

October 28, 2021

**Indivior Announces Q3 and Nine Months 2021 Results;  
 Raises FY 2021 Guidance**

Period to September 30th	Q3 2021 \$m	Q3 2020 \$m	% Change		YTD 2021 \$m	YTD 2020 \$m	% Change
Net Revenue	<b>187</b>	159	18		<b>568</b>	462	23
Operating Profit/(Loss)	<b>38</b>	18	111		<b>168</b>	(147)	NM
Net Income/(Loss)	<b>27</b>	10	170		<b>169</b>	(135)	NM
EPS/(LPS) (cents per share)	<b>4</b>	1	NM		<b>23</b>	(18)	NM
Adj. Operating Profit*	<b>38</b>	30	27		<b>155</b>	56	177
Adj. Net Income*	<b>27</b>	19	42		<b>114</b>	33	NM
Adj. EPS*	<b>4</b>	3	33		<b>16</b>	5	NM

\* *Adjusted (Adj.) basis excludes the impact of exceptional items as referenced and reconciled in Note 4, 5 and 6. NM – Not meaningful.*

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

“We are pleased to report another quarter of good growth and further strengthening of our leadership in addiction treatment. Based on the strong commercial execution behind SUBLOCADE® (buprenorphine extended-release) injection and the resilience of our legacy US film business, we have again raised our 2021 net revenue expectations for the overall Group and for SUBLOCADE. Our strategy to focus on the large and growing opportunity in organized health systems (OHS) has seen us deliver five consecutive quarters of double-digit<sup>(1)</sup> underlying net revenue growth for SUBLOCADE, providing us strong momentum as we look forward to 2022.”

**YTD / Q3 2021 Financial Highlights**

- YTD 2021 total net revenue (NR) of \$568m increased 23% (YTD 2020: \$462m); Q3 2021 total NR of \$187m increased 18% (Q3 2020: \$159m). The strong increase in both periods was primarily driven by higher NR from SUBLOCADE (+86% vs. YTD 2020, +97% vs. Q3 2020), continued growth in the buprenorphine medication-assisted treatment (BMAT) market, and by market share stability for SUBOXONE® (buprenorphine and naloxone) Film in the US.
- YTD 2021 reported operating profit was \$168m (YTD 2020 operating loss: \$147m); Q3 2021 reported operating profit of \$38m increased 111% (Q3 2020: \$18m). On an adjusted basis, YTD 2021 operating profit was \$155m (Adj. YTD 2020: \$56m). Adj. Q3 2021 operating profit of \$38m increased 27% (Adj. Q3 2020: \$30m). The substantial improvement in adjusted operating profit in both periods was primarily driven by strong net revenue growth.
- YTD 2021 reported net income was \$169m (YTD 2020 net loss: \$135m); Q3 2021 reported net income was \$27m (Q3 2020 net income: \$10m). On an adjusted basis, YTD 2021 net income was \$114m (Adj. YTD 2020 net income: \$33m). Adj. Q3 2021 net income was \$27m (Adj. Q3 2020: \$19m). The significant increases in adjusted net income in both periods were primarily driven by higher operating profit, partially offset by increased net finance expense.
- YTD 2021 ending cash balance was \$1,005m (FY 2020: \$858m); net cash was \$756m (FY 2020: \$623m). Higher operating profit, relatively stable government rebate payables and proceeds from the sale of the legacy TEMGESIC® / BUPREX® / BUPREXX® (buprenorphine) analgesic franchise outside of North America was offset by cash used to repurchase ordinary shares as part of the Group’s \$100m share repurchase program.

(1) Assumes net revenue of \$54m in Q2 2021, which excludes a large order of \$7m from a criminal justice customer

### YTD / Q3 2021 Operating Highlights

- YTD 2021 SUBLOCADE NR of \$169m (+86% vs. YTD 2020); Q3 SUBLOCADE NR of \$65m (+97% vs. Q3 2020 and +7% vs. Q2 2021) reflects strong growth in the OHS channel and increased new US patient enrolments. Q3 2021 US dispenses were approx. 48,400 units (+66% vs. Q3 2020 and +13% vs. Q2 2021).
- YTD 2021 PERSERIS® (risperidone) extended-release injection NR of \$12m (+20% vs. YTD 2020); Q3 2021 PERSERIS NR of \$5m (+67% vs. Q3 2020 and +25% vs. Q2 2021) reflects improved commercial access to US healthcare practitioners (HCPs) from the continued reopening of the US healthcare system. The Group is currently investing to expand the PERSERIS sales force to achieve US national coverage in 2022.
- YTD 2021 SUBOXONE Film share averaged 20% (YTD 2020: 21%) and exited the quarter at 20% (Q3 2020: 21%). Share erosion since the “at-risk” launch of generic buprenorphine/naloxone film products in February 2019 has thus far been lower than historical industry analogues<sup>(1)</sup> would suggest.
- Outside the US: SUBLOCADE / SUBUTEX® prolonged release solution for injection is available in Australia, Canada, and Israel; approved in Sweden, Finland, New Zealand, Denmark, Germany, Italy and Norway. SUBOXONE Film now available in Canada, Israel, Germany, UK, Italy, Finland, Denmark, Sweden, and Norway.

### Share Repurchase Program

On July 30, 2021, the Group announced an irrevocable share repurchase program of up to \$100m. Through September 30, 2021, the Group has repurchased and cancelled 11,730,087 of the Group’s ordinary shares at a daily weighted average purchase price of 189.87p at a cost of approximately \$31m. See Note 13 for further discussion.

### FY 2021 Guidance Raised

The Group is raising its FY 2021 guidance for NR and pre-tax income as follows:

- Total FY 2021 NR range expected to be \$750m to \$770m (previously \$705m to \$740m), reflecting strong SUBLOCADE performance and continued market share stability for SUBOXONE Film.
- SUBLOCADE FY 2021 NR range expected to be \$235m to \$245m (previously \$210m to \$230m), based on stronger demand and progress in the US criminal justice system (OHS sub-channel).
- Positive adjusted pre-tax income at a higher level than previous management expectations.

FY 2021 guidance for the below items remains unchanged:

- PERSERIS® (risperidone) extended-release injection FY 2021 NR range of \$17m to \$20m.
- Adjusted gross margin in the low-80% range.
- Adjusted operating expense (SG&A+R&D) range of \$470m to \$480m, primarily reflecting commercial investments to grow the Group’s long-acting injectable (LAI) technologies, principally in the US.

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

YTD 2021, the U.S. BMAT market grew in low single-digits. Moderation in the growth rate versus 2020 reflects the high base period for comparison in the year-ago quarter, 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 access to medication-assisted treatment (MAT) for OUD patients. Over the approximate two year period since the beginning of 2020, BMAT market growth has averaged in the mid- to high-single digits, which is in-line with the historical industry growth rate and the Group’s long-term expectations.

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 Q3 2021.

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

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 9 Mos. YTD and Q3 2021**

Total YTD 2021 net revenue increased 23% to \$568m at actual exchange rates (YTD 2020: \$462m; +21% at constant exchange rates). In Q3 2021, total net revenue increased 18% at actual exchange rates to \$187m (Q3 2020: \$159m; +18% at constant exchange rates).

