

July 30, 2020



Indivior Announces H1 2020 Results

Period to June 30th	Q2 2020 \$m	Q2 2019 \$m	% Δ Actual FX	% Δ Constant FX	H1 2020 \$m	H1 2019 \$m	% Δ Actual FX	% Δ Constant FX
Net Revenue	150	215	-30	-30	303	454	-33	-33
Operating Profit/(Loss)	25	88	-72	-71	(165)	163	NM	NM
Net Income/(Loss)	18	75	-76	-75	(145)	141	NM	NM
EPS (cents per share)	2	10	-80	-75	(20)	19	NM	NM
Adj. Operating Profit*	24	89	-73	-72	26	191	-86	-87
Adj. Net Income*	17	76	-78	-77	14	165	-92	-92
Adj. EPS*	2	10	-80	-77	2	23	-91	-92

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

[Comment by Mark Crossley, CEO of Indivior PLC](#)

“I am proud of the Group’s resilient performance through this unprecedented period brought about by the COVID-19 pandemic. Considering this backdrop, our first-half results were solid. We maintained a good cash buffer and we did so while helping to ensure the safety and wellbeing of our employees. I am particularly encouraged by the performance of SUBLOCADE® (buprenorphine extended-release) Injection through this period, as Q2 net revenue of \$29m was unchanged versus Q1’s level. Furthermore, we came to a satisfactory agreement with the DOJ (subject to judicial approval) that allows us to focus our resources on pursuing our Vision and patient-focused growth strategy. In the short term, we continue to be impacted by the industry-wide reduction in new patient starts in the U.S. However, looking to the future, I am confident that our novel depot technologies, SUBLOCADE® and PERSERIS® (risperidone) extended release injection, have the power to transform lives and to drive a new era of growth.”

[H1 2020 Financial Highlights](#)

- Total net revenue of \$303m declined 33% (H1 2019: \$454m). U.S. net revenue declined 42% due to SUBOXONE® (buprenorphine and naloxone) Film share loss (which was at lower rates than analogues⁽¹⁾) and to the termination of the Group’s authorized buprenorphine/naloxone generic film program in Q4 2019. These factors were partially offset by an increase in the underlying growth rate in the U.S. oral medication-assisted treatment (MAT) market due to the effects of the COVID-19 pandemic (see “U.S. Market Update” on page 4) and by increased net revenue from SUBLOCADE® (H1 2020: \$58m vs. H1 2019: \$28m). Rest of World net revenue was unchanged.
- Reported operating loss was \$165m (H1 2019 operating profit: \$163m). On an adjusted basis, operating profit was \$26m (Adj. H1 2019: \$191m). The decline in adjusted operating profit reflects lower overall net revenue and increased SG&A expense, principally promotional expenses for SUBLOCADE in Q1 2020 and increased legal expenses (related to the agreement on Department of Justice (DOJ) matter) in Q2 2020.
- Reported net loss was \$145m (H1 2019 net income: \$141m). On an adjusted basis, net income was \$14m (Adj. H1 2019 net income: \$165m). The decline mainly reflects the reduction in operating profit and net finance expense (versus finance income in H1 2019).
- Cash balance at the end of H1 2020 was \$908m (FY 2019: \$1,060m). Net cash was \$671m (FY 2019: \$821m). The lower cash balances primarily reflect the negative net working capital impact associated with the timing of payables related to Film share loss in government programs and the collateralization of surety bonds.

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

H1 2020 Operating Highlights

- U.S. buprenorphine medication-assisted treatment (BMAT) market continued to grow at a low teens rate, primarily led by Government channels (see “U.S. Market Update” on page 4 for more detail).
- SUBLOCADE net revenue of \$58m (H1 2019: \$28m); total SUBLOCADE units dispensed in H1 2020 were approximately 48,700 (+114% vs. H1 2019), including 25,300 units dispensed in Q2 2020 (+88% vs. Q2 2019); PERSERIS® net revenue of \$7m.
- COVID-19 pandemic resulted in sharp reduction beginning in mid-March in patient enrollments for SUBLOCADE and PERSERIS; patient enrollments through Q2 2020 were stable with Q1 2020 exit rates.
- SUBOXONE Film market share during H1 2020 averaged 22% (H1 2019: 38%) and exited at 21% (H1 2019: 27%). Share erosion continues to be lower than historical industry analogues⁽¹⁾.
- SUBOXONE Film was approved for marketing in European Union and Canada; listing discussions ongoing in target countries.
- SUBLOCADE (buprenorphine extended-release injection) available in Canada; SUBLOCADE (buprenorphine modified release solution for injection) available in Australia.
- SUBLOCADE / SUBUTEX® prolonged release solution for injection was approved in Israel, Sweden and Finland.

