

February 16, 2022



**FY 2021 Financial Results Announced. FY 2022 Guidance Introduced.  
Will Explore Optimal Listing Structure for Indivior Shares.**

Period to Dec. 31 <sup>st</sup> (Unaudited)	Q4 2021 \$m	Q4 2020 \$m	% Change		FY 2021 \$m	FY 2020 \$m	% Change
Net Revenue	222	185	20		791	647	22
Operating Profit/(Loss)	45	(9)	NM		213	(156)	NM
Net Income/(Loss)	35	(13)	NM		205	(148)	NM
Basic EPS/(LPS) (cents/share)	5	(2)	NM		28	(20)	NM
<b>Adj. Basis</b>							
Adj. Operating Profit*	32	32	-		187	88	113
Adj. Net Income*	25	26	-4		140	59	137
Adj. Basic EPS*	3	4	-25		19	8	138

*\*Adjusted (Adj.) basis excludes the impact of exceptional items as referenced and reconciled in Note 4 and 6. Adjusted results are not a substitute for, or superior to, reported results presented in accordance with International Financial Reporting Standards. NM – Not meaningful.*

**Comment by Mark Crossley, CEO of Indivior PLC**

“In FY 2021 we made excellent progress against our Strategic Priorities and delivered strong financial results. Most importantly, our investment in the Organized Health Systems channel helped us to nearly double SUBLOCADE® (buprenorphine extended-release) injection net revenue to \$244 million, putting us on track to meet our \$1 billion+ annual net revenue target.”

“In FY 2022, we expect to build on this momentum. The commercial investments we are making to extend our leadership in addiction and to accelerate our diversification with PERSERIS® (risperidone) extended-release injection for schizophrenia are expected to provide the Group with a solid foundation for future growth and value creation. Our FY 2022 plans for SUBLOCADE suggest this transformative treatment will become the largest net revenue driver for the Group during the year. Furthermore, with over \$1 billion in cash on our balance sheet, we have the financial strength and flexibility to pursue a balanced capital allocation strategy. Our primary focus remains on reinvesting in the business, but we also have the potential for additive inorganic growth opportunities and consideration of other value enhancement options.”

“Finally, together with the Board we have been assessing the optimal listing structure for Indivior’s shares. Our preliminary view is that an additional US listing is likely to be beneficial to the Group’s profile and visibility, as approximately 80% of the Group’s net revenue is generated in the US. We are aware that this is an important topic, and the Board and management intend to consult extensively with shareholders before concluding on any future path.”

**FY 2021 / Q4 2021 Financial Highlights**

- Net revenue (NR) of \$791m (+22% vs. FY 2020); Q4 2021 NR of \$222m (+20% vs. Q4 2020).
- Reported operating profit of \$213m (FY 2020 operating loss: \$156m); Q4 2021 reported operating profit of \$45m (Q4 2020 operating loss: \$9m). On an adjusted basis, FY 2021 operating profit was \$187m (+113% vs. Adj. FY 2020); Adjusted operating profit for Q4 2021 and Q4 2020 was \$32m.
- Reported net income of \$205m (FY 2020 net loss of \$148m); Q4 2021 reported net income of \$35m (Q4 2020 net loss: \$13m). FY 2021 Adj. net income of \$140m (+137% vs. Adj. FY 2020); Q4 2021 Adj. net income of \$25m (4% decline vs. Adj. Q4 2020).
- FY 2021 ending cash balance of \$1,102m (FY 2020: \$858m); net cash, as calculated in Note 8, was \$853m (FY 2020: \$623m).

**FY 2021 / Q4 2021 Operating Highlights**

- FY 2021 SUBLOCADE NR of \$244m (+88% vs. FY 2020) and Q4 2021 NR of \$75m (+92% vs. Q4 2020); strong growth from the Organized Health Systems (OHS) channel and increased new patient enrolments. FY 2021 US units dispensed were approximately 183,000\* (+66% vs. FY 2020); Q4 2021 US units dispensed were approximately 55,900\* (+74% vs. Q4 2020 and +15% vs. Q3 2021). Total SUBLOCADE patients at the end of 2021 were approximately 49,000.

\* Excludes one-time in-nature orders from criminal justice system customers

- FY 2021 PERSERIS NR of \$17m (+21% vs. FY 2020); Q4 2021 PERSERIS NR of \$5m (+25% vs. Q4 2020). The Group is investing to expand the PERSERIS sales force to achieve US national coverage in 2022.
- FY 2021 SUBOXONE Film share averaged 20% (FY 2020: 21%) and exited the quarter at 22% (Q4 2020: 21%). Share performance since the “at-risk” launch of generic buprenorphine/naloxone film products in February 2019 has continued to diverge from historical industry analogues\*\*.
- Regulatory approval of SUBLOCADE (SUBUTEX® Prolonged Release) outside of the US has now been granted in 10 countries. 2021 approvals include Norway, Germany and Italy. Prior approvals include Canada, Australia, New Zealand, Israel, Sweden, Finland and Denmark. Launched in Canada, Australia, and Israel.
- Regulatory approval of SUBOXONE Film outside of the US in 2021 was granted in New Zealand, Qatar, and United Arab Emirates. Prior approvals include Australia, Canada, Israel, all EU Member States and the UK, Iceland, Norway, and Liechtenstein.
- Indivior has terminated its agreement with Zhejiang Pukang Biotechnology Co., Ltd. (“Pukang”) for the rights related to the Sai Bo Song (buprenorphine, naloxone) tablet in China.

### [Share Repurchase Program Update](#)

On December 23, 2021, the Group completed its \$100m irrevocable share repurchase program. Through the program, the Group repurchased and cancelled 34m or 5% of the Group’s ordinary shares at a daily weighted average purchase price of 219p. See Note 13 for further discussion.

### [FY 2022 Guidance](#)

The Group is introducing the below guidance for FY 2022. The guidance assumes that near-term constraints in the US healthcare system ease as the Omicron wave of COVID-19 subsides. These near-term constraints include challenged access to parts of our OHS platform, particularly the US Criminal Justice System, and healthcare professional staffing shortages due to COVID-related absenteeism. This is expected to result in SUBLOCADE and PERSERIS growth being stronger in the second half of 2022 compared to the first half of 2022.

- Total FY 2022 expected NR range of \$840m to \$900m (+10% vs. FY 2021 at the mid-point); reflects strong SUBLOCADE growth and relative market share stability for SUBOXONE Film, which continues to deviate from industry analogues\*\* as a genericized treatment.
- SUBLOCADE FY 2022 expected NR range of \$360m to \$400m (+56% vs. FY 2021 at the mid-point), primarily based on strong penetration and growth in the OHS channel.
- PERSERIS FY 2022 expected NR range of \$27m to \$32m (+74% vs. FY 2021 at the mid-point).
- Adjusted gross margin expected to be in the low- to mid-80% range mainly due to expected continued relative strength of SUBOXONE Film and higher cost inflation.
- Adjusted SG&A expected to be in the range of \$440m to \$455m, primarily reflecting the annualization of commercial investments to grow SUBLOCADE and PERSERIS together with costs associated with the US listing review.
- R&D expected to be in the range of \$80m to \$85m, primarily reflecting additional SUBLOCADE Lifecycle Management studies, SUBLOCADE manufacturing capacity expansion and early-stage asset advancement.
- Adjusted operating income expected to be broadly similar to FY 2021’s adjusted operating income of \$187m.
- Guidance assumes no material change in exchange rates for key currencies compared with average rates year to date, notably USD/GBP and USD/EUR.

### [Optimal Listing Structure for Indivior Shares](#)

The Board has been assessing the optimal listing structure for Indivior shares for some time. The preliminary view of the Board is that an additional US listing is likely to be beneficial to the Group’s profile and ability to attract a broader group of shareholders. In coming to this view, the Board has considered the fact that approximately 80% of Group NR is generated in the US, the US is the Group’s highest value at-stake opportunity set, the majority of the senior management team are US based, that approximately 40%-plus of shareholders are North American-based and that it provides the Group the optionality to pursue a potential primary or sole US listing over the longer-term.

The Board is aware that this is an important topic for shareholders and intends to consult extensively before deciding whether to put a formal resolution to shareholders regarding an additional listing in the US. The Group expects to start formal consultations with shareholders in the Spring of 2022.

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

### [U.S. Opioid Use Disorder \(OUD\) Market Update](#)

In FY 2021, the U.S. buprenorphine medication-assisted treatment (BMAT) market grew in mid-single digits. Moderation in the growth rate versus 2020 reflects the high base period for comparison, when the BMAT market grew in the low- to mid-teens as a result of COVID-19-related demand and the implementation of new federal and state government actions to facilitate OUD patient access to medication-assisted treatment (MAT). Over the approximate two-year period just ended (2020 and 2021), the BMAT market averaged mid- to high-single digits growth.

