

April 29, 2021



Q1 2021 Results Announced; FY 2021 Guidance Reiterated.

Quarter to March 31	2021 \$m	2020 \$m
Net Revenue	180	153
Operating Profit/(Loss)	57	(189)
Net Income/(Loss)	80	(163)
EPS/(LPS) (cents per share)	11	(22)
Adjusted Operating Profit*	51	3
Adjusted Net Income/(Loss)*	38	(3)
Adjusted EPS* (cents per share)	5	-

* Adjusted (Adj.) basis excludes the impact of exceptional items as referenced in Notes 3 and 4.

Comment by Mark Crossley, CEO of Indivior PLC

“We have seen an encouraging start in FY 2021 with growth in net revenue, operating profit and cash from execution against our strategic priorities. Despite the ongoing impacts of COVID-19, SUBLOCADE® (buprenorphine extended-release) injection achieved solid net revenue growth both on a sequential and year-over-year basis, and we expanded our Organized Health Systems (OHS) platform to build the foundation for future growth. Looking ahead, we are seeing healthcare restrictions in the US begin to ease from the rapid pace of COVID-19 vaccinations, which supports our expectation of increased in-person interactions with healthcare practitioners in the second half of the year. As such, we are reiterating our FY 2021 base case guidance.”

Q1 2021 Financial Highlights

- Net revenue (NR) of \$180m (+18% vs. Q1 2020) primarily benefited from higher NR from SUBLOCADE, continued growth in the buprenorphine medication-assisted (BMAT) market and relative market share stability in the US for SUBOXONE® (buprenorphine and naloxone) Film.
- Reported operating profit of \$57m (Q1 2020 op. loss: \$189m). Excluding exceptional benefits of \$6m, adjusted operating profit was \$51m (adj. Q1 2020: \$3m). The increase over the prior period reflects higher NR and lower SG&A expense principally related to the direct-to-consumer (DTC) advertising campaign for SUBLOCADE in Q1 2020 and lower legal costs primarily due to resolving the Department of Justice (DOJ) matter.
- Reported net income was \$80m which includes an exceptional tax benefit of \$36m recognized in relation to development credits for SUBLOCADE. Adjusted net income of \$38m (Q1 2020 adj. net loss: \$3m), primarily reflecting higher operating profit as described above.
- Cash of \$945m at the end of Q1 2021 (+\$87m vs. FY 2020). Net cash of \$711m (+\$88m vs. FY 2020). The higher cash balance primarily reflects the timing of government rebate payables related to SUBOXONE Film and \$26m of cash collateral returned by a surety bond holder.

Q1 2021 Operating Highlights

- SUBLOCADE NR of \$43m (+48% vs. Q1 2020 and +10% vs. Q4 2020); strong growth in the OHS channel, new US patient enrollments increasing and favorable trade spend accrual updates. Q1 2021 US dispenses approx. 35,700 units (+51% vs. Q1 2020 and +11% vs. Q4 2020).
- PERSERIS® (risperidone) extended-release injection NR of \$3m (unchanged vs. Q1 2020 and -25% vs. Q4 2020).
- SUBOXONE® Film share averaged 20% in Q1 2021 (Q1 2020: 22%) and exited Q1 2021 at 20% (Q1 2020: 22%).

Reiterating FY 2021 Guidance

FY 2021 guidance issued by Indivior on February 18, 2021 is unchanged.

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

In Q1 2021, growth of the U.S. buprenorphine medication-assisted treatment (BMAT) market was 6%. The 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.

The Group continues to expect long-term U.S. market growth to be sustained in the high single-digit to low double-digit percentage range due to increased 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 Q1 2021. As a result, there is increasing patient access to BMAT. Indivior supports efforts to encourage more eligible healthcare practitioners (HCPs) to provide BMAT, and the Group continues to resource its compliance capabilities for the growing number of BMAT prescribers and patients.

The Group's focus is to continue to expand access to SUBLOCADE amongst OHS and core HCPs, in order 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 in Q1 2021

Total net revenue in Q1 2021 increased 18% to \$180m (Q1 2020: \$153m) at actual exchange rates and by 14% at constant FX.

U.S. net revenue increased 25% to \$131m (Q1 2020: \$105m). Growth in the overall U.S. BMAT market was in-line with Group expectations discussed above ("U.S. Market Update"). Underlying market growth, together with SUBLOCADE net revenue growth of 38% to \$40m (Q1 2020: \$29m), relative stability in SUBOXONE Film share (avg. Q1 2021: 20% vs. avg. Q1 2020: 22%) and favorable trade spend accrual updates drove the net revenue increase. PERSERIS net revenue was flat year-on-year at \$3m (Q1 2020: \$3m).