YTD 2021 U.S. net revenue increased 33% to \$428m (YTD 2020: \$323m) and by 29% in Q3 2021 to \$143m (Q3 2020: \$111m). 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.

YTD 2021 Rest of World (ROW) net revenue increased 1% at actual exchange rates to \$140m (YTD 2020: \$139m; -7% at constant exchange rates). YTD 2021 and 2020 ROW SUBLOCADE net revenue were \$11m and \$2m (at actual exchange rates), respectively. Foreign currency translation benefits and SUBLOCADE net revenue contribution were the principal drivers of the YTD net revenue increase. These benefits were partially offset by ongoing competitive pressure in the legacy tablet business in Western Europe.

In Q3 2021, ROW net revenue decreased 8% at actual exchange rates to \$44m (Q3 2020: \$48m; -9% at constant exchange rates). Q3 2021 and 2020 ROW SUBLOCADE net revenue were \$4m and \$2m (at actual exchange rates), respectively. The NR decline in Q3 was mainly attributable to ongoing competitive pressure in the legacy tablet business in Western Europe and the sale of the legacy TEMGESIC®/ BUPREX® / BUPREXX® analgesic franchise.

Gross margin as reported YTD 2021 was 85% (YTD 2020: 84%; Adj. YTD 2020: 86%) and 86% in Q3 2021 (Q3 2020: 79%; Adj. Q3 2020: 82%). There were no exceptional costs recorded in gross margin for the current periods. Adj. YTD 2020 and Q3 2020 excludes \$11m and \$5m, respectively, of net exceptional costs of sales related to inventory provisions due to the adverse impact of COVID-19. The adjusted gross margin improvement in Q3 reflects a more favorable product mix from the continued strong growth of SUBLOCADE while the modest decline in YTD 2021 gross margin reflects the continued relative strength of SUBOXONE Film.

YTD SG&A expenses as reported were \$279m (YTD 2020: \$509m). YTD 2021 included \$13m of net exceptional benefits primarily due to other operating income recorded from the net proceeds received from the sale of the legacy TEMGESIC®/ BUPREX® / BUPREXX® (buprenorphine) analgesic franchise outside of North America (+\$19m), and non-cash adjustments to provisions related to DOJ-related matters (+\$18m) and ANDA litigation matter (-\$24m). YTD 2020 reported SG&A included exceptional costs of \$192m, which were related to the DOJ matter (-\$183m), the Group's strategic alignment actions (-\$7m) and lease impairments (-\$2m).

Q3 SG&A expenses as reported were \$112m in Q3 2021 (Q3 2020: \$100m). Q3 2021 exceptional items netted to \$nil. Net proceeds received from the sale of the legacy TEMGESIC®/ BUPREX® / BUPREXX® (buprenorphine) analgesic franchise outside of North America (+\$19m) were fully offset by non-cash adjustments to provisions related to the ANDA litigation matter (-\$24m) and DOJ related matters (+\$5m). Q3 2020 reported SG&A included exceptional costs (-\$7m) related to the Group's strategic alignment actions.

On an adjusted basis, YTD 2021 SG&A expenses decreased 8% to \$292m (Adj. YTD 2020: \$317m); Q3 2021 adjusted SG&A expense increased 20% to \$112m (Adj. Q3 2020: \$93m). The YTD 2021 decline largely reflects incremental costs in the prior period related to the US direct-to-consumer (DTC) advertising campaign for SUBLOCADE that did not repeat in 2021, as well as lower legal fees and expenses related to the DOJ matter (settled in Q3 2020). Higher Q3 2021 SG&A expense largely reflects planned commercial activity investments, including increased sales and marketing investments for SUBLOCADE and recruiting for the PERSERIS sales force expansion.

YTD 2021 and Q3 2021 R&D expenses were \$33m and \$11m, respectively (YTD 2020: \$26m; Q3 2020: \$8m). 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.

YTD 2021 operating profit as reported was \$168m (YTD 2020 op. loss: \$147m). Exceptional benefits of \$13m are included in the current period while exceptional costs of \$203m are included in the year-ago period. On an adjusted basis, YTD 2021 operating profit was \$155m (Adj. YTD 2020: \$56m). The increase on an adjusted basis primarily reflects higher net revenue along with a decline in SG&A expenses as detailed above.

Q3 2021 operating profit as reported was \$38m (Q3 2020: \$18m). Net exceptional items of \$nil are included in the current period while exceptional costs of \$12m are included in the Q3 2020 reported results. Q3 2021 operating profit of \$38m versus adj. Q3 2020: \$30m primarily reflects higher net revenue.

YTD 2021 net finance expense as reported was \$18m (YTD 2020: \$12m expense). The additional net expense 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 the current period due to the write-off of deferred financing costs on the previous term loan. On an adjusted basis, YTD 2021 net finance expense was \$17m. There was no adjustment in the prior period.

YTD 2021 reported tax benefit was \$19m, or a rate of -13% (YTD 2020 tax benefit: \$24m, 15%). Excluding the YTD 2021 \$43m tax benefit on exceptional items, the effective tax rate was 17% (YTD 2020 adj. tax charge: \$11m; 25% rate). Q3 2021 reported total tax expense was \$4m, or a rate of 13% (Q3 2020: \$3m, 23%). There were no tax exceptional items recorded in Q3 2021. Excluding the QTD tax benefit on exceptional items in Q3 2020, the effective tax rate was 24%.

YTD 2021 reported net income was \$169m (YTD 2020 net loss: \$135m). On an adjusted basis, YTD 2021 net income was \$114m and excludes the \$55m after-tax impact from exceptional items (Adj. YTD 2020: \$33m, excl. \$168m of exceptional items). The increase in net income on an adjusted basis primarily reflects higher net revenue and lower operating expenses mainly due to the SUBLOCADE DTC campaign in Q1 2020.

Q3 2021 net income on a reported basis was \$27m (Q3 2020: \$10m). There were no exceptional items recorded in Q3 2021 (Adj. Q3 2020: \$19m, excl. \$9m of exceptional items). On an adjusted basis, higher Q3 2021 net income was primarily due to increased net revenue.

YTD diluted earnings per share was 22 cents and 15 cents on an adjusted diluted basis (YTD 2020: 18 cents loss per share on a diluted basis and 4 cents earnings per share adjusted diluted basis). In Q3 2021, earnings per share on a diluted and adjusted diluted basis was 3 cents (Q3 2021: 1 cent earnings per share on a diluted and 2 cents on an adjusted diluted basis). Higher YTD 2021 and Q3 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**

September 30, 2021 cash and cash equivalents were \$1,005m, an increase of \$147m versus the \$858m position at year-end 2020. This primarily reflects higher operating profit and relatively stable government rebate payables. Gross borrowings, before issuance costs, were \$249m at the end of Q3 2021 (FY 2020: \$235m). As a

result, net cash (as defined in Note 8) stood at \$756m at the end of Q3 2021 (FY 2020: \$623m), a \$133m increase over the YTD 2021 period.

Net working capital (inventory plus trade receivables, less trade and other payables) was negative \$278m at the end of Q3 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. Separately, the current portion of provisions and other liabilities increased by \$66m in Q3 2021 for the remaining unfunded portion of the Group's share repurchase program.