The Group continues to expect long-term U.S. market growth to be sustained in the mid- to high-single digit percentage range due to increased severity and overall public awareness of the opioid epidemic and approved treatments, together with regulatory and legislative actions that have expanded OUD treatment funding and treatment capacity. 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 2021.

As a result, there is increasing patient access to BMAT. Indivior supports efforts to encourage more eligible healthcare practitioners (HCPs) to provide BMAT, and the Group continues to resource its compliance capabilities for the growing number of BMAT prescribers and patients.

The Group's focus is to continue to expand access to SUBLOCADE amongst OHS and core HCPs to ensure availability of this potentially important treatment option to the estimated 1 million+ patients per month who are prescribed BMAT by HCPs.

### [Financial Performance: FY 2021 & Q4 2021](#)

Total net revenue in FY 2021 grew 22% to \$791m at actual exchange rates (FY 2020: \$647m; +21% at constant exchange rates). In Q4 2021, total net revenue grew 20% to \$222m at actual exchange rates (Q4 2020: \$185m; +21% at constant exchange rates). The strong increase in both periods was primarily driven by higher NR from SUBLOCADE (+88% vs. FY 2020, +92% vs. Q4 2020), continued growth in the BMAT market, and by relatively stable market share for SUBOXONE® (buprenorphine and naloxone) Film in the US.

FY 2021 U.S. net revenue increased 32% to \$603m (FY 2020: \$456m) and by 31% in Q4 2021 to \$176m (Q4 2020: \$134m). Strong year-over-year SUBLOCADE net revenue growth, SUBOXONE Film share resilience along with underlying BMAT market growth were the principal drivers of the net revenue increase in both periods.

FY 2021 Rest of World (ROW) net revenue decreased 2% at actual exchange rates to \$188m (FY 2020: \$191m; -7% at constant exchange rates). The NR decline was mainly due to ongoing competitive pressure in the legacy tablet business in Western Europe, the disposal of the legacy TEMGESIC®/ BUPREX® / BUPREXX® analgesic franchise (FY 2021 NR impact of -\$5m), partially offset by NR from new products (FY 2021 ROW SUBLOCADE NR: \$16m) and favorable foreign currency translation benefits.

In Q4 2021, ROW net revenue decreased 10% at actual exchange rates to \$46m (Q4 2020: \$51m; -8% at constant exchange rates). The NR decline in Q4 was mainly attributable to ongoing competitive pressure in the legacy tablet business in Western Europe and the disposal of the legacy TEMGESIC®/ BUPREX® / BUPREXX® analgesic franchise, partially offset by NR from new products (Q4 2021 ROW SUBLOCADE NR: \$5m).

FY 2021 reported and adjusted gross margin was 84% (FY 2020: 85%; Adj. FY 2020: 86%). FY 2020 adjusted gross margin excludes \$5m of net exceptional costs of sales related to inventory provisions due to the adverse impact of COVID-19. Q4 2021 reported and adjusted gross margin was 83% (Q4 2020: 88%; Adj. Q4 2020: 84%). Q4 2020 adjusted gross margin excludes a \$6m benefit related to a change in estimate used to calculate inventory provisions. The FY2021 and Q4 2021 adjusted gross margin decline primarily reflects the continued relative strength of SUBOXONE Film in the United States, particularly in less profitable government channels.

FY 2021 SG&A expenses as reported were \$431m (FY 2020: \$666m). FY 2021 included \$6m of net exceptional costs which include the adjustments to provisions related to DOJ-related matters (+\$18m) and ANDA litigation matters (-\$24m). FY 2020 SG&A expenses included exceptional costs of \$239m, primarily related to resolution of litigation matters. Q4 2021 SG&A expenses as reported were \$132m (Q4 2020: \$158m). In Q4 2021, an exceptional benefit of \$1m was recorded related to the release of a restructuring provision. Exceptional costs in Q4 2020 were \$47m. See Note 4 for details on exceptional costs.

On an adjusted basis, FY 2021 SG&A expense decreased slightly from FY 2020 to \$425m (FY 2020: \$427m). The decline largely reflects one-time costs related to the US direct-to-consumer (DTC) advertising campaign for SUBLOCADE in the prior period and lower legal fees and expenses related to the DOJ matter (settled in Q3 2020). These were essentially offset by sales and marketing investments to grow the Group's long-acting injectable technologies, SUBLOCADE and PERSERIS in the current period. On an adjusted basis, Q4 2021 SG&A expenses increased 20% to \$133m (Q4 2020: \$111m). The increase in the quarter largely reflects the sales and marketing investments to grow SUBLOCADE and PERSERIS.

FY 2021 and Q4 2021 other operating income was \$32m and \$12m, respectively (FY 2020 and Q4 2020: \$nil). FY 2021 included \$32m of net exceptional other operating income related to the net proceeds received from the disposal of the legacy TEMGESIC®/ BUPREX® / BUPREXX® (buprenorphine) analgesic franchise outside of North America (+\$19m), net proceeds received from the out-licensing of nasal naloxone opioid overdose patents (+\$1m) and Directors & Officers insurance claim settlement (+\$12m in Q4 2021).

FY 2021 and Q4 2021 R&D expenses were \$52m and \$19m, respectively (FY 2020: \$40m; Q4 2020: \$13m). The increases over the year-ago periods reflect planned higher R&D activity, as certain projects and post-market studies were suspended in 2020 due to the pandemic, and strategic pipeline and production capacity investments in 2021.

FY 2021 operating profit as reported was \$213m (FY 2020 operating loss: \$156m). Net exceptional benefits of \$26m are included in FY 2021 and exceptional costs of \$244m are included in FY 2020. On an adjusted basis, FY 2021 operating profit was \$187m (FY 2020 adj. op. profit: \$88m). The improvement in FY 2021 adjusted operating profit was primarily driven by strong net revenue growth.

Q4 2021 operating profit as reported was \$45m (Q4 2020 operating loss: \$9m). Exceptional benefits of \$13m are included in Q4 2021 and exceptional costs of \$41m are included in Q4 2020. On an adjusted basis, Q4 2021 operating profit was \$32m (Adj. Q4 2020: \$32m). In Q4 2021, while net revenue increased, operating expenses were higher versus Q4 2020 due to sales and marketing investments to grow SUBLOCADE and PERSERIS (risperidone) extended-release injection and increased R&D expenditures, as discussed above.

FY 2021 net finance expense as reported was \$23m (FY 2020: \$17m). The increase primarily reflects lower interest income on the Group's cash balance due to lower short-term interest rates versus the year-ago period and higher expense primarily related to interest on the Group's outstanding DOJ settlement amount. An exceptional expense of \$1m is included in FY 2021 due to the write-off of deferred financing costs on the previous term loan. On an adjusted basis, FY 2021 net finance expense was \$22m. There were no exceptional items in the prior period.

FY 2021 reported total tax benefit was \$15m, an effective tax rate of -8% (FY 2020 tax benefit: \$25m, 14% rate). Excluding the \$40m tax benefit on exceptional items in FY 2021, total tax expense was \$25m, an effective tax rate of 15% (FY 2020: \$12m, 17% rate). Q4 2021 reported total tax expense was \$4m, representing an effective tax rate of 10% (Q4 2020 tax benefit: \$1m, 7% rate). Excluding the \$3m tax on exceptional items in Q4 2021, the effective tax rate was 4% (Q4 2020 excluding tax benefit of \$2m, 4% rate).

FY 2021 reported net income was \$205m (FY 2020 net loss: \$148m). Excluding the \$65m after-tax benefit from exceptional items, FY 2021 adjusted net income was \$140m (Adj. FY 2020: \$59m). The significant increases in FY 2021 adjusted net income was primarily driven by higher operating profit, partially offset by higher tax and net finance expenses.

Q4 2021 net income on a reported basis was \$35m (Q4 2020 reported net loss: \$13m). Excluding the \$10m after-tax benefit from exceptional items, Q4 2021 adjusted net income was \$25m (Adj. Q4 2020: \$26m). The slight decline in Q4 2021 adjusted net income was primarily driven by net revenue growth that was more than offset by an increase in strategic SG&A investments and higher finance expense.

FY 2021 diluted earnings per share was 27 cents and 18 cents on an adjusted diluted basis (FY 2020: 20 cents loss per share on a diluted basis and 8 cents earnings per share adjusted diluted basis). Q4 2021 diluted earnings per share was 5 cents and 3 cents on an adjusted diluted basis (Q4 2020: 2 cents loss per share on a diluted basis and 3 cents earnings per share on an adjusted diluted basis). Higher FY 2021 EPS on an adjusted diluted basis is primarily due to higher net revenue and the impact of the share repurchase program.