Rest of World net revenue increased 2% at actual exchange rates to \$49m (Q1 2020: \$48m) and -8% at constant FX. ROW SUBLOCADE net revenue contributed \$3m in the Q1 2021 period. This benefit along with favourable foreign currency translation was partially offset by continued austerity measures and generic competition in Western European markets.

Gross margin as reported was 82% (Q1 2020: 85%). On an adjusted basis, excluding \$7m of exceptional costs related to inventory provisions due to the adverse impact of COVID-19, Q1 2020 gross margin was 90%. The expected gross margin decline on a reported and adjusted basis reflects unfavourable product mix due to the continued market share resilience of SUBOXONE film, which is less profitable due to the high proportion of revenue now coming from government channels.

SG&A expenses as reported were \$82m (Q1 2020: \$309m). Q1 2021 SG&A expenses included an exceptional \$5m release of DOJ related matters provisions and a benefit of \$1m related to the out-licensing of nasal naloxone patents. Q1 2020 SG&A included exceptional costs of \$185m. The exceptional costs comprised \$183m related to the Department of Justice (DOJ) matter and \$2m for restructuring-related lease impairments.

On an adjusted basis, Q1 2021 SG&A expenses decreased 29% to \$88m (Q1 2020: \$124m). The decrease reflects lower marketing expenses, mainly resulting from the Q1 2020 U.S. DTC television advertising campaign for SUBLOCADE, as well as a decline in legal expenses following the resolution with the DOJ in 2020. The year-ago period benefitted from Executive Committee members forgoing any bonus payment associated with the Group's Annual Incentive Bonus Plan (AIP).

R&D expenses were \$9m (Q1 2020: \$10m). Both periods primarily reflect R&D activities as part of the completed strategic alignment to principally support SUBLOCADE Health Economics and Outcomes Research (HEOR) and post-marketing study commitments for SUBLOCADE and PERSERIS, as well as lower than expected investments for supply-related projects.

Operating profit as reported was \$57m (Q1 2020 op. loss: \$189m). Exceptional benefits of \$6m are included in the current period. Exceptional costs of \$192m were included in the Q1 2020 results.

On an adjusted basis, Q1 2021 operating profit was \$51m versus \$3m in Q1 2020. The increase primarily reflects higher net revenue along with the decrease in operating expenses (principally SG&A) related to the promotional initiatives for SUBLOCADE (primarily the DTC campaign) in the prior-year period and lower legal expenses following the DOJ resolution in 2020.

Net finance expense in the quarter was \$4m (Q1 2020 net finance expense: \$2m). The 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 additional interest expense associated with legal provisions/liabilities.

Tax benefit in the quarter was \$27m at a rate of -51% (Q1 2020 tax benefit: \$28m, 15%). On an adjusted basis, excluding a \$36m tax exceptional benefit for the approval of prior year orphan drug credits, Q1 2021 tax expense was \$9m at a rate of 19% (Q1 2020 a non-meaningful rate excluding \$32m of tax benefits on exceptional costs).

Net income was \$80m (Q1 2020 net loss: \$163m), and \$38m on an adjusted basis excluding the \$42m after-tax impact from exceptional items (Q1 2020 adj. net loss: \$3m). Q1 2020 adjusted net loss excludes \$160m after-tax impact from exceptional items.

Basic earnings per share was 11 cents and 5 cents on an adjusted basic basis (Q1 2020 basic loss per share of 22 cents and nil on an adjusted basis).

Balance Sheet & Cash Flow

Cash and cash equivalents at the end of Q1 2021 were \$945m (FY 2020: \$858m). Borrowings, net of issuance costs, were \$234m at the end of Q1 2021 (FY 2020: \$235m). As a result, net cash stood at \$711m at the end of Q1 2021 (FY 2020: \$623m).

Net working capital (inventory plus trade receivables and other assets, less trade and other payables) was negative \$250m at the end of Q1 2021 versus negative \$202m at the end of FY 2020. The \$48m change in the period was primarily driven by \$26m of cash collateral returned by a surety bond holder. Trade and other payables remained relatively unchanged primarily due sustained government rebate payables related to SUBOXONE Film.

Cash generated from operations in Q1 2021 was \$95m (Q1 2020 cash used in operations: \$141m), a change of \$236m primarily due positive Q1 2021 operating profit, timing of government rebate payables related to SUBOXONE Film and \$26m of cash collateral returned by a surety bond holder. Net cash inflow from operating activities was \$89m in the quarter (Q1 2020 net cash outflow: \$146m) reflecting the higher cash from operating activities and tax and interest payments in the quarter.

Q1 2021 cash inflow from investing activities was \$1m (Q1 2020: nil) reflecting proceeds received from out-licensing of nasal naloxone patents.

