settlement (see Note 9).