## Balance Sheet & Cash Flow

December 31, 2021, cash and cash equivalents were \$1,102m, an increase of \$244m versus the \$858m position at year-end 2020. The increase was due to higher operating profit, timing of payments made on government rebate payables, proceeds from the disposal of the legacy TEMGESIC® / BUPREX® / BUPREXX® (buprenorphine) analgesic franchise outside of North America, offset by cash used to repurchase approximately 34m ordinary shares as part of the Group's \$100m share repurchase program. Gross borrowings, before issuance costs, were \$249m at December 31, 2021 (Ending FY 2020: \$235m). As a result, net cash (as defined in Note 8) stood at \$853m at December 31, 2021 (FY 2020: \$623m), a \$230m increase over the fiscal year.

Net working capital (inventory plus trade receivables, less trade and other payables) was negative \$423m at December 31, 2021, versus negative \$252m at the end of FY 2020. The change in the period was primarily a result of timing of payments made on government rebate and trade payables.

Cash generated by operating activities in FY 2021 was \$395m (FY 2020 cash used: \$148m), representing a change of \$543m primarily due to strong FY 2021 operating profit, timing of government rebates payable and the surety bond refunded in Q1 2021. Net cash inflow from operating activities was \$353m in FY 2021 (FY 2020 net cash outflow: \$193m) reflecting higher cash from operations and an exceptional tax refund from the IRS which were offset by taxes paid, interest paid, and transaction costs paid related to the Group's debt refinancing.

FY 2021 cash outflow from investing activities was \$14m (FY 2020: \$4m) which reflects a payment made to Aelis Farma for an exclusive option and license agreement to develop its leading compound (AEF0117) targeting cannabis use disorders which was partially offset by the proceeds received from the sale of the legacy TEMGESIC® / BUPREX® / BUPREXX® (buprenorphine) analgesic franchise outside of North America.

FY 2021 cash outflow from financing activities was \$94m (FY 2020: \$10m) which reflects payments made for the Group's share repurchase program and principal lease payments which were partially offset by the gross proceeds received upon refinancing of the Group's term loan facility. See Note 8 for further discussion related to the debt refinancing.

## R&D / Pipeline Update

Indivior's quarterly R&D and pipeline update may be found [Indivior.com](https://www.indivior.com/en/our-science/research-and-development-publications) under "Our Science" and "Research and Development Publications." <https://www.indivior.com/en/our-science/research-and-development-publications>

## 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, 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 condition. The principal risks and uncertainties are not listed in order of significance.

The COVID-19 pandemic is continuing longer than expected with the emergence of new variants, resulting in continuing uncertainty. Governments worldwide have deployed vaccination programs and other health measures to lower virus infection and mortality rates, which should, in time, enable businesses to return to normal or near normal operations. While operations continue to be disrupted, our focus has been on the health, safety and wellbeing of our employees, patients, and the workforce of our partners.

## 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 - In response to COVID-19, the Group 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, and ensures our mitigation and contingency actions are as appropriate and effective as possible. In the fourth quarter of 2021, we introduced a hybrid working model (i.e., in-office and remote working) in those countries where work from home restrictions were no longer in place. Given the shift to a remote working environment started in 2020, the Group continues to closely monitor cybersecurity threats and the overall operating effectiveness of the monitoring and control activities.

The current industry-wide challenging labor environment may have a potential negative impact on the Group's attrition rate and its ability to recruit for certain key positions in some geographies. The Group has established tools, development, performance management and reward programs to develop, retain, and recruit key personnel.

The incidence of sophisticated phishing and malware attacks, including ransomware, across industries, is rising with an increase of companies suffering operational disruption and loss of data. The Group continuously assesses cyber risk and manages the maturity of our infrastructure to effectively defend against any cyber attacks.

### **Product Pipeline, Regulatory and Safety**

The development and approval of the Group's products is an inherently uncertain and lengthy process requiring significant financial, research and development resources, and strategic partnerships. The Group is developing its early-stage assets (i.e., preclinical to phase- two assets) in partnership with external organizations. Complex regulations with strict and high safety standards govern the development, manufacturing, and distribution of our products. 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. In addition, strong competition exists for strategic collaborations, licensing arrangements and acquisition targets. If we are unable to execute strategic transactions or if such transactions do not yield the expected product development, synergies or financial performance, our business prospects may suffer.

COVID-19 Pandemic – The COVID-19 pandemic continues to negatively impact our R&D operations, specifically trial patient enrollments and chemistry, manufacturing & controls (CMC) operations, therefore causing certain delays in the execution of our internal and third-party clinical and/or CMC studies.

### **Commercialization**

Successful commercialization of our products is a critical factor for the Group's sustained growth and robust financial position. New products involve 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: final label claims; healthcare professionals (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 continues to result 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, safety concerns, quarantines, other travel restrictions, or elect to have remote consultations with their providers. Furthermore, even though the Group has developed remote (digital) meeting capability with healthcare providers, the Group's commercial organization continues to only be able to engage with a limited number of HCPs and OHS. Although we experienced an overall increase in new US patient enrollments and number of interactions with HCPs and OHS in 2021 as compared to 2020, we have not yet returned to pre-pandemic levels. Potential significant decline in patient enrollments, or adherence to the patient journey, or the inability to effectively engage with HCPs and OHS due to the continuing COVID-19 pandemic could have a negative impact on the Group's financial results and position.

Governments across the world continue to consider and take actions to lower drug prices. In the US, there is bi-partisan 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 continuing 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, capital markets, and tax regulation 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). Major 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 continuing pandemic could adversely impact our broad supply chain (i.e., "supply to patient delivery" process) if we experience either a significant absence of our employees and/or employees at our CMOs, vendors and service providers due to infection and/or government containment measures, and/or capacity issues at our airfreight and road logistics providers. Through ongoing management and proactive risk mitigation, internally and with our CMOs, the Group has not experienced any significant COVID-19 related disruptions to its supply to patient delivery process to date.

The Company's products are filled and packaged by CMOs in the US and Europe, and some are single sourced. The Company's supply monitoring and contingency planning processes include: proactive management of inventories throughout the supply to patient delivery process, initiatives to identify and qualify alternative sites and/or suppliers. Despite these mitigating measures, if major delays, interruptions, or quality events occur at those CMOs, the delivery of products to our patients could be significantly disrupted.

### **Legal and Intellectual Property**

Our pharmaceutical operations, which include the use of 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.

IP rights protecting our products may be challenged by external parties, including generic pharmaceutical manufacturers. Although we have developed patent protection for our products, including SUBLOCADE, 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 entered in 2020 to resolve criminal charges and civil complaints related to SUBOXONE Film, the Group has specific requirements that are in addition to the Group's preexisting 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. Some of the civil claims in part relate to the same conduct at issue in the Superseding Indictment filed by the DOJ.

The Group is also a defendant in approximately 400 civil lawsuits brought by various plaintiffs as part of the opioid class action litigation. These cases are at a preliminary 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).

## **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. The Group has processes and procedures to identify, analyze and investigate any potential or actual violations of policy or law and, if necessary, take appropriate remedial or corrective actions. Effective procedures and controls are necessary to provide reliable information, prevent and detect potential fraud. 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.

In 2020, 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), 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. 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, or 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 2026, 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 Chief Executive Officer (a) certify on an annual basis that, to the best of their knowledge, after a reasonable inquiry, the Group was in compliance with the US 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 2021 financial year will contain additional details on these principal 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, 2021	Full Year to December 31, 2020
GB £ period end	1.3532	1.3651
GB £ average rate	1.3763	1.2833
€ Euro period end	1.1378	1.2226
€ Euro average	1.1840	1.1403

## Webcast Details

There will be a live webcast presentation at 13:00 GMT (8:00 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](http://www.indivior.com).

Webcast link: <https://edge.media-server.com/mmc/p/8tao6fad>

**Confirmation Code:** 8268632

Participants, Local - London, United Kingdom: +44 (0) 2071 928338

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## For Further Information

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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.

## About Indivior

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat addiction and serious mental illnesses. Our vision is that all patients around the world will have access to evidence-based treatment for the chronic conditions and co-occurring disorders of addiction. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of opioid dependence treatments, Indivior has a pipeline of product candidates designed to both expand on its heritage in this category and potentially address other chronic conditions and cooccurring disorders of addiction, including alcohol use disorder. Headquartered in the United States in Richmond, VA, Indivior employs more than 800 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit [www.indivior.com](http://www.indivior.com) to learn more. Connect with Indivior on LinkedIn by visiting [www.linkedin.com/company/indivior](http://www.linkedin.com/company/indivior).

## 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 2022 and its medium- and long-term growth outlook, its operational goals, its product development pipeline, ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "potential", "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, the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases, and: 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 commercial execution; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including the Indivior Group's compliance with its agreements with the U.S. Department of Justice and with the Office of Inspector General of the Department of Health and Human Services, non-compliance with which could result in potential exclusion from participating in U.S. Federal health care programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; 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.