Q1 2021 cash outflow from financing activities was \$3m (Q1 2020: \$2m), reflecting the principal portion of lease payments and the quarterly amortisation on the term loan facility. In Q1 2020 cash used in financing activities was partially offset by proceeds from issuance of shares to satisfy the vesting of options under an employee stock purchase plan.

[R&D / Pipeline Update](#)

Indivior's quarterly R&D and pipeline update may be found [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 and do not consider there to be any changes from those reported within the 2020 Indivior PLC Annual Report. The principal risks and uncertainties affecting the Group's business activities are detailed on pages 38 to 45 of the 2020 Indivior PLC Annual Report. These include the following: business operations; product pipeline, regulatory and safety; commercialization; economic and financial; supply; legal and intellectual property; and compliance. Please click [here](#) to access the report or go to www.indivior.com/annual-reports/.

[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:

	Q1 2021	Q1 2020
GB £ period end	1.3778	1.2460
GB £ average rate	1.3785	1.2820
€ Euro period end	1.1774	1.1143
€ Euro average	1.2069	1.1026

[Webcast Details](#)

There will be a webcast today (April 29, 2021) at 1:00 PM BST (8:00 am EDT) hosted by Mark Crossley, CEO. The details are below. All required materials are available on the Group's website at www.indivior.com.

Webcast link: <https://edge.media-server.com/mmc/p/k5suijpmj>

Confirmation Code: 7968136

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

Forward-Looking Statements

This announcement contains certain statements that are forward-looking. By their nature, forward-looking statements involve risks and uncertainties as they relate to events or circumstances that may or may not occur in the future. Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding the Indivior Group's financial guidance for 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.

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

Indication

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

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

Important Safety Information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

This is not a complete list of potential adverse events associated with SUBOXONE Film. Please see full Prescribing Information www.suboxoneREMS.com for a complete list.

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

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

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

INDICATION

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

SUBLOCADE should be used as part of a complete treatment plan that includes 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® 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 pruritis 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.

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.

Condensed consolidated interim income statement

For the three months ended March 31	Notes	Unaudited 2021 \$m	Unaudited 2020 \$m
Net Revenues	2	180	153
Cost of sales		(32)	(23)
Gross Profit		148	130
Gross profit before exceptional items	4	148	137
Exceptional items	3	-	(7)
Selling, general and administrative expenses	3	(82)	(309)
Research and development expenses	3	(9)	(10)
Operating Profit/(Loss)		57	(189)
Operating profit before exceptional items	4	51	3
Exceptional items	3	6	(192)
Finance income		2	4
Finance expense		(6)	(6)
Net finance expense		(4)	(2)
Profit/(Loss) Before Taxation		53	(191)
Income tax benefit		27	28
Taxation before exceptional items	5	(9)	(4)
Exceptional items within taxation	3,5	36	32
Net Income/(loss)		80	(163)
Earnings/(loss) per ordinary share (cents)			
Basic earnings/(loss) per share	6	11	(22)
Diluted earnings/(loss) per share	6	10	(22)

Condensed consolidated interim statement of comprehensive income/(loss)

For the three months ended March 31	Unaudited 2021 \$m	Unaudited 2020 \$m
Net income/(loss)	80	(163)
Other comprehensive income/(loss)		
<i>Items that may be reclassified to profit or loss in subsequent years:</i>		
Net exchange adjustments on foreign currency translation	1	(10)
Other comprehensive income/(loss)	1	(10)
Total comprehensive income/(loss)	81	(173)

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

Condensed consolidated interim balance sheet

	Notes	Unaudited Mar 31, 2021 \$m	Audited Dec 31, 2020 \$m
ASSETS			
Non-current assets			
Intangible assets		60	62
Property, plant and equipment		59	60
Right-of-use assets		41	43
Deferred tax assets		81	75
Other assets	7	103	104
		344	344
Current assets			
Inventories		91	93
Trade receivables		165	179
Other assets	7	23	50
Current tax receivable	5	43	7
Cash and cash equivalents	8	945	858
		1,267	1,187
Total assets		1,611	1,531
LIABILITIES			
Current liabilities			
Borrowings	8	(4)	(4)
Provisions and other liabilities	9	(89)	(48)
Trade and other payables	12	(529)	(524)
Lease liabilities		(8)	(8)
Current tax liabilities	5	(26)	(15)
		(656)	(599)
Non-current liabilities			
Borrowings	8	(229)	(230)
Provisions and other liabilities	9	(521)	(577)
Lease liabilities		(41)	(43)
		(791)	(850)
Total liabilities		(1,447)	(1,449)
Net assets		164	82
EQUITY			
Capital and reserves			
Share capital	13	73	73
Share premium		6	6
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(12)	(13)
Retained earnings		1,392	1,311
Total equity		164	82