FY 2020 Planning Assumptions

The impact of the COVID-19 pandemic on Indivior’s operations remains highly uncertain. The extent of any adverse impact on the Group’s operations will depend on the unforeseeable duration, extent and severity of the pandemic, notably in the U.S., Indivior’s largest market. The Group is, however, sharing the following planning assumptions for the remainder of 2020, which are based on the Group’s current expectations:

- U.S. BMAT market: continued low teens volume growth.
- SUBLOCADE: modest growth in new patient enrollments compared with Q2 exit levels.
- SUBOXONE Film: significant reduction in H2 2020 net revenue compared with H1 2020 as a result of share loss reaching historical industry analogues⁽¹⁾ and negative channel mix.
- Rest of World: sustained competitive pressures, mainly in Western Europe.
- Operating expenses: combined SG&A and R&D expenses in H2 2020 to be slightly below H1 2020 level, despite expected increases in compliance and R&D expenses.
- Tax rate: mid-to-high teens.

Indivior will monitor closely the development of the pandemic and anticipates providing an update with its Q3/nine-month 2020 results, currently scheduled for October 29, 2020.

To the extent the pandemic continues for an extended period, Indivior expects it to have the effect of heightening many of the risks described beginning on page 7 in the Risk Factors section. In the current environment, the Directors have considered the impact of a range of possible future COVID-19 related scenarios and believe the Group retains sufficient liquidity to continue to operate.

COVID-19 Response Update

Indivior continues to enact the carefully managed response to COVID-19 detailed in its Q1 2020 results release. The Group’s overriding objectives in formulating its response were to maintain the safety and wellbeing of its global employee base and help ensure that patients around the world continue to have access to treatment and to build a strong foundation for future growth. These objectives remain unchanged. However, as population movement restrictions have begun to ease, Indivior is adjusting its employee response in the following respects:

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

- Employees are being allowed to return to work on a carefully phased basis where restrictions have either been lifted or eased in accordance with guidelines by local government and health organizations across the world.
- To facilitate safe working practices, the Group is providing personal protection equipment to all global employees.
- Indivior at this time commits to respect individual requests to maintain remote working status either due to the individual's comfort level in returning to a group setting, or need to continue to provide eldercare or childcare, or in consideration of pre-existing medical conditions.
- In all of the foregoing, Indivior will remain in compliance with all regulatory and safety standards and the Group will work to ensure that supply of all of its approved treatments remains uninterrupted.

[Agreement to Resolve Criminal Charges and Civil Complaints Related to SUBOXONE Film](#)

The Group has reached an agreement with the United States Department of Justice (Justice Department), the Federal Trade Commission ("FTC"), and U.S. state attorneys general to resolve the Company's criminal and civil liability in connection with a multi-count indictment brought in April 2019 by a grand jury in the Western District of Virginia, a civil lawsuit joined by the Justice Department in 2018, and an FTC investigation. Under the terms of the agreement, Indivior Solutions Inc. ("Solutions Inc."), a wholly owned subsidiary of Indivior PLC, has pleaded guilty to a single count of making a false statement relating to health care matters in 2012 in violation of 18 U.S.C. Section 1035. Indivior will make payments to federal and state authorities totalling \$600 million (plus applicable interest of 1.25%) over a period of seven years, has agreed to a stipulated injunction with the FTC, and entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services (HHS). Under the terms of the agreement, the Justice Department will move to dismiss all other charges upon judicial approval of the agreements and sentencing.

Under the terms of a related agreement with the HHS, Solutions Inc. will be excluded from participating in government health programs. This exclusion will not apply to any other entities within the Group. The Company does not anticipate the exclusion of Solutions Inc. will have any material impact on the Group's ability to continue to participate in government health programs.