## Condensed consolidated income statement

For the three and twelve months ended December 31	Notes	Unaudited Q4 2021 \$m	Unaudited Q4 2020 \$m	Unaudited FY 2021 \$m	Audited FY 2020 \$m
<b>Net Revenue</b>	2	<b>222</b>	185	<b>791</b>	647
Cost of Sales		<b>(38)</b>	(23)	<b>(127)</b>	(97)
<b>Gross Profit</b>		<b>184</b>	162	<b>664</b>	550
Gross profit before exceptional items		<b>184</b>	156	<b>664</b>	555
Exceptional items	4	-	6	-	(5)
Selling, general and administrative expenses	3	<b>(132)</b>	(158)	<b>(431)</b>	(666)
Research and development expenses	3	<b>(19)</b>	(13)	<b>(52)</b>	(40)
Other operating income	3	<b>12</b>	-	<b>32</b>	-
<b>Operating Profit/(Loss)</b>		<b>45</b>	(9)	<b>213</b>	(156)
Operating profit before exceptional items		<b>32</b>	32	<b>187</b>	88
Exceptional items	4	<b>13</b>	(41)	<b>26</b>	(244)
Finance income		<b>1</b>	3	<b>4</b>	9
Finance expense		<b>(7)</b>	(8)	<b>(27)</b>	(26)
<b>Net Finance Expense</b>		<b>(6)</b>	(5)	<b>(23)</b>	(17)
Net finance expense before exceptional items		<b>(6)</b>	(5)	<b>(22)</b>	(17)
Exceptional items within finance expense	4	-	-	<b>(1)</b>	-
<b>Profit/(Loss) Before Taxation</b>		<b>39</b>	(14)	<b>190</b>	(173)
Income tax (expense)/benefit	5	<b>(4)</b>	1	<b>15</b>	25
Taxation before exceptional items		<b>(1)</b>	(1)	<b>(25)</b>	(12)
Exceptional items within taxation	4	<b>(3)</b>	2	<b>40</b>	37
<b>Net Income/(Loss)</b>		<b>35</b>	(13)	<b>205</b>	(148)
<b>Earnings/(loss) per ordinary share (cents)</b>					
Basic earnings/(loss) per share	6	<b>5</b>	(2)	<b>28</b>	(20)
Diluted earnings/(loss) per share	6	<b>5</b>	(2)	<b>27</b>	(20)

## Condensed consolidated statement of comprehensive income/(loss)

For the three and twelve months ended December 31	Notes	Unaudited Q4 2021 \$m	Unaudited Q4 2020 \$m	Unaudited FY 2021 \$m	Audited FY 2020 \$m
Net income/(loss)		<b>35</b>	(13)	<b>205</b>	(148)
<b>Other comprehensive (loss)/income</b>					
<i>Items that may be reclassified to profit or loss in subsequent years:</i>					
Net exchange adjustments on foreign currency translation		<b>(1)</b>	15	<b>(7)</b>	10
Other comprehensive (loss)/income		<b>(1)</b>	15	<b>(7)</b>	10
<b>Total comprehensive income/(loss)</b>		<b>34</b>	2	<b>198</b>	(138)

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

## Condensed consolidated balance sheet

	Notes	Unaudited Dec 31, 2021 \$m	Audited Dec 31, 2020 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		82	62
Property, plant, and equipment		58	60
Right-of-use assets		37	43
Deferred tax assets	5	105	75
Other assets	7	106	104
		<b>388</b>	<b>344</b>
<b>Current assets</b>			
Inventories		95	93
Trade receivables		202	179
Other assets	7	32	50
Current tax receivable	5	13	7
Cash and cash equivalents	8	1,102	858
		<b>1,444</b>	<b>1,187</b>
<b>Total assets</b>		<b>1,832</b>	<b>1,531</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	8	(3)	(4)
Provisions	9	(5)	(38)
Other liabilities	9	(61)	(10)
Trade and other payables	12	(720)	(524)
Lease liabilities		(8)	(8)
Current tax liabilities	5	(7)	(15)
		<b>(804)</b>	<b>(599)</b>
<b>Non-current liabilities</b>			
Borrowings	8	(239)	(230)
Provisions	9	(76)	(51)
Other liabilities	9	(474)	(526)
Lease liabilities		(36)	(43)
		<b>(825)</b>	<b>(850)</b>
<b>Total liabilities</b>		<b>(1,629)</b>	<b>(1,449)</b>
<b>Net assets</b>		<b>203</b>	<b>82</b>
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	13	70	73
Share premium		7	6
Capital redemption reserve	13	3	-
Other reserves		(1,295)	(1,295)
Foreign currency translation reserve		(20)	(13)
Retained earnings		1,438	1,311
<b>Total equity</b>		<b>203</b>	<b>82</b>

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

## Condensed consolidated statement of changes in equity

Audited	Notes	Share	Share redemption	Capital	Other	Foreign	Retained	Total
		capital	Premium	reserve	reserve	translation	earnings	
		\$m	\$m	\$m	\$m	\$m	\$m	\$m
<b>Balance at January 1, 2020</b>		<b>73</b>	<b>5</b>	<b>-</b>	<b>(1,295)</b>	<b>(23)</b>	<b>1,449</b>	<b>209</b>
<b>Comprehensive loss</b>								
Net loss		-	-	-	-	-	(148)	(148)
Other comprehensive income		-	-	-	-	10	-	10
<b>Total comprehensive loss</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>10</b>	<b>(148)</b>	<b>(138)</b>
<b>Transactions recognized directly in equity</b>								
Shares issued		-	1	-	-	-	-	1
Share-based plans		-	-	-	-	-	8	8
Deferred taxation on share-based plans		-	-	-	-	-	2	2
<b>Balance at December 31, 2020</b>		<b>73</b>	<b>6</b>	<b>-</b>	<b>(1,295)</b>	<b>(13)</b>	<b>1,311</b>	<b>82</b>
<b>Unaudited</b>								
<b>Balance at January 1, 2021</b>		<b>73</b>	<b>6</b>	<b>-</b>	<b>(1,295)</b>	<b>(13)</b>	<b>1,311</b>	<b>82</b>
<b>Comprehensive income</b>								
Net income		-	-	-	-	-	205	205
Other comprehensive loss		-	-	-	-	(7)	-	(7)
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(7)</b>	<b>205</b>	<b>198</b>
<b>Transactions recognized directly in equity</b>								
Shares issued		-	1	-	-	-	-	1
Shares repurchased and cancelled		(3)	-	3	-	-	(101)	(101)
Share-based plans		-	-	-	-	-	11	11
Settlement of equity awards		-	-	-	-	-	(1)	(1)
Deferred taxation on share-based plans		-	-	-	-	-	13	13
<b>Balance at December 31, 2021</b>		<b>70</b>	<b>7</b>	<b>3</b>	<b>(1,295)</b>	<b>(20)</b>	<b>1,438</b>	<b>203</b>

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

## Condensed consolidated cash flow statement

	Unaudited 2021 \$m	Audited 2020 \$m
<b>For the twelve months ended December 31</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit/(Loss)	213	(156)
Depreciation, amortization, and impairment	15	18
Gain on disposal of right-of-use assets	-	(2)
Net gain on disposal of intangible asset	(20)	-
Depreciation and impairment of right-of-use assets	7	8
Share-based payments	11	8
Settlement of tax on employee awards	(1)	-
Impact from foreign exchange movements	(3)	(5)
(Increase)/Decrease in trade receivables	(25)	15
Decrease/(Increase) in current and non-current other assets	16	(44)
Increase in inventories	(3)	(16)
Increase/(Decrease) in trade and other payables	201	(103)
(Decrease)/Increase in provisions and other liabilities <sup>1</sup>	(16)	129
<b>Cash generated from/(used in) operations</b>	<b>395</b>	<b>(148)</b>
Interest paid	(18)	(20)
Interest received	1	9
Exceptional tax refund	31	-
Taxes paid	(48)	(34)
Transaction costs related to debt refinancing	(8)	-
<b>Net cash inflow/(outflow) from operating activities</b>	<b>353</b>	<b>(193)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant, and equipment	(4)	(4)
Purchase of intangible asset	(30)	-
Exceptional net proceeds from disposal of intangible assets	20	-
<b>Net cash outflow from investing activities</b>	<b>(14)</b>	<b>(4)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from borrowings	250	-
Repayment of borrowings	(236)	(4)
Payment of lease liabilities	(8)	(7)
Proceeds from the issuance of ordinary shares	1	1
Cash paid for the repurchase and cancellation of shares (including direct transaction costs)	(101)	-
<b>Net cash outflow from financing activities</b>	<b>(94)</b>	<b>(10)</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>245</b>	<b>(207)</b>
Cash and cash equivalents at beginning of the period	858	1,060
Exchange difference	(1)	5
<b>Cash and cash equivalents at end of the period</b>	<b>1,102</b>	<b>858</b>

<sup>1</sup>Changes in provisions and other liabilities for FY 2021 line include exceptional payments of \$10m for the RB settlement agreement and \$9m for DOJ related matters (FY 2020 includes a \$103m initial payment under the DOJ resolution).