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

Condensed consolidated interim statement of changes in equity

	Share capital	Share premium	Other reserve	Foreign currency translation reserve	Retained earnings	Total equity
	\$m	\$m	\$m	\$m	\$m	\$m
Unaudited						
Balance at January 1, 2021	73	6	(1,295)	(13)	1,311	82
Comprehensive income						
Net income	-	-	-	-	80	80
Other comprehensive income	-	-	-	1	-	1
Total comprehensive income	-	-	-	1	80	81
Transactions recognised directly in equity						
Share-based plans	-	-	-	-	1	1
Balance at March 31, 2021	73	6	(1,295)	(12)	1,392	164
Balance at January 1, 2020	73	5	(1,295)	(23)	1,449	209
Comprehensive loss						
Net loss	-	-	-	-	(163)	(163)
Other comprehensive loss	-	-	-	(10)	-	(10)
Total comprehensive loss	-	-	-	(10)	(163)	(173)
Transactions recognised directly in equity						
Share-based plans	-	1	-	-	2	3
Balance at March 31, 2020	73	6	(1,295)	(33)	1,288	39

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

Condensed consolidated interim cash flow statement

For the three months ended March 31	Unaudited 2021 \$m	Unaudited 2020 \$m
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating Profit/(Loss)	57	(189)
Depreciation, amortization, and impairment	3	6
Depreciation and impairment of right-of-use assets	2	3
Gain on disposal of ROU assets	-	(2)
Gain on disposal of intangible assets	(1)	-
Share-based payments	-	2
Impact from foreign exchange movements	-	5
Decrease in trade receivables	13	36
Decrease/(Increase) in other assets	28	(44)
Decrease/(increase) in inventories	3	(7)
Increase/(decrease) in trade and other payables	7	(133)
(Decrease)/increase in provisions*	(17)	182
Cash generated from/(used in) operations	95	(141)
Interest paid	(4)	(5)
Interest received	-	4
Taxes paid	(2)	(4)
Net cash inflow/(outflow) from operating activities	89	(146)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from disposal of intangible assets	1	-
Net cash inflow from investing activities	1	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of borrowings	(1)	(1)
Payment of lease liabilities	(2)	(2)
Proceeds from the issuance of ordinary shares	-	1
Net cash outflow from financing activities	(3)	(2)
Net increase/(decrease) in cash and cash equivalents	87	(148)
Cash and cash equivalents at beginning of the period	858	1,060
Cash and cash equivalents at end of the period	945	912

* - Changes in provisions and other liabilities line includes an exceptional payment of \$10m to RB in accordance with the settlement agreement

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.

These Condensed Financial Statements have been prepared in conformity with International accounting standard 34, 'Interim Financial Reporting', as contained in UK-adopted international accounting standards ("IAS 34"). The financial information herein has been prepared based on the accounting policies set out in the annual accounts of the Group for the year ended December 31, 2020 and should be read in conjunction with those annual accounts. The Group prepared its annual accounts in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006, and in accordance with International Financial Reporting Standards adopted pursuant to Regulation (EC) No 1606/2002 as it applies in the European Union (adopted IFRSs). 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 Q1 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 as at December 31, 2020. These Condensed Financial Statements have been reviewed and not audited. These Condensed Financial Statements were approved for issue on April 28, 2021.

As disclosed in Notes 9, 10 and 11, the Group has liabilities and provisions totaling \$555m (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 financial covenants 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 modeled the risk that SUBLOCADE will not meet revenue growth expectations due to the continued impact from the COVID-19 pandemic (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, impact of the cost saving actions taken to date, and timing of the final balloon payment on the term loan in Q4 2022 which is outside the going concern assessment period. As a result of the factors set out above, the Directors of the Group have a reasonable expectation that 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 it appropriate to adopt the going concern basis for accounting and preparing 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 will be delivered to the Registrar of Companies.

2. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker ('CODM'). The CODM, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer (CEO). The Group is 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

Revenues are attributed to countries based on the country where the sale originates. The following table represents net revenues from continuing operations and non-current assets, net of accumulated depreciation and amortization, by country. Non-current assets for this purpose consist of intangible assets, property, plant and equipment, right-of-use assets, and other assets. Net revenues and non-current assets for the three months to March 31, 2021 and 2020 were as follows:

Net revenue:

	2021	2020
	\$m	\$m
For the three months ended March 31		
United States	131	105
Rest of World	49	48
Total net revenues	180	153

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

	2021	2020
For the three months ended March 31	\$m	\$m
Sublingual/other	134	121
SUBLOCADE	43	29
PERSERIS	3	3
Total	180	153

Non-current assets:

	Mar 31, 2021	Dec 31, 2020
	\$m	\$m
United States	138	141
Rest of World	125	128
Total	263	269

3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

	2021	2020
For the three months ended March 31	\$m	\$m
Research and development expenses	(9)	(10)
Selling and general expenses	(37)	(74)
Administrative expenses ¹	(42)	(229)
Depreciation, amortization and impairment ²	(3)	(6)
Total	(82)	(309)

¹Administrative expenses include exceptional items in the current and prior period as outlined in the table below.