Under the terms of the agreement, the Company will make a payment of \$100 million the week the plea is finalized and approved by a judge. Subsequently, there will be six annual instalments of \$50 million due every January 15 from 2022 to 2027. The final instalment of \$200 million will be due on December 15, 2027. The Group carries a provision of \$624 million (FY19: \$438 million) for Department of Justice and related matters.

Under the terms of the five-year Corporate Integrity Agreement (CIA) 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 and annual Board and CEO certifications submitted to the U.S. Attorney's Office. In addition, the Group will be subject to monitoring by an Independent Review Organization, who will submit audit findings to HHS-OIG, and review by a Board Compliance Expert, who will prepare two compliance assessment reports in the first and third reporting periods of the Corporate Integrity Agreement. See Risk Factors section on page 7.

Operating Review

U.S. Market Update

In H1 2020, growth of the U.S. BMAT market was sustained at a low teens rate. The acceleration in market growth compared with the low double-digit growth observed in 2019 was primarily driven by an increase in the underlying growth rate in the oral medication-assisted treatment (MAT) market due to the effects of the COVID-19 pandemic. The increase followed implementation of several new federal and state government actions to facilitate access to MAT, including counselling, for patients suffering from opioid use disorder in light of the COVID-19 pandemic and social distancing requirements. For example, the Drug Enforcement Administration (DEA), jointly with the Substance Abuse and Mental Health Services Administration (SAMHSA), has allowed healthcare providers to initiate and continue buprenorphine treatment by telemedicine and telephone. The Group is uncertain how long the elevated underlying BMAT growth rate will continue but anticipates the growth rate will revert to the previously observed low double-digit growth rate.

Underlying market volume growth continues to benefit both from increased overall public awareness of the opioid epidemic and approved treatments, and from regulatory and legislative changes that have expanded OUD treatment funding and treatment capacity. States are also realizing that, while providing treatment brings substantial value to both patients and society, BMAT remains under-utilized⁽¹⁾.

In response, both the number of physicians who have received a waiver to administer MAT and those able to treat to the permitted level of 275 patients continued to grow in the first half of 2020. The number of nurse practitioners and physician assistants who have received a waiver also continued to grow in the first half of 2020. Indivior supports efforts to encourage more eligible healthcare practitioners to provide treatment, and the Group continues to resource its compliance capabilities for the growing number of BMAT prescribers and patients.

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

As a result of the launch of generic buprenorphine/naloxone film products, branded SUBOXONE Film experienced significant market share loss in 2019, albeit at a lower rate than suggested by historical industry analogues⁽²⁾. SUBOXONE Film market share exiting the first half of 2020 was 21% compared to first half of 2019 exit share of 27%. Overall formulary access for SUBOXONE Film remains above expectations at this point in the lifecycle of the treatment, although Indivior notes the loss of formulary coverage at Express Scripts (ESI) with effect from July 1, 2020. Looking forward, Indivior prudently assumes the pace of market share loss will intensify for SUBOXONE Film, ultimately resulting in a branded market share position in-line with industry analogues⁽²⁾. However, the exact timing for reaching this level is uncertain at this point.

In Q4 2019, the Group terminated its authorized generic (AGx) buprenorphine/naloxone sublingual film program with Sandoz. Final shipments of Indivior-produced AGx film were made in Q4 2019, which Sandoz continued to market during H1 2020. The termination of the AGx program has not affected availability of branded or generic buprenorphine/naloxone sublingual film.

Financial Performance in H1 and Q2 2020

Total net revenue in H1 2020 decreased 33% to \$303m (H1 2019: \$454m) at actual exchange rates (-33% at constant exchange rates). In Q2 2020, total net revenue decreased 30% at actual exchange rates (-30% at constant exchange rates) to \$150m (Q2 2019: \$215m).

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

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

U.S. net revenue decreased 42% in H1 2020 to \$211m (H1 2019: \$362m) and by 34% in Q2 2020 to \$107m (Q2 2019: \$163m). Growth in the overall U.S. BMAT market was sustained at a low-teens rate as discussed above (“U.S. Market Update”), primarily due to strength in government channels. Underlying market strength and SUBLOCADE net revenue growth to \$58m (H1 2019: \$28m) were more than offset by SUBOXONE Film share loss due to generic buprenorphine/naloxone film alternatives (launched in Q1 2019) and the absence of net revenue contribution from the AGx film program that the Group terminated in October 2019. U.S. net revenue dynamics in Q2 2020 were substantially the same as those for H1 2020, but with the additional impacts of lower new patient enrollments for SUBLOCADE and PERSERIS due to the COVID-19 pandemic.