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 Condensed Financial Statements should be read in conjunction with the annual financial statements for the year ended December 31, 2020 which have been prepared in accordance with International Financial Reporting Standards (IFRS) and IFRS Interpretations Committee interpretations in conformity with the Companies Act 2006 and pursuant to Regulation (EC) No 1606/2002 as it applies to the European Union. In respect of accounting standards applicable to the Group in the current period, there is no difference between IFRS in conformity with the Companies Act 2006, the UK-adopted International Accounting Standards and International Accounting Standards Board (IASB)-adopted IFRS. 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 the same as those that applied to the consolidated financial statements for the year ended December 31, 2020, except for the inclusion of estimates and judgements used in impairment review of intangible assets. The estimates used in calculating the recoverable amount for one of the Group's intangible assets amounting to \$10m is considered significant due to the sensitivity of key assumptions and limited headroom which could give rise to future impairment. The 2020 balance sheet has been expanded to present provisions and other liabilities on separate lines to improve the presentation and transparency.

The Condensed Financial Statements are unaudited and 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, 2020. These Condensed Financial Statements were approved for issue on February 15, 2022.

As disclosed in Notes 9, 10, and 11, the Group has liabilities and provisions totaling \$537m (FY 2020: \$568m) for the Department of Justice (DOJ) Resolution and related matters and the Reckitt Benckiser (RB) settlement. The Directors have assessed the Group's ability to comply with the minimum liquidity covenant in the Group's debt facility, maintain sufficient liquidity to fund its operations and fulfill obligations under the DOJ resolution and RB agreement. The Directors have also modeled the risk that SUBLOCADE will not meet revenue growth expectations (considering a 15% decline on forecasts), an accelerated reversion to generic analogues for SUBOXONE Film, and the risk the ongoing legal proceedings may result in reasonably possible payments as part of the Group's going concern assessment and downside scenario. These risks were balanced against the Group's current and forecast working capital position. As a result of the factors set out above, the Directors have a reasonable expectation the Group has adequate resources to continue in operational existence for at least one year from the approval of these Condensed Financial Statements and therefore consider the going concern basis to be appropriate for the accounting and preparation of these Condensed Financial Statements.

The financial information contained in this document does not constitute statutory accounts as defined in section 434 and 435 of the Companies Act 2006. The Group's statutory financial statements for the year ended December 31, 2020, were approved by the Board of Directors on March 18, 2021, and have been filed with Companies House.

### 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 on a geographical and product basis. Financial results are reviewed on a consolidated basis for evaluating financial performance and allocating resources. Accordingly, the Group operates in a single reportable segment.

#### Net revenue and non-current assets

Revenues are attributed to countries based on the country where the sale originates. The following tables represent net revenues from continuing operations and non-current assets, net of accumulated depreciation and amortization, by country. Non-current assets for this purpose consist of 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, 2021, and 2020 were as follows:

Net revenue:

	Q4 2021	Q4 2020	FY 2021	FY 2020
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
United States	176	134	603	456
Rest of World (ROW)	46	51	188	191
<b>Total</b>	<b>222</b>	<b>185</b>	<b>791</b>	<b>647</b>

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

	Q4 2021	Q4 2020	FY 2021	FY 2020
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
SUBLOCADE	75	39	244	130
PERSERIS	5	4	17	14
Sublingual/Other	142	142	530	503
<b>Total</b>	<b>222</b>	<b>185</b>	<b>791</b>	<b>647</b>

Non-current assets:

	Dec 31, 2021 \$m	Dec 31, 2020 \$m
United States	133	141
ROW	150	128
<b>Total</b>	<b>283</b>	<b>269</b>

In FY 2021, the Group entered into a strategic collaboration for \$30m with Aelis Farma that includes an exclusive option for the license of the global rights to AEF0117, a leading compound to treat cannabis-related disorders. The increase in non-current assets reflects the investment in Aelis partially offset by depreciation and amortization of intangible and right-of-use assets.

### 3. OPERATING EXPENSES AND OTHER OPERATING INCOME

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

#### Operating expenses

	Q4 2021	Q4 2020	FY 2021	FY 2020
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
Research and development expenses	(19)	(13)	(52)	(40)
Selling and general expenses	(63)	(53)	(192)	(202)
Administrative expenses	(69)	(105)	(239)	(464)
<b>Selling, general and administrative expenses</b>	<b>(132)</b>	<b>(158)</b>	<b>(431)</b>	<b>(666)</b>
<b>Depreciation, amortization, and impairment<sup>1</sup></b>	<b>(3)</b>	<b>(3)</b>	<b>(13)</b>	<b>(17)</b>

<sup>1</sup> Depreciation and amortization expense is included in research and development and selling, general and administrative expenses. Depreciation and amortization expense in FY 2021 of \$9m (FY 2020: \$9m) for intangibles and ROU assets is included within cost of sales.

Medical affairs functional costs are included in administrative expenses. Administrative expenses include exceptional items in the current and prior period as outlined in Note 4.

#### Other operating income

	Q4 2021	Q4 2020	FY 2021	FY 2020
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
Other operating income	12	-	32	-

Other operating income include exceptional items in the current periods as outlined in Note 4.

### 4. EXCEPTIONAL ITEMS AND ADJUSTED RESULTS

#### Exceptional items

Where significant expenses or income occur 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 income or restructuring and related expenses for the reconfiguration of the Group's activities and/or capital structure, impairment of current and non-current assets, proceeds from the sale of intangible assets, certain costs arising as a result of material and non-recurring regulatory and litigation matters, certain non-recurring benefits, and certain tax related matters. Exceptional items are excluded from adjusted results consistent with the internal reporting provided to Management and the Directors. Adjusted results are not a substitute for, or superior to, reported results presented in accordance with IFRS. Exceptional items with an impact of less than \$1m are not considered for exceptional treatment.



The table below sets out exceptional income/(expense) recorded in each period:

	Q4 2021 \$m	Q4 2020 \$m	FY 2021 \$m	FY 2020 \$m
<b>For the three and twelve months ended December 31</b>				
<b>Exceptional items within cost of sales</b>				
Cost of sales credit/(charge) <sup>1</sup>	-	6	-	(5)
Total exceptional items within cost of sales	-	6	-	(5)
<b>Exceptional items within SG&amp;A</b>				
Restructuring costs <sup>2</sup>	1	(2)	1	(11)
Legal expenses/provision <sup>3</sup>	-	(45)	18	(228)
ANDA litigation <sup>4</sup>	-	-	(24)	-
Debt refinancing <sup>5</sup>	-	-	(1)	-
Total exceptional items within SG&A	1	(47)	(6)	(239)
<b>Exceptional items within other operating income</b>				
Net proceeds from disposal of intangible asset <sup>6</sup>	-	-	20	-
Insurance reimbursement <sup>7</sup>	12	-	12	-
Total exceptional items within other operating income	12	-	32	-
<b>Exceptional items within net finance expense</b>				
Finance expense <sup>5</sup>	-	-	(1)	-
Total exceptional items within net finance expense	-	-	(1)	-
<b>Total exceptional items before taxes</b>	<b>13</b>	<b>(41)</b>	<b>25</b>	<b>(244)</b>
Tax on exceptional items	(3)	2	(3)	37
Exceptional tax item <sup>8</sup>	-	-	43	-
<b>Total exceptional items</b>	<b>10</b>	<b>(39)</b>	<b>65</b>	<b>(207)</b>

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 offsetting the exceptional charge taken in Q3 2020.
2. Restructuring costs incurred in Q4 2020 and FY 2020 relate to cost saving actions taken by the Group in response to ongoing challenges posed by COVID-19. In Q4 2021 the restructuring program concluded, and the remaining provision was released which resulted in an exceptional benefit of \$1m.
3. Negotiation with DOJ related plaintiffs in FY 2021 led to a change in the Group's provision for DOJ related matters which resulted in a provision release of \$18m. 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 FY 2020 relate to resolution with RB and DOJ, \$50m and \$178m, respectively.
4. In Q3 2021, upon conclusion of expert discovery, the Group increased the provision for intellectual property related matters - ANDA Litigation, to \$73m, resulting in an exceptional charge for \$24m. See Note 9 and 11 for further discussion.
5. Debt refinancing costs in FY 2021 consist of advisory and legal fees incurred related to the Group's 2021 debt refinancing. These costs are included in SG&A. Additionally, in FY 2021 the Group wrote-off \$1m of unamortised deferred financing costs due to extinguishment and settlement of the previous term loan. These costs are included within finance expense.
6. Exceptional other operating income in FY 2021 relates to the net gain on disposal received from the sale of the TEMGESIC / BUPREX / BUPREXX (buprenorphine) analgesic franchise outside of North America to Eumedica Pharmaceuticals AG for \$19m. Remaining exceptional income in FY 2021 relates to the proceeds received from the out-licensing of nasal naloxone opioid overdose patents for \$1m.
7. In Q4 2021, the Group recognized \$12m exceptional other income related to a Directors & Officers insurance reimbursement claim.
8. Exceptional tax benefit recorded in FY 2021 relates to the approval of tax credits by the Internal Revenue Service in relation to development credits for SUBLOCADE claimed for years 2014 to 2017 and the tax impact of settlement costs incurred with Reckitt Benckiser (RB) which were recorded in the prior year.