²Additional depreciation and amortization of \$2m (2020: \$3m) for intangibles and ROU assets is included within cost of sales.

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 restructuring and related expenses for the reconfiguration of the Group's activities and/or capital structure, impairment of current and non-current assets, certain costs arising as a result of material and non-recurring regulatory and litigation matters, and certain tax related matters.

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

	2021	2020
For the three months ended March 31	\$m	\$m
Cost of sales ¹	-	(7)
Restructuring costs ²	-	(2)
Legal expenses/provision ³	5	(183)
Other operating income ⁴	1	-
Total exceptional items before taxes	6	(192)
Tax benefit on exceptional items ³	-	32
Exceptional tax item ⁵	36	-
Total exceptional items	42	(160)

- \$7m of exceptional cost of sales in Q1 2020 relate to inventory provisions due to the adverse impact of Covid-19 on the business.
- Restructuring costs in Q1 2020 consist primarily of lease disposals. Restructuring costs are included in SG&A.
- Negotiations with DOJ related plaintiffs in Q1 2021 led to a change in the Group's provision for DOJ related matters which resulted in a provision release of \$5m. In Q1 2020, \$183m of legal costs and an exceptional tax benefit of \$32m were recorded in relation to the DOJ Resolution. Exceptional legal costs are included within SG&A.
- Exceptional income in Q1 2021 relates to the proceeds received from the out-licensing of nasal naloxone opioid overdose patents which are included within SG&A.
- \$36m exceptional tax benefit item 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.

4. 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 Q1 2021 and 2020. Refer to Note 3 for more information on exceptional items.

Reconciliation of gross profit to adjusted gross profit

For the three months ended March 31	2021 \$m	2020 \$m
Gross profit	148	130
Exceptional cost of sales	-	7
Adjusted gross profit	148	137

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

For the three months ended March 31	2021 \$m	2020 \$m
Operating profit/(loss)	57	(189)
Exceptional cost of sales	-	7
Exceptional selling, general and administrative expenses	(6)	185
Adjusted operating profit	51	3

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

For the three months ended March 31	2021 \$m	2020 \$m
Profit/(loss) before taxation	53	(191)
Exceptional cost of sales	-	7
Exceptional selling, general and administrative expenses	(6)	185
Adjusted profit before taxation	47	1

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

For the three months ended March 31	2021 \$m	2020 \$m
Net income/(loss)	80	(163)
Exceptional cost of sales	-	7
Exceptional selling, general and administrative expenses	(6)	185
Tax benefit on exceptional items	-	(32)
Tax exceptional	(36)	-
Adjusted net income/(loss)	38	(3)

5. TAXATION

The Group calculates tax expense for interim periods using the expected full year rates, considering the pre-tax income and statutory rates for each jurisdiction. The resulting expense is allocated between current and deferred taxes based upon the forecasted full year ratio.

In the three months ended March 31, 2021, the reported total tax benefit was \$27m, or a rate of -51% (Q1 2020 tax charge: \$28m, 15%). On an adjusted basis tax expense of \$9m (Q1 2020: \$4m) excluding tax exceptionals of \$36m (Q1 2020: tax benefit on exceptional costs \$32m), on adjusted profit before tax of \$47m (Q1 2020: \$1m) represented a 19% quarterly effective tax rate (Q1 2020: a non-meaningful rate). The current period exceptional tax benefit of \$36m relates to the tax credit receivable in relation to development credits for SUBLOCADE claimed in prior years.

The Group's balance sheet at March 31, 2021 includes a current tax receivable of \$43m (FY 2020: \$7m), a current tax payable of \$26m (FY 2020: \$15m), and deferred tax asset of \$81m (FY 2020: \$75m). The current tax receivable balance has increased due to recording the receivable for SUBLOCADE development credits and advance cash tax payments.

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

Other tax matters

The European Commission issued a press release on April 2, 2019 announcing its conclusion that the United Kingdom ('UK') Finance Company Partial Exemption Rules are partly justified. The UK government has made an annulment application to the General Court against this decision. The UK government is now required to initiate recovery of the alleged State Aid irrespective of any appeal against the decision. The Group continues to monitor its position regarding the potential State Aid challenge and based upon our fact pattern has

determined that no provision is required at this time. The Group has benefited from the UK controlled foreign company financing exemption and the tax thereon is approximately \$25m including interest.