Rest of World (ROW) net revenue was unchanged at actual exchange rates in H1 2020 to \$92m (H1 2019: \$92m) (+4% at constant exchange rates). In Q2 2020, ROW net revenue decreased 17% at actual exchange rates to \$43m (Q2 2019: \$52m) (-14% at constant exchange rates). ROW net revenue performance in H1 2020 primarily reflects the impact of a prior year one-time net revenue adjustment in Canada that was offset by continued competitive pressure, principally in Western Europe. The Q2 2020 decline in ROW net revenue was primarily due to competitive pressure in Western Europe.

Gross margin as reported in H1 2020 was 86% (H1 2019: 86%) and 88% in Q2 2020 (Q2 2019: 87%), respectively. Excluding \$6m of net exceptional costs of sales related to inventory provisions due to the adverse impact of COVID-19 in Q1 2020 and an exceptional benefit of \$1m in Q2 2020 related to releases of inventory provisions, adjusted gross margin in H1 2020 and Q2 2020 was 88% (Adj. H1 2019: 86%) and 87% (Adj. Q2 2019: 87%), respectively. The adjusted gross margin performance in both periods primarily reflects a more favorable product mix primarily from the discontinuation of the AGx film program.

SG&A expenses as reported in H1 2020 were \$408m (H1 2019: \$202m) and \$99m as reported in Q2 2020 (Q2 2019: \$87m). H1 2020 reported SG&A included exceptional costs of \$185m. The exceptional costs comprised \$183m related to the DOJ matter and \$2m for restructuring-related lease impairments. H1 2019 SG&A expenses included exceptional costs of \$28m, primarily related to restructuring and redundancy costs.

On an adjusted basis, H1 2020 SG&A expenses increased 28% to \$223m (Adj. H1 2019: \$174m). The increase largely reflects greater SUBLOCADE marketing expenses primarily due to the national direct-to-consumer (DTC) advertising campaign (Q1 2020), as well as higher legal expenses related to the agreement on the DOJ matter (Q2 2020). These items were partially offset by lower overall administrative expenses from savings actions completed in 2019. In Q2 2020 SG&A expenses on an adjusted basis increased 15% to \$99m (Adj. Q2 2019: \$86m). The increase in the period largely reflects the aforementioned Q2 2020 item.

H1 2020 and Q2 2020 R&D expenses decreased by 24% to \$19m and by 38% to \$8m, respectively (H1 2019: \$25m; Q2 2019: \$13m). The decrease in both periods primarily reflects lower clinical activities due to COVID-19 population movement restrictions, as well as ongoing prioritization of R&D activities on SUBLOCADE Health Economics and Outcomes Research (HEOR) and post-marketing study commitments for SUBLOCADE and PERSERIS.

H1 2020 operating loss as reported was \$165m (H1 2019 op. profit: \$163m). Exceptional costs of \$191m and \$28m are included in the H1 2020 and H1 2019 reported results, respectively. On an adjusted basis, H1 2020 operating profit was \$26m (H1 2019: \$191m). The decline on an adjusted basis primarily reflects lower net revenue along with increased SG&A expenses as detailed above. These items were partially offset by lower R&D expenses and administrative expense savings from actions completed in H1 2019.

Q2 2020 operating profit as reported was \$25m (Q2 2019: \$88m). An exceptional benefit of \$1m and exceptional costs of \$1m are included in the Q2 2020 and Q2 2019 reported results, respectively. On an adjusted basis, Q2 2020 operating profit was \$24m (Adj. Q2 2019: \$89m). The decline on an adjusted basis primarily reflects lower net revenue and increased SG&A expenses partially offset by lower R&D expenses.

H1 2020 net finance expense was \$6m (H1 2019: \$3m income). The 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 interest expense primarily related to the Group's DOJ settlement amount.

H1 2020 reported tax benefit was \$26m, or a rate of 15% (H1 2019 tax charge: \$25m, 15%). Excluding the \$32m tax benefit on exceptional items in H1 2020, the effective tax rate was 27% (H1 2019 adj. tax charge: \$29m; 15% rate). Q2 2020 reported tax charge was \$2m, or a rate of 10% (Q2 2019: \$14m, 16%), with no exceptional tax items for the quarter or prior year quarter.