## Adjusted results

The Board and management team use adjusted results and measures to provide incremental 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 results for both Q4/FY 2021 and Q4/FY 2020.

### Reconciliation of gross profit to adjusted gross profit

	Q4 2021	Q4 2020	FY 2021	FY 2020
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
<b>Gross profit</b>	<b>184</b>	<b>162</b>	<b>664</b>	<b>550</b>
Exceptional cost of sales (credit)/charge	-	(6)	-	5
<b>Adjusted gross profit</b>	<b>184</b>	<b>156</b>	<b>664</b>	<b>555</b>

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

	Q4 2021	Q4 2020	FY 2021	FY 2020
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
<b>Operating profit/(loss)</b>	<b>45</b>	<b>(9)</b>	<b>213</b>	<b>(156)</b>
Exceptional cost of sales credit/(charge)	-	(6)	-	5
Exceptional selling, general and administrative expenses	(1)	47	6	239
Exceptional other operating income	(12)	-	(32)	-
<b>Adjusted operating profit</b>	<b>32</b>	<b>32</b>	<b>187</b>	<b>88</b>

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

	Q4 2021	Q4 2020	FY 2021	FY 2020
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
<b>Profit/(loss) before taxation</b>	<b>39</b>	<b>(14)</b>	<b>190</b>	<b>(173)</b>
Exceptional cost of sales credit/(charge)	-	(6)	-	5
Exceptional selling, general and administrative expenses	(1)	47	6	239
Exceptional other operating income	(12)	-	(32)	-
Exceptional finance expense	-	-	1	-
<b>Adjusted profit before taxation</b>	<b>26</b>	<b>27</b>	<b>165</b>	<b>71</b>

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

	Q4 2021	Q4 2020	FY 2021	FY 2020
	\$m	\$m	\$m	\$m
<b>For the three and twelve months ended December 31</b>				
<b>Net income/(loss)</b>	<b>35</b>	<b>(13)</b>	<b>205</b>	<b>(148)</b>
Exceptional cost of sales credit/(charge)	-	(6)	-	5
Exceptional selling, general and administrative expenses	(1)	47	6	239
Exceptional other operating income	(12)	-	(32)	-
Exceptional finance expense	-	-	1	-
Tax on exceptional items	3	(2)	3	(37)
Tax exceptional	-	-	(43)	-
<b>Adjusted net income</b>	<b>25</b>	<b>26</b>	<b>140</b>	<b>59</b>

## 5. TAXATION

In the twelve months ended December 31, 2021, the reported total tax benefit was \$15m, or a rate of -8% (FY 2020 tax benefit: \$25m, 14%). The tax expense on adjusted profits amounted to \$25m (FY 2020: \$12m) and represented a year-to-date effective tax rate of 15% (FY 2020: 17%). The decrease in the adjusted effective tax rate from 2020 was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the year.

The current year tax benefit on exceptional items of \$40m predominantly relate to approval of tax credits by the Internal Revenue Service in relation to development credits for SUBLOCADE claimed for years 2014 to 2017 (\$34m). Other elements include the tax impact of settlement costs incurred with Reckitt Benckiser (RB) which were recorded in the prior year, impact of the ANDA accrual and a tax expense in relation to exceptional other operating income.

The Group's balance sheet on December 31, 2021, included a current tax receivable of \$13m (FY 2020: \$7m), current tax payable of \$7m (FY 2020: \$15m), and deferred tax asset of \$105m (FY 2020: \$75m). The increase in the deferred tax asset is due to current year activity including the deferred benefit of inventory costs capitalized for tax purposes and the increase in anticipated tax relief for share awards due to increases in the group's share price.

The Group recognizes deferred tax assets to the extent that sufficient future taxable profits are probable against which these future tax deductions can be utilized. At December 31, 2021, the Group's net deferred tax assets of \$105m includes \$81m (FY 2020: \$51m) in USA and \$11m (FY 2020: \$7m) in UK. Deferred tax assets relate primarily to inventory costs capitalized for tax purposes, litigation liabilities (including exceptional items that are not expected to recur), share-based compensation, and other short term timing differences. Recognition of deferred tax assets is driven by the Group's ability to utilize the deferred tax asset which is reliant on forecast taxable profits arising in the jurisdiction in which the deferred tax asset is recognized. The Group has assessed recoverability of deferred tax assets using Group-level budgets and forecasts consistent with those used for the assessment of viability and asset impairments, particularly in relation to levels

of future sales. These forecasts are therefore subject to similar uncertainties to those assessments. This exercise is reviewed each year and, to the extent required, an adjustment to the recognized deferred tax asset may be made. With the exception of specific assets that are not currently considered accessible, Management have concluded full recognition of deferred tax assets to be appropriate and do not consider there a significant risk of a material change in their assessment in the next 12 months.

#### Other tax matters

In 2019, a European Commission review into State Aid concluded that the UK's Finance Company Partial Exemption rules are only partly justified. The UK government was required to initiate recovery of the alleged State Aid where they assess a benefit of the potential State Aid has been received. HMRC has confirmed that there has been no such benefit to the Group and therefore the enquiry in relation to this matter up to FY2017 is closed. HMRC has opened enquiries in relation to FY18 and FY19 in relation to this matter. Based on the similar fact pattern applicable to the later years, the Group has determined no provision is required.

The enacted United Kingdom Statutory Corporation Tax rate is 19% for the year ended December 31, 2021. On March 3, 2021, the UK Chancellor announced an increase in the corporation tax rate from 19% to 25% with effect from April 1, 2023. The increase to the corporation tax rate was substantively enacted on May 24, 2021. The effect of the rate change is immaterial.

As disclosed in Note 9, the Group reached a settlement with Reckitt Benckiser on January 25, 2021. Based on the strength of external advice received, an \$8m tax benefit from the settlement cost has been recognized in the year. Tax authorities may potentially challenge the Group's position.

As a multinational group, tax uncertainties remain in relation to Group financing, intercompany pricing, the location of taxable operations and the tax treatment of exceptional items. Management have concluded tax provisions made to be appropriate and do not believe a significant risk of material change to uncertain tax positions exists in the next 12 months.

#### 6. EARNINGS/(LOSS) PER SHARE

	Q4 2021 cents	Q4 2020 cents	FY 2021 cents	FY 2020 cents
<b>For the three and twelve months ended December 31</b>				
Basic earnings/(loss) per share	5	(2)	28	(20)
Diluted earnings/(loss) per share	5	(2)	27	(20)
Adjusted basic earnings per share	3	4	19	8
Adjusted diluted earnings per share	3	3	18	8

#### Basic

Basic earnings/(loss) per share ("EPS" or "LPS") is calculated by dividing profit/(loss) for the period attributable to owners of the Group by the weighted average number of ordinary shares in issue during the period.

#### Diluted

Diluted earnings/(loss) per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. The Group 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.

The weighted average number of ordinary shares outstanding for 2021 (on a basic basis) includes the favorable impact of the share repurchase program. Refer to Note 13 for further details.

	2021 thousands	2020 thousands
<b>Weighted average number of shares</b>		
On a basic basis	728,299	732,863
Dilution from share awards and options	42,842	37,132
On a diluted basis	771,141	769,995

#### Adjusted Earnings

The Directors believe that diluted earnings per share, adjusted for the impact of exceptional items after the appropriate tax amount, provides more meaningful information on underlying trends to shareholders in respect of earnings per ordinary share. A reconciliation of net income to adjusted net income is included in Note 4.

#### 7. CURRENT AND NON-CURRENT OTHER ASSETS

	Dec 31 2021 \$m	Dec 31 2020 \$m
<b>Current and non-current other assets</b>		
Short-term prepaid expenses	18	17
Other current assets	14	33
<b>Total other current assets</b>	32	50
Long-term prepaid expenses	22	22
Other non-current assets	84	82
<b>Total other non-current assets</b>	106	104
<b>Total</b>	138	154

Other current and non-current assets as of December 31, 2020, primarily represent the funding of surety bonds in relation to intellectual property related matters (see Note 11 for further discussion). In FY 2021, one of the surety bond holders returned \$26m causing a decrease in other current assets, which is partially offset by a \$6m increase related to a Directors & Officers insurance claim settlement receivable.