The enacted United Kingdom (“UK”) Statutory Corporation Tax rate was 19% for the year ended December 31, 2020. 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 rate is not substantively enacted or enacted at March 31, 2021. The impact of the rate increase to the UK deferred tax assets held at March 31, 2021 would be less than \$1m.

6. EARNINGS/(LOSS) PER SHARE

For the three months ended March 31	2021	2020
	cents	cents
Basic earnings/(loss) per share	11	(22)
Diluted earnings/(loss) per share	10	(22)
Adjusted basic earnings per share	5	-
Adjusted diluted earnings per share	5	-

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.

Weighted average number of shares	2021	2020
	Thousands	thousands
On a basic basis	734,220	731,982
Dilution from share awards and options	47,124	45,106
On a diluted basis	781,344	777,088

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

Current and non-current other assets	Mar 31	Dec 31
	2021	2020
	\$m	\$m
Short-term prepaid expenses	17	17
Other current assets	6	33
Total other current assets	23	50
Long-term prepaid expenses	21	22
Other non-current assets	82	82
Total other non-current assets	103	104
Total	126	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. Long-term prepaid expenses relate primarily to payments for contract manufacturing capacity.

8. FINANCIAL LIABILITIES – BORROWINGS

Bank loans	Mar 31	Dec 31
	2021	2020
	\$m	\$m
Bank loans – current	(4)	(4)
Bank loans – non-current	(229)	(230)
Total bank loans	(233)	(234)

	Mar 31 2021 \$m	Dec 31 2020 \$m
Analysis of net debt		
Cash and cash equivalents	945	858
Borrowings*	(234)	(235)
Total net cash	711	623

*Borrowings reflect the principal amount drawn before debt issuance costs of \$1m (FY 2020: \$1m). These do not include lease liabilities of \$49m (FY 2020: \$51m).

	Mar 31 2021 \$m	Dec 31 2020 \$m
Reconciliation of net debt		
The movements in the period were as follows:		
Net cash at beginning of period	623	821
Net increase/(decrease) in cash and cash equivalents	87	(202)
Net repayment of borrowings	1	4
Net cash at end of period	711	623

Net cash is presented as it is relevant to our term loan maximum leverage ratio. Net cash is not reduced for lease liabilities of \$49m (FY 2020: \$51m), in accordance with the term loan ratio calculations.

At March 31, 2021, the term loan was trading at approximately 100% (FY 2020: 98%) of par value. Cash at bank, trade receivables, and trade payables are assumed to approximate their fair values. The terms of the loan in effect at March 31, 2021 are as follows:

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

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

- Nominal interest margin is calculated over three-month LIBOR subject to the LIBOR floor of 1%.
- The maximum leverage ratio (adjusted aggregated net debt divided by Adjusted EBITDA) is a financial covenant to maintain net secured leverage below 3.0x.
- A \$50m revolving credit facility is available to the Group which remained undrawn at the balance sheet date.

9. PROVISIONS AND OTHER LIABILITIES

	Mar 31 2021 \$m	Dec 31 2020 \$m
Provisions & other liabilities		
Provisions		
DOJ related matters	(27)	(32)
Intellectual property related matters	(48)	(47)
Restructuring costs	(3)	(6)
Other	(4)	(4)
Total provisions	(82)	(89)
Other liabilities		
DOJ resolution	(488)	(486)
RB indemnity settlement	(40)	(50)
Total other liabilities	(528)	(536)
Total provisions and other liabilities	(610)	(625)

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 \$27m (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 \$5m in Q1 2021 (see Note 3). DOJ related matters of \$27m which are expected to be settled within the year.

The Group carries provisions totaling \$48m (FY 2020: \$47m) for intellectual property related matters, all of which relate to potential redress for ongoing intellectual property litigation with DRL and Alvogen should the Group not be successful with those cases outlined in Note 11, Intellectual property related matters: ANDA litigation. The provision represents the Group's estimate of potential damages for lost profits owed to DRL and Alvogen for the period between FDA approval and lifting of the preliminary injunction based on industry

analogous for generic market share capture. Finance costs are recognized in the income statement at an interest rate of 5.25%. In Q1 2021, the Group recorded finance expense totaling \$1m (Q1 2020: \$1m). The Group does not expect this matter to be settled within a year and therefore the provision of \$48m has been classified as non-current.