Cash generated by operating activities in YTD 2021 was \$200m (YTD 2020 cash used: \$94m), representing a change of \$294m primarily due to strong YTD 2021 operating profit, timing of government rebates payable and the surety bond refunded in Q1 2021. Net cash inflow from operating activities was \$186m in YTD 2021 (YTD 2020 net cash outflow: \$122m) 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.

YTD 2021 cash outflow from investing activities was \$12m (YTD 2020: \$2m) 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.

YTD 2021 cash outflow from financing activities was \$26m (YTD 2020: \$7m) 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 by clicking [here](#).

#### [Principal Risk Factors](#)

The Group utilizes a formal process to identify, evaluate and manage significant risks. The Directors have reviewed the principal risks and uncertainties for the remainder of the 2021 financial year. In addition to the principal risks and uncertainties affecting the Group's business activities, detailed on pages 39 to 45 of the Indivior PLC Annual Report 2020:

- Business Operations
- Product Pipeline, Regulatory & Safety
- Commercialization
- Economic & Financial
- Supply
- Legal & Intellectual Property
- Compliance

During 2021, the COVID-19 pandemic has continued to impact the Group's principal risks. Governments worldwide have started deploying vaccination programs and other health measures to lower virus infection and mortality rates and enable people and companies to start resuming normality. However, infections caused by the virus (including its variants) have resurged to various degrees in some countries the Group has operations in or is targeting for growth. In June 2021, the Group started to partially reopen its offices worldwide following local guidelines and regulations while also continuing to ensure the welfare of its employees. A full reopening is planned for the fourth quarter, which assumes the virus or its variants remain relatively contained and that local guidelines and regulations permit reopening. Reopenings have eased the challenging business environment in which the Group and companies across industries have been operating for over a year, and the Group has

experienced some improvements (e.g., increased number of in-person engagements with healthcare professionals and members of Organized Health Systems and easing of certain travel restrictions). However, some new challenges associated with the reopening of the economy also have emerged (e.g., high demand with limited supply for several goods and services resulting in price increases and project delays). As a result, pre-pandemic business conditions have not yet been observed or experienced. Therefore, the overall risks related to the Group’s business and operations have only marginally decreased for the following principal risks: business operations; product pipeline and regulatory; commercialization; supply; and economic and financial.

Given the dynamic nature of the current environment, the Group is closely monitoring health, business, and economic conditions (including a virus resurgence or new government containment measures) and their related impact on our employees, as well as on the workforce of our key third parties, which ultimately may impact our operations. Given the still mostly remote working environment, the Group is also continuing to closely monitor the cross-industry increase in cybersecurity threats and the overall operating effectiveness of its monitoring and control activities. Despite the risk mitigation measures the Group has taken, and its on-going efforts to ensure that contingency actions are appropriate and effective, if health and business conditions deteriorate, they may adversely affect Indivior’s operations and/or performance, and have a heightened effect on certain principal risks, including as related to business operations, product pipeline and regulatory, commercialization, supply, and economic and financial

Other than in respect to the above, the Directors consider the principal risks and uncertainties which could have a material impact on the Group’s performance for the rest of the year to remain the same as described on pages 39 to 45 of the Annual Report 2020.

#### **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:

	<b>9 Months to September 30, 2021</b>	<b>9 Months to September 30, 2020</b>
GB £ period end	1.3530	1.2852
GB £ average rate	1.3853	1.2716
€ Euro period end	1.1682	1.1656
€ Euro average	1.1971	1.1237

#### **Webcast Details**

**There will be a live webcast presentation at 13:00 BST (8:00 am EDT) 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/oy28w6i3>

**Confirmation Code:** 6677702  
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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 2021 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

Various factors may cause differences between Indivior's expectations and actual results, including, among others (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases): factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing and in the supply chain; disruptions in or failure of information technology systems; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; challenges in the commercial execution; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including compliance with the Group's agreements with the U.S. Department of Justice and with the Office of Inspector General of the Department of Health and Human Services, noncompliance with which could result in potential exclusion from U.S. Federal health care programs; the ongoing investigative and antitrust litigation matters; the opioid multi-district 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.

## About SUBOXONE®

### SUBOXONE (buprenorphine and naloxone) Sublingual Film (CIII)

#### INDICATION AND USAGE

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

#### HIGHLIGHTED SAFETY INFORMATION

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

#### CONTRAINDICATIONS

SUBOXONE Film is contraindicated in patients with a history of hypersensitivity to buprenorphine or naloxone.

#### WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: Buprenorphine can be abused in a manner similar to other opioids and is subject to criminal diversion. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits.

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

Strongly consider prescribing naloxone at the time SUBOXONE Film is initiated or renewed because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and, if naloxone is prescribed, how to treat with naloxone.

Unintentional Pediatric Exposure: Store SUBOXONE Film safely out of the sight and reach of children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children.

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

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

Risk of Opioid Withdrawal with Abrupt discontinuation: If treatment is temporarily interrupted or discontinued, monitor patients for withdrawal and treat appropriately.

Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events.

Precipitation of Opioid Withdrawal Sign and Symptoms: An opioid withdrawal syndrome is likely to occur with parenteral misuse of SUBOXONE Film by individuals physically dependent on full opioid agonists, or by sublingual or buccal administration before the agonist effects of other opioids have subsided.

Risk of Overdose in Opioid Naïve Patients: SUBOXONE Film is not appropriate as an analgesic. There have been reported deaths of opioid naïve individuals who received a 2 mg sublingual dose.

#### ADVERSE REACTIONS

Adverse events commonly observed with the sublingual/buccal administration of the SUBOXONE Film are oral hypoesthesia, glossodynia, oral mucosal erythema, headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.

#### DRUG INTERACTIONS

Benzodiazepines: Use caution in prescribing SUBOXONE Film for patients receiving benzodiazepines or other CNS depressants and warn patients against concomitant self-administration/misuse.

CYP3A4 Inhibitors and Inducers: Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over- or under- dosing.

Antiretrovirals: Patients who are on chronic buprenorphine treatment should have their dose monitored if NNRTIs are added to their treatment regimen. Monitor patients taking buprenorphine and atazanavir with and without ritonavir. Dose reduction of buprenorphine may be warranted.

Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue SUBOXONE Film if serotonin syndrome is suspected.

#### USE IN SPECIFIC POPULATIONS

Lactation: Buprenorphine passes into the mother's milk.

Geriatric Patients: Monitor geriatric patients receiving SUBOXONE Film for sedation or respiratory depression.

Moderate or Severe Hepatic Impairment: Buprenorphine/naloxone products are not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment.

To report pregnancy or side effects associated with taking SUBOXONE Film, please call 1-877-782-6966.

For more information about SUBOXONE Film, the full Prescribing Information, and Medication Guide visit [www.suboxone.com](http://www.suboxone.com). For REMS information visit [www.suboxoneREMS.com](http://www.suboxoneREMS.com).