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

## 8. FINANCIAL LIABILITIES – BORROWINGS AND NET CASH

On June 30, 2021, the Group completed a refinancing of its term loan, repaying in full the existing \$235m term loan and replacing it with a new term loan with a principal amount of \$250m. As a result of the debt refinancing, in FY 2021, the Group incurred a collective charge of \$2m related to writing off unamortized deferred financing costs due to the extinguishment and settlement of previous term loan (\$1m) and advisory fees incurred in conjunction with the refinancing (\$1m). These costs were classified as exceptional. See Note 4 for further details.

The Group capitalized \$8m of deferred financing and original issue discount costs related to the new term loan, which were netted against the total amount borrowed and are amortized over the maturity period. The key terms of the new term loan in effect at December 31, 2021, are as follows:

	Currency	Nominal interest margin	Maturity	Required annual repayments	Minimum liquidity
Term Loan facility	USD	Libor* (0.75%) + 5.25%	2026	1%	Larger of \$100m or 50% of Loan Balance

\*While the new term loan is USD LIBOR based, the new term loan contains fallback language to convert to a new reference rate when USD LIBOR is discontinued or becomes non-representative, which is expected to occur in early 2023.

- Nominal interest margin is calculated over three-month USD LIBOR subject to a floor of 0.75%.
- The minimum liquidity is the larger of \$100m or 50% of the outstanding loan balance.
- There are no revolving credit commitments under the new Term Loan.

The table below sets out the current and non-current portion obligation of the Term Loan:

	Dec 31 2021 \$m	Dec 31 2020 \$m
<b>Term loan</b>		
Term loan – current	(3)	(4)
Term loan – non-current	(239)	(230)
Total term loan	(242)	(234)

At December 31, 2021, the term loan fair value was approximately 99% (FY 2020: 98%) of par value. Cash at bank, trade receivables, and trade payables are assumed to approximate their fair values.

Net cash, as presented below, is presented consistently with prior periods, and represents a measure of liquidity considered by the Directors.

	Dec 31 2021 \$m	Dec 31 2020 \$m
<b>Analysis of net cash</b>		
Cash and cash equivalents	1,102	858
Term loan borrowings*	(249)	(235)
Total net cash	853	623

\*Borrowings reflect the principal amount drawn before debt issuance costs of \$7m (FY 2020: \$1m). These do not include lease liabilities of \$44m (FY 2020: \$51m).

	FY 2021 \$m	FY 2020 \$m
<b>Reconciliation of net cash</b>		
The movements in the period were as follows:		
Net cash at beginning of period	623	821
Net increase/(decrease) in cash and cash equivalents	245	(207)
New borrowings	(250)	-
Repayment of borrowings	236	4
Exchange adjustments	(1)	5
Net cash at end of period	853	623

## 9. PROVISIONS AND OTHER LIABILITIES

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

### Provisions

Current and non-current provisions	Current	Non-Current	Total	Current	Non-Current	Total
	\$m	\$m	Dec 31 2021 \$m	\$m	\$m	Dec 31 2020 \$m
DOJ related matters	(5)	-	(5)	(32)	-	(32)
Intellectual property related matters	-	(73)	(73)	-	(47)	(47)
Restructuring costs	-	-	-	(6)	-	(6)
Other	-	(3)	(3)	-	(4)	(4)
<b>Total provisions</b>	<b>(5)</b>	<b>(76)</b>	<b>(81)</b>	<b>(38)</b>	<b>(51)</b>	<b>(89)</b>

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 probable, 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 \$5m (FY 2020: \$32m) pertaining to DOJ related matters as discussed in Note 11. Negotiations with DOJ related plaintiffs resulted in an exceptional provision release of \$18m in FY 2021 (see Note 4). The remaining movement of \$9m in the provision relates to amounts settled and paid in the year. DOJ related matters of \$5m are expected to be settled within the next 12 months.

The Group carries provisions totaling \$73m (FY 2020: \$47m) for intellectual property related matters, all of which relate to potential redress for ongoing intellectual property litigation with Dr. Reddy's Laboratories, S.A., and Dr. Reddy's Laboratories Inc. (collectively, "DRL") and Alvogen Pharmaceuticals (Alvogen), should the Group not be successful with those cases outlined in Note 11, Intellectual property related matters - ANDA litigation. In Q3 2021, upon conclusion of expert discovery, the Group increased the provision for intellectual property related matters to \$73m, resulting in an exceptional charge of \$24m. The provision represents the Group's best estimate of potential damages owed to DRL and Alvogen for the period between FDA approval and lifting of the preliminary injunction. This provision has been recorded at the net present value, using a risk-free rate, considering the estimated timing of settlement in 2023/2024. In FY 2021, the Group recorded finance expense totaling \$2m (FY 2020: \$2m) for time value of money on this provision. The Group does not expect this matter to be settled within a year and therefore the provision of \$73m is classified as non-current.

The restructuring provision related to cost saving initiatives announced and implemented in 2020 which consisted of redundancy and related costs has been fully utilized as of December 31, 2021.

Other provisions totaling \$3m (FY 2020: \$4m) primarily represent retirement benefit costs which are not expected to be settled within one year.

### Other liabilities

Current and non-current other liabilities	Current	Non-Current	Total	Current	Non-Current	Total
	\$m	\$m	Dec 31 2021 \$m	\$m	\$m	Dec 31 2020 \$m
DOJ resolution	(53)	(439)	(492)	-	(486)	(486)
RB indemnity settlement	(8)	(32)	(40)	(10)	(40)	(50)
Other	-	(3)	(3)	-	-	-
<b>Total other liabilities</b>	<b>(61)</b>	<b>(474)</b>	<b>(535)</b>	<b>(10)</b>	<b>(526)</b>	<b>(536)</b>

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 a risk-free rate.

On July 24, 2020, the Group reached a resolution with the DOJ and other litigants described in Note 11 under "DOJ Resolution", which was finalized in November 2020 and the first payment of \$103m (including interest) was made. Subsequently, six annual instalments of \$50m will be due every January 15 from 2022 to 2027 with the final instalment of \$200m due in December 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 2021, the Group recorded interest expense totaling \$6m (FY 2020: \$3m). As of December 31, 2021, \$53m has been classified as current on the Group's balance sheet.

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 an initial payment of \$10m 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 \$40m (FY 2020: \$50m) related to this settlement. The effect of discounting was not material. The next instalment payment is due in January 2022 and therefore \$8m has been classified as current.

Other liabilities primarily represent deferred revenue related to a supply agreement which is non-current as of December 31, 2021.

## 10. CONTINGENT LIABILITIES

The Group has assessed certain legal and other matters to be not probable based upon current facts and circumstances, including any potential impact the DOJ resolution could have on these matters. These represent contingent liabilities. Except for those matters discussed in Note 11 under “DOJ Resolution”, “DOJ Related Matters” and “Intellectual Property Related Matters”, for which provisions have been recognized, Note 11 sets out the contingent liabilities for legal and other disputes for which the Group has assessed as contingent liabilities. Refer to Note 5 for discussion on State Aid and other tax related contingent liabilities.

## 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 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.
- As part of the resolution with the FTC and 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.
- 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 is subject to reporting and monitoring requirements, including annual reports and compliance certifications from key management and the Board’s Nominating & Governance Committee, which is submitted to HHS-OIG. In addition, the Group is subject to monitoring by an Independent Review Organization, who submits audit findings to HHS-OIG, and review by a Board Compliance Expert, who prepared a compliance assessment report in the first reporting period and will prepare a compliance assessment report in the third reporting period.

In November 2020, the Group made a payment of \$103m (including interest) when the resolution was approved by the Court and made a subsequent payment in January 2022 of \$54m (including interest). Subsequently, five annual instalments of \$50m will be due every January 15 from 2023 through 2027. The final instalment of \$200m will be due in December 2027. The Group carries a liability totaling of \$492m (FY 2020: \$486m) pertaining to the DOJ resolution.

### Reckitt Benckiser

- On January 25, 2021, the Group reached a resolution with Reckitt Benckiser as discussed in Note 9.

### DOJ Related Matters

#### *Federal False Claims Act 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 sought reasonable attorney’s fees and costs. Three other cases were filed in the District Court of the District of New Jersey that also 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 Group settled these matters in 2020 and 2021.

#### *State and Local Matters*

- 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. 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 settled with the relators and the California Department of Insurance in 2021.
- 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 settled with the relators and the Illinois Insurance Department in 2021.
- 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 resolved the matter with the City of Chicago in 2020.

#### *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. The Group filed a Motion to Dismiss on June 24, 2021.

- In May 2018, Indivior Inc. received an informal request from the Office of the United States Attorney (“OUSA”) for the Southern District of New York, seeking records relating to the Suboxone manufacturing process and the Group is discussing with the OUSA certain information and allegations regarding the Suboxone manufacturing process the government received.

#### *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 was granted by the court in September 2021. A settlement fairness occurred in January 2022 and the case was dismissed.