Other liabilities

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

On July 24, 2020, the Group reached a resolution with the DOJ and other litigants described in Note 11 under “DOJ 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 Q1 2021 the Group recorded interest expense totaling \$2m (Q1 2020: nil). As of March 31, 2021, \$51m 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 a \$10m payment in February 2021, following the resolution. Subsequently, annual instalment payments of \$8m will be due every January from 2022 to 2026. The Group carries a liability totaling \$40m (FY 2020: \$50m) related to this settlement. The effect of discounting was not material.

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 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. The Group has also assessed the State Aid matter discussed in Note 5 to be a contingent liability.

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 \$488 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 also seek reasonable attorney’s fees and costs. Many of the civil claims concern the same conduct at issue in the Superseding Indictment filed by the Justice Department. Indivior is aware of additional

claims 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 October 2016, Indivior was served with a subpoena for records from the State of Connecticut Office of the Attorney General under its Connecticut civil false claims act authority. The subpoena requests documents related to the Group's marketing and promotion of SUBOXONE products and its interactions with a non-profit third-party organization. The Group has reached an agreement to resolve this matter and has finalized the settlement agreement.
- In November 2016, Indivior was served with a subpoena for records from the State of California Department of Insurance under its civil California insurance code authority. The subpoena requests documents related to SUBOXONE® Film, SUBOXONE® Tablet, and SUBUTEX® Tablet. The State of California served additional deposition subpoenas on Indivior in 2017 and served a subpoena in 2018 requesting documents relating to the bioavailability / bioequivalency of SUBOXONE Film, manufacturing records for the product and its components, and the potential to develop dependency on SUBOXONE Film. The Group has fully cooperated in this civil investigation and is in discussions aimed toward resolving the matter. Certain of the qui tam suits filed in the Western District of Virginia and the District of New Jersey assert claims under the civil California insurance code. The Group is in discussions toward resolving these claims and claims for associated attorney's fees and costs.
- In June 2019, the Group learned that the State of Illinois Insurance Department is investigating potential violations of its civil Insurance Claims Fraud Prevention Act with respect to its sales and marketing activity. Certain of the qui tam suits filed in the Western District of Virginia and the District of New Jersey assert claims under this statute, including claims for associated attorney's fees and costs. The Group is in discussions aimed toward resolving this matter.
- In addition to the federal and state health program claims, claims have been asserted under the city false claims acts of Chicago and New York City regarding the promotion of Suboxone film. The Group has resolved the matter with the City of Chicago.

False Claims Act Allegations

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

Securities Class Action Litigation

- In April 2019, Michael Van Dorp filed a putative class action lawsuit in the United States District Court for the District of New Jersey on behalf of holders of publicly traded Indivior securities alleging violations of U.S. federal securities laws under the Securities Exchange Act of 1934. The complaint names Indivior PLC, Shaun Thaxter, Mark Crossley and Cary J. Claiborne as defendants. In February 2021, the parties reached a settlement agreement. A Motion for Entry of Order Preliminarily Approving Settlement is pending with the court.

Intellectual Property Related Matters

ANDA Litigation

- Litigation against DRL is currently pending in the District of New Jersey regarding U.S. Patent No. 9,687,454 and 9,931,305 ("the '454 and '305 Patents"). DRL received final FDA approval for all four strengths of its generic buprenorphine/naloxone film product in June 2018, and immediately launched its generic buprenorphine/naloxone film product "at-risk." In July 2018, the District Court issued a ruling granting Indivior a Preliminary Injunction (PI) pending the outcome of a trial on the merits of the '305 Patent. Indivior was required to post a surety bond for \$72 million in connection with the PI. In November 2018, the CAFC issued a decision vacating the PI against DRL. DRL launched its product at-risk in February 2019. In June 2019, DRL filed a motion for leave to file their first amended Answer, Affirmative Defenses, and Counterclaims to add various antitrust counterclaims resulting from the injunction that was issued against DRL. The motion was granted in November 2019. 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. No court date has been set yet.

- Litigation against Alvogen is pending in the United States District Court for the District of New Jersey regarding the '454 and '305 Patents. 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 are scheduled to take place in September 2021.
- 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 will respond to the Opposition on or before the deadline 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 were filed in March 2021. Opposition briefs were filed in April 2021 and reply briefs are due in May 2021.
- 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 plead guilty to one count of making a false statement relating to health care matters in one state in 2012. The Group continues to believe in its defenses and continues to vigorously defend itself. Select plaintiffs in these matters have previously made settlement demands (which were not accepted and most of which are not current offers), totaling approximately \$290m, which was used for contingency planning only to model possible downside financial effects. The final aggregate cost of these matters, whether resolved by litigation or by settlement, may be materially different. If the Group were to entertain further settlement discussions, we make no representations as to what amounts, if any, it may agree to pay, nor regarding what amounts the plaintiffs will demand.