#### About SUBLOCADE<sup>®7</sup>

#### SUBLOCADE (buprenorphine extended-release) injection, for subcutaneous use (CIII) INDICATION AND HIGHLIGHTED SAFETY INFORMATION

##### INDICATION

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

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

##### HIGHLIGHTED SAFETY INFORMATION

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

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

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

##### CONTRAINDICATIONS

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

##### WARNINGS AND PRECAUTIONS

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

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

Opioids can cause sleep-related breathing disorders e.g., central sleep apnea (CSA), sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. Consider decreasing the opioid using best practices for opioid taper if CSA occurs.

Strongly consider prescribing naloxone at SUBLOCADE initiation or renewal because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and how to treat with naloxone if prescribed.

**Risk of Serious Injection Site Reactions:** The most common injection site reactions are pain, erythema and pruritus with some involving abscess, ulceration, and necrosis. The likelihood of serious injection site reactions may increase with inadvertent intramuscular or intradermal administration.

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

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

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

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

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

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

#### ADVERSE REACTIONS

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

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

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

#### INDICATION AND HIGHLIGHTED SAFETY INFORMATION

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

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

See full prescribing information for complete boxed warning.

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

#### CONTRAINDICATIONS

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

#### WARNINGS AND PRECAUTIONS

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

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

Tardive Dyskinesia: Discontinue treatment if clinically appropriate.

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

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

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

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

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

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

#### **ADVERSE REACTIONS**

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

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

## Condensed consolidated interim income statement

For the three and nine months ended September 30	Notes	Unaudited	Unaudited	Unaudited	Unaudited
		Q3 2021	Q3 2020	YTD 2021	YTD 2020
		\$m	\$m	\$m	\$m
<b>Net Revenue</b>	2	<b>187</b>	159	<b>568</b>	462
Cost of sales		<b>(26)</b>	(33)	<b>(88)</b>	(74)
<b>Gross Profit</b>		<b>161</b>	126	<b>480</b>	388
Gross profit before exceptional items	4	<b>161</b>	131	<b>480</b>	399
Exceptional items	4	-	(5)	-	(11)
Selling, general and administrative expenses	3	<b>(112)</b>	(100)	<b>(279)</b>	(509)
Research and development expenses	3	<b>(11)</b>	(8)	<b>(33)</b>	(26)
<b>Operating Profit/(Loss)</b>		<b>38</b>	18	<b>168</b>	(147)
Operating profit before exceptional items	4	<b>38</b>	30	<b>155</b>	56
Exceptional items	4	-	(12)	<b>13</b>	(203)
Finance income		-	1	<b>3</b>	6
Finance expense		<b>(7)</b>	(6)	<b>(21)</b>	(18)
<b>Net Finance Expense</b>		<b>(7)</b>	(5)	<b>(18)</b>	(12)
Net finance expense before exceptional items		<b>(7)</b>	(5)	<b>(17)</b>	(12)
Exceptional items within finance expense	4	-	-	<b>(1)</b>	-
<b>Profit/(Loss) Before Taxation</b>		<b>31</b>	13	<b>150</b>	(159)
Income tax (expense)/benefit		<b>(4)</b>	(3)	<b>19</b>	24
Taxation before exceptional items	5	<b>(4)</b>	(6)	<b>(24)</b>	(11)
Exceptional items within taxation	4,5	-	3	<b>43</b>	35
<b>Net Income/(Loss)</b>		<b>27</b>	10	<b>169</b>	(135)

### Earnings/(loss) per ordinary share (cents)

Basic earnings/(loss) per share	6	<b>4</b>	1	<b>23</b>	(18)
Diluted earnings/(loss) per share	6	<b>3</b>	1	<b>22</b>	(18)

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

For the three and nine months ended September 30	Unaudited	Unaudited	Unaudited	Unaudited	
	Q3 2021	Q3 2020	YTD 2021	YTD 2020	
		\$m	\$m	\$m	\$m
Net income/(loss)	<b>27</b>	10	<b>169</b>	(135)	
<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>(8)</b>	8	<b>(6)</b>	(5)	
Other comprehensive (loss)/income	<b>(8)</b>	8	<b>(6)</b>	(5)	
<b>Total comprehensive income/(loss)</b>	<b>19</b>	18	<b>163</b>	(140)	

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

## Condensed consolidated interim balance sheet

	Notes	Unaudited Sep 30, 2021 \$m	Audited Dec 31, 2020 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		84	62
Property, plant and equipment		57	60
Right-of-use assets		38	43
Deferred tax assets		102	75
Other assets	7	105	104
		<b>386</b>	<b>344</b>
<b>Current assets</b>			
Inventories		97	93
Trade receivables		175	179
Other assets	7	37	50
Current tax receivable		-	7
Cash and cash equivalents	8	1,005	858
		<b>1,314</b>	<b>1,187</b>
<b>Total assets</b>		<b>1,700</b>	<b>1,531</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	8	(3)	(4)
Provisions and other liabilities	9	(136)	(48)
Trade and other payables	12	(550)	(524)
Lease liabilities		(8)	(8)
Current tax liabilities	5	(15)	(15)
		<b>(712)</b>	<b>(599)</b>
<b>Non-current liabilities</b>			
Borrowings	8	(239)	(230)
Provisions and other liabilities	9	(550)	(577)
Lease liabilities		(38)	(43)
		<b>(827)</b>	<b>(850)</b>
<b>Total liabilities</b>		<b>(1,539)</b>	<b>(1,449)</b>
<b>Net assets</b>		<b>161</b>	<b>82</b>
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	13	72	73
Share premium		7	6
Capital redemption reserve	13	1	-
Other reserves		(1,295)	(1,295)
Foreign currency translation reserve		(19)	(13)
Retained earnings		1,395	1,311
<b>Total equity</b>		<b>161</b>	<b>82</b>

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

## Condensed consolidated interim statement of changes in equity

	Notes	Share capital	Share redemption premium	Capital reserve	Other reserve	Foreign currency translation reserve	Retained earnings	Total equity
		\$m	\$m	\$m	\$m	\$m	\$m	\$m
<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		-	-	-	-	-	169	169
Other comprehensive loss		-	-	-	-	(6)	-	(6)
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(6)</b>	<b>169</b>	<b>163</b>
<b>Transactions recognised directly in equity</b>								
Shares issued		-	1	-	-	-	-	1
Share-based plans		-	-	-	-	-	7	7
Deferred taxation on share-based plans		-	-	-	-	-	8	8
Transfer to share repurchase liability		-	-	-	-	-	(100)	(100)
Transfer to capital redemption reserve for shares repurchased and cancelled	(1)	-	-	1	-	-	-	-
<b>Balance at September 30, 2021</b>		<b>72</b>	<b>7</b>	<b>1</b>	<b>(1,295)</b>	<b>(19)</b>	<b>1,395</b>	<b>161</b>
<b>Balance at January 1, 2020</b>								
<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		-	-	-	-	-	(135)	(135)
Other comprehensive loss		-	-	-	-	(5)	-	(5)
<b>Total comprehensive loss</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(5)</b>	<b>(135)</b>	<b>(140)</b>
<b>Transactions recognised directly in equity</b>								
Shares issued		-	1	-	-	-	-	1
Share-based plans		-	-	-	-	-	9	9
Deferred taxation on share-based plans		-	-	-	-	-	1	1
<b>Balance at September 30, 2020</b>		<b>73</b>	<b>6</b>	<b>-</b>	<b>(1,295)</b>	<b>(28)</b>	<b>1,324</b>	<b>80</b>