#### **Intellectual Property Related Matters**

##### *ANDA Litigation*

- Indivior filed actions against Dr. Reddy’s Laboratories S.A. and Dr. Reddy’s Laboratories, Inc. (together, “DRL”) in the United States District Court for the District of New Jersey (“NJ District Court”) alleging that DRL’s generic buprenorphine/naloxone film product infringes U.S. Patent Nos. 9,687,454 and 9,931,305 (“the ‘454 and ‘305 Patents”) in 2017 and 2018, respectively. The cases were consolidated in May 2018. 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 NJ District Court granted Indivior a Preliminary Injunction (PI) pending the outcome of a trial on the merits of the ‘305 Patent, and required Indivior to post a surety bond for \$72m in connection with the PI. In November 2018, the Court of Appeals for the Federal Circuit (CAFC) issued a decision vacating the PI against DRL. On remand, the NJ District Court construed the claims of the ‘454 and ‘305 Patents. Indivior and DRL stipulated to noninfringement of the ‘305 Patent under the court’s claim construction, but Indivior retained its rights to appeal the construction and pursue its infringement claims pending appeal. Separately, DRL filed an amended answer alleging various antitrust counterclaims. Indivior’s infringement claims concerning the ‘454 patent and DRL’s antitrust counterclaims remain pending in the NJ District Court. Summary judgment motions have been fully briefed, but the NJ District Court has not ruled on those motions. No trial date has been set. In February 2022, the NJ District Court ordered the parties to mediation.
- In November 2018, DRL filed two petitions for *inter partes* review (“IPR”) of the ‘454 Patent with the U.S. Patent and Trademark Office’s Patent Trial and Appeal Board (“PTAB”). The PTAB denied institution of one IPR petition but granted institution for the other. The PTAB issued a decision in June 2020, finding 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 CAFC. In December 2021, the CAFC affirmed the PTAB’s decision. Indivior filed a petition with the CAFC for a panel rehearing or rehearing *en banc* in January 2022. The CAFC has not yet ruled on Indivior’s petition.
- Indivior filed actions against Alvogen Pine Brook LLC and Alvogen Inc. (together, “Alvogen”) in the NJ District Court alleging that Alvogen’s generic buprenorphine/naloxone film product infringes U.S. Patent Nos. 9,687,454 and 9,931,305 (“the ‘454 and ‘305 Patents”) in 2017 and 2018, respectively. The cases were consolidated in May 2018. In January 2019, the NJ District Court granted Indivior a temporary restraining order (“TRO”) to restrain the launch of Alvogen’s generic buprenorphine/naloxone film product pending a trial on the merits of the ‘305 Patent and Indivior was required to post a surety bond of \$36M. Indivior and Alvogen entered into an agreement whereby Alvogen was enjoined from selling in the US its generic buprenorphine/naloxone film product unless and until the CAFC issued a mandate vacating Indivior’s separate PI against DRL. The CAFC’s mandate vacating Indivior’s PI as to DRL issued in February 2019 and Alvogen launched its generic product. Any sales in the US by Alvogen are on an “at-risk” basis, subject to the ongoing litigation against Alvogen in the NJ District Court. In November 2019, Alvogen filed an amended answer alleging various antitrust counterclaims. In January 2020, Indivior and Alvogen stipulated to noninfringement of the ‘305 Patent under the court’s claim construction, but Indivior retained its rights to appeal the construction and pursue its infringement claims pending appeal. Indivior’s infringement claims concerning the ‘454 patent and Alvogen’s antitrust counterclaims remain pending in the NJ District Court. Summary judgment motions have been fully briefed, but the NJ District Court has not ruled on those motions. No trial date has been set. In February 2022, the NJ District Court ordered the parties to mediation.

##### *Opposition to SUBLOCADE European Patent*

- In October 2018, Teva Pharmaceutical Industries Ltd. (“Teva”) filed a Notice of Opposition with the European Patent Office (“EPO”) seeking to revoke European Patent No. EP 2579874 (“EP 874”), which relates to the formulation for SUBLOCADE. Oral proceedings took place in September 2021 and the patent was maintained as granted. Teva filed a notice of appeal in November 2021 and has until the end of February 2022 to submit their grounds for appeal.
- In March 2021, the law firm Elkington & Fife LLP filed a Notice of Opposition with the EPO seeking to revoke European Patent No. EP 3215223 (“EP 223”), which relates to the dosing regimen for SUBLOCADE. The Opposition alleges that the claims of EP 223 lack inventive step and extend beyond the content of the application as originally filed. The Group responded to the Opposition in August 2021. No oral hearing date has been set by the EPO.

#### **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. Summary judgment motions related to the Direct Purchaser, End Payor, and States actions were fully briefed and were argued in December 2021. The deadline for the class exclusion or “opt out” is April 17, 2022.
- 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 pled guilty to one count of making a false statement relating to health care matters in one state in 2012 (as discussed above under DOJ Resolution). The Group continues to believe 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 has cooperated fully in this civil investigation.
- In 2020, the 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 were pending in the Eastern District of Pennsylvania. The complaints were dismissed in July 2021. Plaintiffs filed Notices of Appeal in August 2021 to the United States Court of Appeals for the Third Circuit (“Third Circuit”). The Third Circuit has indicated it may hear oral arguments on this appeal in March 2022. Humana also filed a Complaint in state court in Kentucky with substantially the same claims as were raised in the Federal Court case. That case has been stayed pending a decision in the Third Circuit appeal. 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), (5) Molina Healthcare, Inc., and (6) Aetna Inc. are pending in the Circuit Court for the County of Roanoke, Virginia (the “Roanoke Plaintiffs”). 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. In June 2021, defendants’ motion to stay was denied and certain claims were dismissed without prejudice. The Roanoke Plaintiffs have filed amended complaints, and the Group has filed demurrers, seeking dismissal of some of the asserted claims. Briefing is scheduled to be completed on these demurrers in March of 2022.

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

### **Civil Opioid Litigation**

- Indivior has been named as a defendant in approximately 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. At the present time, litigation against Indivior in the MDL is stayed. Given the status and preliminary stage of litigation in both the MDL and state courts, no estimate of possible loss in the opioid litigation can be made at this time.



## 12. TRADE AND OTHER PAYABLES

	Dec 31 2021 \$m	Dec 31 2020 \$m
<b>Trade and other payables</b>		
Sales returns and rebates	(436)	(396)
Trade payables	(137)	(20)
Accruals	(136)	(99)
Other tax and social security payables	(11)	(9)
<b>Total</b>	<b>(720)</b>	<b>(524)</b>

Sales return and rebate accruals, primarily in the U.S., are provided in respect of the estimated rebates, discounts, or allowances payable to direct and indirect customers. Accruals are made at the time of sale while the actual amounts to be paid are based on claims made some time after the initial recognition of the sale. The estimated amounts may not reflect the final outcome and are subject to change dependent upon, amongst other things, the payor channel (e.g., Medicaid, Medicare, Managed Care, etc.) and product mix. Accrual balances are reviewed and adjusted quarterly in the light of actual experience of rebates, discounts or allowances given and returns made and any changes in arrangements. Future events may cause the assumptions on which the accruals are based to change, which could affect the future results of the Group.

The increase in trade payables is primarily driven by timing of payments made on government rebate payables in the U.S.

## 13. SHARE CAPITAL

	Equity Ordinary Shares	Nominal value paid per share	Aggregate nominal value \$m
Issued and fully paid			
<b>At January 1, 2021</b>	<b>733,635,511</b>	<b>\$0.10</b>	<b>73</b>
<b>Ordinary shares issued</b>	<b>2,311,560</b>	<b>\$0.10</b>	<b>-</b>
<b>Shares repurchased and cancelled</b>	<b>(33,507,433)</b>	<b>\$0.10</b>	<b>(3)</b>
<b>At December 31, 2021</b>	<b>702,439,638</b>		<b>70</b>

In addition, 256,055 ordinary shares purchased as part of the share repurchase program (discussed below) were cancelled in January 2022. These shares are included in the total number of share capital outstanding as at December 31, 2021.

	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
Ordinary shares issued	2,847,792	\$0.10	-
At December 31, 2020	733,635,511		73

### Ordinary shares issued

During the period, 2,311,560 ordinary shares (2020: 2,847,792) were allotted to satisfy vesting/exercises under the Group's Long-Term Incentive Plan and U.S. Employee Stock Purchase Plan.

### Shares repurchased and cancelled

On July 30, 2021, the Group commenced an irrevocable share repurchase program for the aggregate purchase price up to no more than \$100m or 73,462,098 of ordinary shares. On December 23, 2021, the program concluded with the Group repurchasing 33,763,488 of the Group's ordinary shares over the duration of the program for an aggregate nominal value of \$3m (\$0.10 per share). All ordinary shares repurchased during the program were cancelled (except for those cancelled in January 2022 as noted above) which resulted in a transfer of the aggregate nominal value to a capital redemption reserve. The total cost of the share repurchase program was \$101m, consisting of \$100m paid for the repurchase of shares and \$1m of directly attributable transaction costs paid, which include advisory fees and stamp duties.