Other Antitrust and Consumer Protection Claims

- In July 2019, the Indiana Attorney General issued a Civil Investigative Demand investigating potential violations of Indiana's Civil Deceptive Consumer Sales Act with respect to sales and marketing activity by the Company. The Group is cooperating fully in this civil investigation.
- In 2020, 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 are pending in the Eastern District of Pennsylvania. Cases filed by (1) Blue Cross and Blue Shield of Massachusetts, Inc., Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., (2) Health Care Service Corp., (3) Blue Cross and Blue Shield of Florida, Inc., Health Options, Inc., (4) BCBSM, Inc. (d/b/a Blue Cross and Blue Shield of Minnesota) and HMO Minnesota (d/b/a Blue Plus), and (5) Molina Healthcare, Inc. are pending in the Circuit Court for the County of Roanoke, Virginia. The allegations in these cases include many allegations made in other litigations, including prior antitrust complaints, indictments, and qui tam complaints. These plaintiffs have asserted claims under federal and state RICO statutes, state antitrust statutes, state statutes prohibiting unfair and deceptive

practices, state statutes prohibiting insurance fraud, and common law fraud, negligent misrepresentation, and unjust enrichment. Defendants' motions to dismiss are fully briefed and pending.

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 fewer than 400 civil lawsuits brought by state and local governments, public health agencies, and individuals against manufacturers, distributors and retailers of opioids alleging that they engaged in a longstanding practice to market opioids as safe and effective for the treatment of long term chronic pain in order to increase the market for opioids and their own market share. The vast majority of these cases have been consolidated and are pending in a federal multi-district litigation (MDL) in U.S. District Court for the Northern District of Ohio. At the present time, litigation against Indivior in the MDL is stayed. There remain three (3) cases against Indivior pending in state courts located in Arizona, Pennsylvania and Virginia, which are similarly stayed at the current time. 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

	Mar 31 2021 \$m	Dec 31 2020 \$m
Sales returns and rebates	(408)	(396)
Trade payables	(25)	(20)
Accruals	(85)	(99)
Other tax and social security payables	(11)	(9)
Total	(529)	(524)

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			
At January 1, 2021	733,635,511	\$0.10	73
Allotments	985,478	\$0.10	-
At March 31, 2021	734,620,989		73

	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	1,620,613	\$0.10	-
At March 31, 2020	732,408,332		73

Allotment of ordinary shares

During the period, 985,478 ordinary shares (2020: 1,620,613) were allotted to satisfy vestings/exercises under the Group's Long-Term Incentive Plan and U.S. Employee Stock Purchase Plan.

14. POST BALANCE SHEET EVENTS

On April 12, 2021 the Internal Revenue Service approved a tax credit in relation to development credits for SUBLOCADE claimed in prior years and issued a refund for approximately \$36m. The Group accounted for this event as an adjusting post balance sheet event. See Notes 3 and 5 for further discussion.

DIRECTORS' RESPONSIBILITY STATEMENT

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

- This set of Condensed Consolidated Interim Financial Statements, which have been prepared in accordance with International account standard 34, 'Interim Financial Reporting', as contained in UK-adopted international accounting standards ("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.

Indivior PLC's Directors are listed in the Annual Report and Accounts for 2020. Jerome Lande, Jo Le Couilliard, Mark Stejbach and Juliet Thompson were appointed as Non-Executive Directors on March 23, 2021.

Details of all current Directors are available on our website at www.indivior.com

By order of the Board

Mark Crossley
Chief Executive Officer

Ryan Preblich
Chief Financial Officer

April 28, 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 Q1 2021 Results of Indivior PLC for the three month period ended 31 March 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 International Accounting Standard 34, 'Interim Financial Reporting', as contained in UK-adopted international accounting standards ("IAS 34").

What we have reviewed

The interim financial statements comprise:

- the Condensed consolidated interim balance sheet as at 31 March 2021;
- the Condensed consolidated interim income statement and Condensed consolidated interim statement of comprehensive income/(loss) for the period then ended;
- the Condensed consolidated interim statement of changes in equity for the period then ended;
- the Condensed consolidated interim cash flow statement for the period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the Q1 2021 Results of Indivior PLC have been prepared in accordance with IAS 34.

As disclosed in note 1 to the interim financial statements, the financial reporting framework that will be applied in the preparation of the next full annual financial statements of the group is applicable law and UK-adopted international accounting standards.

Responsibilities for the interim financial statements and the review

Our responsibilities and those of the directors

The Q1 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 Q1 2021 Results in accordance with IAS 34.

Our responsibility is to express a conclusion on the interim financial statements in the Q1 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 Q1 2021 Results and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP
Chartered Accountants
London
28 April 2021