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

## Condensed consolidated interim cash flow statement

	Unaudited 2021 \$m	Unaudited 2020 \$m
<b>For the nine months ended September 30</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit/(Loss)	168	(147)
Depreciation, amortization, and impairment	12	14
Gain on disposal of right-of-use assets	-	(2)
Gain on disposal of intangible assets	(20)	-
Depreciation and impairment of right-of-use assets	6	6
Share-based payments	7	9
Impact from foreign exchange movements	(3)	(3)
Decrease in trade receivables	3	31
Decrease/(Increase) in current and non-current other assets	12	(47)
Increase in inventories	(5)	(11)
Increase/(Decrease) in trade and other payables	30	(132)
(Decrease)/Increase in provisions and other liabilities*	(10)	188
<b>Cash generated from/(used in) operations</b>	<b>200</b>	<b>(94)</b>
Interest paid	(14)	(13)
Interest received	1	8
Exceptional tax refund	31	-
Taxes paid	(24)	(23)
Transaction costs related to debt refinancing	(8)	-
<b>Net cash inflow/(outflow) from operating activities</b>	<b>186</b>	<b>(122)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(2)	(2)
Purchase of intangible asset	(30)	-
Exceptional net proceeds from disposal of intangible assets	20	-
<b>Net cash outflow from investing activities</b>	<b>(12)</b>	<b>(2)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from borrowings	250	-
Repayment of borrowings	(236)	(3)
Payment of lease liabilities	(6)	(5)
Proceeds from the issuance of ordinary shares	-	1
Cash paid for the repurchase and cancellation of shares	(34)	-
<b>Net cash outflow from financing activities</b>	<b>(26)</b>	<b>(7)</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>148</b>	<b>(131)</b>
Cash and cash equivalents at beginning of the period	858	1,060
Exchange difference	(1)	-
<b>Cash and cash equivalents at end of the period</b>	<b>1,005</b>	<b>929</b>

\* - Changes in provisions and other liabilities line include exceptional payments of \$10m for the RB settlement agreement and \$6m for DOJ related matters.

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

## Notes to the condensed consolidated interim financial statements

### 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

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

The Condensed Financial Statements have been prepared in accordance with UK adopted International Accounting Standard 34, 'Interim Financial Reporting' ("IAS 34"). The Condensed Financial Statements should be read in conjunction with the annual financial statements for the year ended 31 December 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 IFRS 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, with the exception of changes in estimates that are required in determining the provision for income taxes. The Q3 2020 statement of cash flows has been expanded to present trade receivables and other assets (current) in separate line items to improve the transparency and consistency.

The Condensed Financial Statements do not include all the information and disclosures required in the annual financial statements and should be read in conjunction with the Group's annual financial statements at December 31, 2020. These Condensed Financial Statements have been reviewed and not audited. These Condensed Financial Statements were approved for issue on October 27, 2021.

As disclosed in Notes 9, 10, and 11, the Group has liabilities and provisions totaling \$539m (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, fulfill obligations under the DOJ and RB agreements, and address the reasonably possible financial implications of the ongoing legal proceedings. The Directors have also modeled the risk that SUBLOCADE will not meet revenue growth expectations due to the continued impact from the COVID-19 pandemic or other market driven factors (considering a 15% decline on forecasts) 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 and impact of the cost saving actions taken to date. As a result of the factors set out above, the Directors of the Group have a reasonable expectation the Group has adequate resources to continue in operational existence for at least one year from the approval of these 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 revenues 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 nine months to September 30, 2021 and 2020 were as follows:

Net revenue:

	Q3 2021	Q3 2020	YTD 2021	YTD 2020
	\$m	\$m	\$m	\$m
<b>For the three and nine months ended September 30</b>				
United States	143	111	428	323
Rest of World	44	48	140	139
<b>Total net revenues</b>	<b>187</b>	<b>159</b>	<b>568</b>	<b>462</b>

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

	Q3 2021	Q3 2020	YTD 2021	YTD 2020
	\$m	\$m	\$m	\$m
<b>For the three and nine months ended September 30</b>				
Sublingual/other	117	123	387	361
SUBLOCADE	65	33	169	91
PERSERIS	5	3	12	10
<b>Total</b>	<b>187</b>	<b>159</b>	<b>568</b>	<b>462</b>

Non-current assets:

	Sep 30, 2021 \$m	Dec 31, 2020 \$m
United States	135	141
Rest of World	149	128
<b>Total</b>	<b>284</b>	<b>269</b>

### 3. OPERATING EXPENSES

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

	Q3 2021	Q3 2020	YTD 2021	YTD 2020
	\$m	\$m	\$m	\$m
<b>For the three and nine months ended September 30</b>				
Research and development expenses	(11)	(8)	(33)	(26)
Selling and general expenses	(51)	(40)	(128)	(149)
Administrative expenses <sup>1</sup>	(58)	(57)	(141)	(346)
Depreciation, amortization, and impairment <sup>2</sup>	(3)	(3)	(10)	(14)
<b>Total</b>	<b>(112)</b>	<b>(100)</b>	<b>(279)</b>	<b>(509)</b>

<sup>1</sup>Administrative expenses include exceptional items in the current and prior period as outlined in Note 4.

<sup>2</sup>Additional YTD 2021 depreciation and amortization of \$8m (YTD 2020: \$6m) for intangibles and ROU assets is included within cost of sales.

### 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.

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

	Q3 2021	Q3 2020	YTD 2021	YTD 2020
	\$m	\$m	\$m	\$m
<b>For the three and nine months ended September 30</b>				
<b>Exceptional items within cost of sales</b>				
Cost of sales <sup>1</sup>	-	(5)	-	(11)
Total exceptional items within cost of sales	-	(5)	-	(11)
<b>Exceptional items within SG&amp;A</b>				
Restructuring <sup>2</sup>	-	(7)	-	(9)
Legal expenses/provision <sup>3</sup>	5	-	18	(183)
ANDA litigation <sup>4</sup>	(24)	-	(24)	-
Other operating income <sup>5</sup>	19	-	20	-
Debt refinancing <sup>6</sup>	-	-	(1)	-
Total exceptional items within SG&A	-	(7)	13	(192)
<b>Exceptional items within net finance expense</b>				
Finance expense <sup>6</sup>	-	-	(1)	-
Total exceptional items within net finance expense	-	-	(1)	-
<b>Total exceptional items before taxes</b>	-	(12)	12	(203)
Tax benefit on exceptional items <sup>3</sup>	-	3	-	35
Exceptional tax item <sup>7</sup>	-	-	43	-
<b>Total exceptional items</b>	-	(9)	55	(168)

1. Exceptional cost of sales relate to inventory provisions due to the adverse impact of COVID-19 on the business.
2. Restructuring costs incurred in Q3 2020 relate to cost saving actions taken by the Group to protect the financial and operational flexibility in response to ongoing challenges posed by COVID-19. Remaining restructuring costs in YTD 2020 consist primarily of lease disposals. These costs are included in SG&A.
3. Negotiation with DOJ related plaintiffs in Q3 2021 and YTD 2021 led to a change in the Group's provision for DOJ related matters which resulted in a provision release of \$5m and \$18m, respectively. \$183m of legal costs and an exceptional tax benefit of \$35m were recorded YTD 2020 in relation to the DOJ Resolution. Exceptional legal costs are included within SG&A.
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. Exceptional legal costs are included within SG&A.
5. Exceptional other operating income in Q3 2021 relates to the net proceeds 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 YTD 2021 relates to the proceeds received from the out-licensing of nasal naloxone opioid overdose patents for \$1m. Exceptional income items are included within SG&A.
6. Debt refinancing costs in YTD 2021 consist of advisory and legal fees incurred related to the Group's June 2021 debt refinancing. These costs are included in SG&A. Additionally, in YTD 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.
7. Exceptional tax benefit recorded YTD 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, the tax impact of settlement costs incurred with Reckitt Benckiser (RB) which were recorded in the prior year, reactivation of prior year interest expense restriction, impact of the ANDA accrual and a tax expense in relation to exceptional other operating income. Q3 2021 exceptional tax benefit of \$nil includes the reactivation of prior year interest expense restriction, impact of the ANDA accrual and a tax expense in relation to exceptional other operating income.

#### 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 Q3/YTD 2021 and Q3/YTD 2020.

#### Reconciliation of gross profit to adjusted gross profit

	Q3 2021 \$m	Q3 2020 \$m	YTD 2021 \$m	YTD 2020 \$m
<b>For the three and nine months ended September 30</b>				
<b>Gross profit</b>	<b>161</b>	<b>126</b>	<b>480</b>	<b>388</b>
Exceptional cost of sales	-	5	-	11
<b>Adjusted gross profit</b>	<b>161</b>	<b>131</b>	<b>480</b>	<b>399</b>

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

	Q3 2021 \$m	Q3 2020 \$m	YTD 2021 \$m	YTD 2020 \$m
<b>For the three and nine months ended September 30</b>				
<b>Operating profit/(loss)</b>	<b>38</b>	<b>18</b>	<b>168</b>	<b>(147)</b>
Exceptional cost of sales	-	5	-	11
Exceptional selling, general and administrative expenses	-	7	(13)	192
<b>Adjusted operating profit</b>	<b>38</b>	<b>30</b>	<b>155</b>	<b>56</b>

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

	Q3 2021 \$m	Q3 2020 \$m	YTD 2021 \$m	YTD 2020 \$m
<b>For the three and nine months ended September 30</b>				
<b>Profit/(loss) before taxation</b>	<b>31</b>	<b>13</b>	<b>150</b>	<b>(159)</b>
Exceptional cost of sales	-	5	-	11
Exceptional selling, general and administrative expenses	-	7	(13)	192
Exceptional finance expense	-	-	1	-
<b>Adjusted profit before taxation</b>	<b>31</b>	<b>25</b>	<b>138</b>	<b>44</b>

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

	Q3 2021	Q3 2020	YTD 2021	YTD 2020
For the three and nine months ended September 30	\$m	\$m	\$m	\$m
<b>Net income/(loss)</b>	<b>27</b>	<b>10</b>	<b>169</b>	<b>(135)</b>
Exceptional cost of sales	-	5	-	11
Exceptional selling, general and administrative expenses	-	7	(13)	192
Exceptional finance expense	-	-	1	-
Tax benefit on exceptional items	-	(3)	-	(35)
Tax exceptional	-	-	(43)	-
<b>Adjusted net income</b>	<b>27</b>	<b>19</b>	<b>114</b>	<b>33</b>

## 5. TAXATION

The Group calculates tax expense for interim periods using the expected full year rates, considering the pre-tax income and statutory rates for each jurisdiction. To the extent practicable, a separate estimated average annual effective income tax rate is determined for each taxing jurisdiction and applied individually to the interim period pre-tax income of each jurisdiction. Similarly, if different income tax rates apply to different categories of income (such as capital gains or income earned in particular industries), to the extent practicable a separate rate is applied to each individual category of interim period pre-tax income. The resulting expense is allocated between current and deferred taxes based upon the forecasted full year ratio. The effective tax rate was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the period and permanent differences.

In the nine months ended September 30, 2021, the reported total tax benefit was \$19m, or a rate of -13% (YTD 2020 tax benefit: \$24m, 15%). The tax expense on adjusted profits amounted to \$24m (YTD 2020: \$11m) and represented a year-to-date effective tax rate of 17% (YTD 2020: 25%).

The YTD 2021 exceptional benefit recorded in tax of \$43m 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, and reactivation of prior year interest expense restriction, impact of ANDA accrual and a tax expense in relation to the exceptional income, as set out in Note 4.

The Group's balance sheet at September 30, 2021 included a current tax payable of \$15m (FY 2020: \$15m), and deferred tax asset of \$102m (FY 2020: \$75m). The increase in the deferred tax asset is due to current year activity including the tax impact of the settlement costs and share awards.

### Other tax matters

The European Commission issued a press release on April 2, 2019 announcing its conclusion that the UK Finance Company Partial Exemption Rules are partly justified. The UK government has made an annulment application to the General Court against this decision. The UK government was required to initiate recovery of the alleged State Aid irrespective of any appeal against the decision and 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 is regarded as closed.

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 less than \$1m.

As disclosed in Note 9, the Group reached a settlement with Reckitt Benckiser (RB) on January 25, 2021. Based on the strength of external advice received, a \$7m tax benefit from the settlement cost has been recognized as of September 30, 2021. Tax authorities may potentially challenge the Group's position.

## 6. EARNINGS/(LOSS) PER SHARE

	Q3 2021	Q3 2020	YTD 2021	YTD 2020
For the three and nine months ended September 30	cents	cents	cents	cents
Basic earnings/(loss) per share	<b>4</b>	<b>1</b>	<b>23</b>	<b>(18)</b>
Diluted earnings/(loss) per share	<b>3</b>	<b>1</b>	<b>22</b>	<b>(18)</b>
Adjusted basic earnings per share	<b>4</b>	<b>3</b>	<b>16</b>	<b>5</b>
Adjusted diluted earnings per share	<b>3</b>	<b>2</b>	<b>15</b>	<b>4</b>

### Basic

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

## Diluted

Diluted earnings/(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 Company has dilutive potential ordinary shares in the form of stock options and awards. The weighted average number of shares is adjusted for the number of shares granted assuming the exercise of stock options.

The weighted average number of ordinary shares outstanding for 2021 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	<b>733,324</b>	732,634
Dilution from share awards and options	<b>43,800</b>	40,001
On a diluted basis	<b>777,124</b>	772,635

## 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

	Sep 30 2021 \$m	Dec 31 2020 \$m
<b>Current and non-current other assets</b>		
Short-term prepaid expenses	<b>27</b>	17
Other current assets	<b>10</b>	33
<b>Total other current assets</b>	<b>37</b>	50
Long-term prepaid expenses	<b>23</b>	22
Other non-current assets	<b>82</b>	82
<b>Total other non-current assets</b>	<b>105</b>	104
<b>Total</b>	<b>142</b>	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 Q1 2021, one of the surety bond holders returned \$26m causing a decrease in other current assets.

## 8. FINANCIAL LIABILITIES – BORROWINGS

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 YTD 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 September 30, 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:

	Sep 30 2021 \$m	Dec 31 2020 \$m
<b>Term loan</b>		
Term loan – current	<b>(3)</b>	(4)
Term loan – non-current	<b>(239)</b>	(230)
Total term loan	<b>(242)</b>	(234)

At September 30, 2021, the term loan fair value was approximately 98% (FY 2020: 98%) of par value. Cash at bank, trade receivables, and trade payables are assumed to approximate their fair values.

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

	Sep 30 2021 \$m	Dec 31 2020 \$m
<b>Analysis of net cash</b>		
Cash and cash equivalents	1,005	858
Term loan borrowings*	(249)	(235)
<b>Total net cash</b>	<b>756</b>	<b>623</b>

\*Borrowings reflect the principal amount drawn before debt issuance costs of \$7m (FY 2020: \$1m). These do not include lease liabilities of \$46m (FY 2020: \$51m).

	YTD 2021 \$m	YTD 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	148	(202)
New borrowings	(250)	-
Repayment of borrowings	236	4
Exchange adjustments	(1)	-
<b>Net cash at end of period</b>	<b>756</b>	<b>623</b>

## 9. PROVISIONS AND OTHER LIABILITIES

	Sep 30 2021 \$m	Dec 31 2020 \$m
<b>Provisions and other liabilities</b>		
<b>Provisions</b>		
DOJ related matters	(8)	(32)
Intellectual property related matters	(73)	(47)
Restructuring costs	(1)	(6)
Other	(3)	(4)
<b>Total provisions</b>	<b>(85)</b>	<b>(89)</b>
<b>Other liabilities</b>		
DOJ resolution	(491)	(486)
RB indemnity settlement	(40)	(50)
Share repurchase program	(66)	-
Other	(4)	-
<b>Total other liabilities</b>	<b>(601)</b>	<b>(536)</b>
<b>Total provisions and other liabilities</b>	<b>(686)</b>	<b>(625)</b>

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

### Provisions

Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events, an outflow of resources to settle that obligation is 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 \$8m (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 YTD 2021 (see Note 4). The remaining movement of \$6m in the provision relates to amounts settled and paid in the year. DOJ related matters of \$8m 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 YTD 2021, the Group recorded finance expense totaling \$2m (YTD 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 relates to cost saving initiatives announced and implemented in 2020 and consist of redundancy and related costs, which are expected to be paid within one year.

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

## Other liabilities

Other liabilities represent contractual obligations to third parties where the amount and timing of payments is fixed. Where other liabilities are not interest-bearing and the impact of discounting is significant, other liabilities are recorded at their present value, generally using 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 YTD 2021, the Group recorded interest expense totaling \$5m (YTD 2020: \$4m). As of September 30, 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.

On July 30, 2021, the Group commenced an irrevocable share repurchase program of up to \$100m. As of September 30, 2021, the Group recorded a liability for \$66m, which represents the remaining amount to be spent under the program. This liability has been classified as current as the Group expects the remaining shares will be purchased within one year. Refer to Note 13 for further discussion.

Other liabilities represent deferred revenue related to a supply agreement which is non-current as of September 30, 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 will be subject to reporting and monitoring requirements, including annual reports and compliance certifications from key management and the Board Nominating & Governance Committee submitted to HHS-OIG. In addition, the Group will be subject to monitoring by an Independent Review Organization, who will submit audit findings to HHS-OIG, and review by a Board Compliance Expert, who will prepare two compliance assessment reports in the first and third reporting periods of the Corporate Integrity Agreement.

In November 2020, the Group made a payment of \$103 million (including interest) when the resolution was approved by a judge. Subsequently, six annual instalments of \$50 million will be due every January 15 from 2022 through 2027. The final instalment of \$200 million will be due in December 2027. The Group carries a liability totaling of \$491 million (FY 2020: \$486m) pertaining to the DOJ resolution.

## **DOJ Related Matters**

### *Federal FCA Qui Tam Suits*

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

### *State and Local Matters*

- In 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 for approximately \$3 million plus attorney fees.
- 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 for approximately \$1.5 million plus attorney fees.
- In addition to the federal and state health program claims, claims have been asserted under the city false claims acts of Chicago and New York City regarding the promotion of Suboxone film. The Group has resolved the matter with the City of Chicago.

### *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 for the Southern District of New York, seeking records relating to the Suboxone manufacturing process.

### *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 hearing is scheduled for January 2022.

## **Intellectual Property Related Matters**

### *ANDA Litigation*

- Litigation against DRL is currently pending in the District of New Jersey regarding U.S. Patent No. 9,687,454 and 9,931,305 ("the '454 and '305 Patents"). DRL received final FDA approval for all four strengths of its generic buprenorphine/naloxone film product in June 2018, and immediately launched its generic buprenorphine/naloxone film product "at-risk." In July 2018, the District Court issued a ruling granting Indivior a Preliminary Injunction (PI) pending the outcome of a trial on the merits of the '305 Patent. Indivior was required to post a surety bond for \$72 million in connection with the PI. In November 2018, the CAFC issued a decision vacating the PI against DRL. DRL launched its product at-risk in February 2019. In June 2019, DRL filed a motion for leave to file their first amended Answer, Affirmative Defenses, and Counterclaims to add various antitrust counterclaims resulting from the injunction that was issued against DRL. The motion was granted in November 2019. In January 2020, Indivior and DRL entered into a joint stipulation that DRL did not infringe the '305 Patent based on the District Court's claim construction ruling, but that Indivior retained its right to appeal the issue of infringement of the '305 Patent. Indivior maintains its infringement claims on the '454 patent, and DRL maintains its counterclaims. No trial date has been set for either the patent claims or the antitrust counterclaims.
- In November 2018, DRL filed two separate petitions for inter partes review ("IPR") of the '454 Patent with the USPTO. The USPTO denied institution of one of the IPR petitions but granted institution for the second IPR petition. The Patent Trial and Appeal Board (USPTO) issued a decision in June 2020, holding that claims 1-5, 7, and 9-14 were unpatentable, but that DRL had not shown that claim 8 is unpatentable. Claim 6 was not challenged and therefore

was not addressed in the PTAB decision. Indivior appealed to the Court of Appeals for the Federal Circuit in July 2020. Oral argument took place in September 2021 and a decision is pending with the court.

- Litigation against Alvogen is pending in the United States District Court for the District of New Jersey regarding the '454 and '305 Patents. In January 2019, Indivior filed a motion for a temporary restraining order ("TRO") and preliminary injunction in the District of New Jersey, requesting that the Court restrain the launch of Alvogen's generic buprenorphine/naloxone film product until a trial on the merits of the '305 Patent. Alvogen received approval for its generic product in January 2019. The same day, the District of New Jersey granted a TRO until February 7, 2019. In January 2019, Indivior and Alvogen entered into an agreement whereby Alvogen was enjoined from the use, offer to sell, or sale within the United States, or importation into the United States, of its generic buprenorphine and naloxone sublingual film product unless and until the CAFC issued a mandate vacating the PI against DRL. The mandate vacating the DRL PI issued in February 2019, and Alvogen launched its generic product. Any sales in the US are on an "at-risk" basis, subject to the ongoing litigation against Alvogen in the District of New Jersey. In August 2019, Alvogen filed a motion for leave to file an amended Answer to Complaint and Separate Defenses and Counterclaims to add various antitrust counterclaims. The motion was granted in November 2019. In January 2020, Indivior and Alvogen entered into a joint stipulation that Alvogen did not infringe the '305 Patent based on the District Court's claim construction ruling, but that Indivior retained its right to appeal the issue of infringement of the '305 Patent. Indivior maintains its infringement claims on the '454 patent, and Alvogen maintains its counterclaims. No trial date has been set for either the patent claims or the antitrust counterclaims.

#### *Opposition to SUBLOCADE European Patent*

- In October 2018, Teva Pharmaceutical Industries Ltd. ("Teva") filed a Notice of Opposition with the European Patent Office seeking to revoke European Patent No. EP 2579874 ("EP 874"), which relates to the formulation for SUBLOCADE. Oral proceedings took place in September 2021 and the patent was maintained as granted.
- In March 2021, the law firm Elkington & Fife LLP filed a Notice of Opposition with the European Patent Office 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.

### **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 are fully briefed, and no hearing date has been set.
- 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.). In February 2021, the Court sent a Notice of Proposed Termination. 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. The Group continues to believe in its defenses and continues to vigorously defend itself. Select plaintiffs in these matters have previously made settlement demands (which were not accepted and most of which are not current offers), totaling approximately \$290m, which was used for contingency planning only to model possible downside financial effects. The final aggregate cost of these matters, whether resolved by litigation or by settlement, may be materially different. If the Group were to entertain further settlement discussions, we make no representations as to what amounts, if any, it may agree to pay, nor regarding what amounts the plaintiffs will demand.

#### *Other Antitrust and Consumer Protection Claims*

- In July 2019, the Indiana Attorney General issued a Civil Investigative Demand investigating potential violations of Indiana's Civil Deceptive Consumer Sales Act with respect to sales and marketing activity by the Company. The Group 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 with prejudice on July 22, 2021. Plaintiffs filed Notices of Appeal in August 2021. 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 Federal Court 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 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. At a June 17, 2021 hearing, defendants' motion to stay was denied and certain claims were dismissed without prejudice.

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

#### Civil Opioid Litigation

- 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

	Sep 30 2021 \$m	Dec 31 2020 \$m
Sales returns and rebates	(404)	(396)
Trade payables	(33)	(20)
Accruals	(103)	(99)
Other tax and social security payables	(10)	(9)
<b>Total</b>	<b>(550)</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. As the amounts are estimated, they may not fully 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. The level of accrual is reviewed and adjusted in the light of historical experience of actual rebates, discounts or allowances given and returns made, and any changes in arrangements or rules. Future events may cause the assumptions on which the accruals are based to change, which could affect the future results of the Group.

## 13. SHARE CAPITAL

	Equity ordinary shares	Nominal value paid per share	Aggregate nominal value \$m
Issued and fully paid			
<b>At January 1, 2021</b>	<b>733,635,511</b>	<b>\$0.10</b>	<b>73</b>
Allotments	1,679,825	\$0.10	-
Shares repurchased and cancelled	(11,730,087)	\$0.10	(1)
<b>At September 30, 2021</b>	<b>723,585,249</b>		<b>72</b>

	Equity ordinary shares	Nominal value paid per share	Aggregate nominal value \$m
Issued and fully paid			
At January 1, 2020	730,787,719	\$0.10	73
Allotments	2,716,823	\$0.10	-
At September 30, 2020	733,504,542		73

#### Allotment of ordinary shares

During the period, 1,679,825 ordinary shares (YTD 2020: 2,716,823) were allotted to satisfy vestings/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 an aggregate purchase price up to no more than \$100m or 73,462,098 of ordinary shares. Through September 30, 2021, the Group has repurchased and cancelled 11,730,087 of the Company's ordinary shares for an aggregate nominal value of \$1m (\$0.10 per share). All

ordinary shares repurchased under the share repurchase program were cancelled resulting in a transfer of the aggregate nominal value to a capital redemption reserve. The total cost of the purchases made under the share repurchase program during the period, including directly attributable transaction costs, was \$31m. A net repurchase amount of \$66m has been recorded as a financial liability which represents the remaining amount to be spent under the program of \$69m offset by \$3m of advanced funding remitted to the agent bank. The effect of discounting is not material. Total purchases under the share repurchase program will be made out of distributable profits and accordingly \$100m has been transferred from retained earnings. The share repurchase program is expected to end in Q1/Q2 2022.

## DIRECTORS' RESPONSIBILITY STATEMENT

The Directors declare that, to the best of their knowledge:

- This set of Condensed Financial Statements, which have been prepared in accordance with UK adopted International Accounting Standard 34, 'Interim Financial Reporting' ("IAS 34"), gives a true and fair view of the assets, liabilities, financial position, and profit or loss of Indivior; and
- The interim management report gives a fair review of the information in line with regulations 4.2.7 and 4.2.8 of the Disclosure Guidance and Transparency Rules.

The Directors are responsible for the maintenance and integrity of the Group's website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Details of all current Directors are available on our website at [www.indivior.com](http://www.indivior.com)

By order of the Board

Mark Crossley  
Chief Executive Officer

Ryan Preblich  
Chief Financial Officer

October 27, 2021

# **Independent review report to Indivior PLC**

## **Report on the Condensed consolidated interim financial statements**

### **Our conclusion**

We have reviewed Indivior PLC's Condensed consolidated interim financial statements (the "interim financial statements") in the Q3 and Nine Months 2021 Results of Indivior PLC for the three and nine month periods ended 30 September 2021 (the "period").

Based on our review, nothing has come to our attention that causes us to believe that the interim financial statements are not prepared, in all material respects, in accordance with UK adopted International Accounting Standard 34, 'Interim Financial Reporting' ("IAS 34").

### **What we have reviewed**

The interim financial statements comprise:

- the Condensed consolidated interim balance sheet as at 30 September 2021;
- the Condensed consolidated interim income statement and Condensed consolidated interim statement of comprehensive (loss) / income for the three and nine month periods then ended;
- the Condensed consolidated interim statement of changes in equity for the nine month period then ended;
- the Condensed consolidated interim cash flow statement for the nine month period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the Q3 and Nine Months 2021 Results of Indivior PLC have been prepared in accordance with IAS 34.

## **Responsibilities for the interim financial statements and the review**

### **Our responsibilities and those of the directors**

The Q3 and Nine Months 2021 Results, including the interim financial statements, is the responsibility of, and has been approved by the directors. The directors are responsible for preparing the Q3 and Nine Months 2021 Results in accordance with IAS 34.

Our responsibility is to express a conclusion on the interim financial statements in the Q3 and Nine Months 2021 Results based on our review. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

### **What a review of interim financial statements involves**

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, 'Review of Interim Financial Information Performed by the Independent Auditor of the Entity' issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures.

A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK) and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

We have read the other information contained in the Q3 and Nine Months 2021 Results and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.