H1 2020 reported net loss was \$145m (H1 2019 net income: \$141m). On an adjusted basis, H1 2020 net income was \$14m and excludes the \$159m after-tax impact from exceptional items (Adj. H1 2019: \$165m). The decline in net income on an adjusted basis primarily reflects lower net revenue, increased operating expenses mainly due to the SUBLOCADE DTC campaign in Q1 2020 and net finance expense (versus H1 2019 finance income). Q2 2020 net income on a reported basis was \$18m (Q2 2019: \$75m), and \$17m on an adjusted basis excluding the \$1m after-tax impact from exceptional items (Adj. Q2 2019: \$76m). Lower Q2 2020 net income on an adjusted basis was primarily due to the decline in net revenue, increased SG&A expense and net finance expense (versus Q2 2019 finance income).

Loss per share was 20 cents in H1 2020 and earnings per share of 2 cents on an adjusted diluted basis (H1 2019: 19 cents on a diluted and 22 cents adjusted diluted basis). In Q2 2020, EPS on a diluted basis was 2 cents and 2 cents on an adjusted diluted basis (Q2 2019: 10 cents on a diluted and adjusted diluted basis).

Balance Sheet & Cash Flow

Cash and cash equivalents at the end of H1 2020 were \$908m, a decrease of \$152m versus the \$1,060m position at FY 2019 primarily due to rebates in the U.S. within payables. Borrowings, net of issuance costs, were \$237m at the end of H1 2020 (FY 2019: \$239m). As a result, net cash (as defined in Note 8) stood at \$671m at H1 2020 (FY 2019: \$821m), a \$150m decrease over the half year.

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative \$212m at the end of H1 2020 versus negative \$323m at the end of FY 2019. The \$111m change over the period was primarily driven by a decrease in sales returns and rebates in the U.S. within payables and a reduction in accrual levels partially offset by a decrease in trade and other receivable balances.

Cash used by operating activities in H1 2020 was \$132m (H1 2019 cash generated: \$45m), representing an increased use of cash of \$177m primarily due to lower revenues and trade receivables in the period exacerbated by timing of payments of sales rebates and other payables. Net cash outflow from operating activities was \$148m in the half year (H1 2019 net cash inflow: \$72m) reflecting the lower cash from operating activities and net tax payments in the quarter.

H1 2020 cash outflow from investing activities was nil (H1 2019: \$2m). The prior year outflow related to the purchase of property, plant and equipment.

H1 2020 cash outflow from financing activities was \$4m (H1 2019: \$6m), reflecting the principal portion of lease payments and the quarterly repayment on the term loan facility partially offset by proceeds from issuance of shares to satisfy the vesting of options under an employee stock purchase plan.

R&D / Pipeline Update

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

Risk Factors

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 2020 financial year. In addition to the principal risks and uncertainties affecting the Group's business activities, detailed on pages 41 to 44 of the Indivior PLC Annual Report 2019, during the first half of 2020, changes to the Group's environment have occurred which are impacting the Group's Principal Risks.

On July 24, 2020 the Group reached an agreement with the U.S. Department of Justice (DOJ) to settle an investigation regarding alleged charges of health care fraud, wire fraud, mail fraud, and conspiracy in connection with the marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE Film and/or SUBOXONE Tablet by certain physicians (for more details, refer to the section "Agreement to Resolve Criminal Charges and Civil Complaints Related to SUBOXONE Film" on page 3 of this press release). The DOJ agreement is still pending final judicial approval in the Western District of Virginia scheduled for October 2020 (for more details on legal proceedings, any related provisions, and going concern refer to Notes 1, 9 and 11 to consolidated interim financial statements). As part of this agreement, the Group has also entered into a CIA with HHS-OIG. The five-year CIA requires, among other things, that the Group implement measures designed to ensure compliance with the statutes, regulations, and written directives of US Medicare, US Medicaid, and all other US Federal health care programs, as well as with the statutes, regulations, and written directives of the US Food and Drug Administration. In addition, the CIA requires reviews by an independent review organization, compliance-related certifications from the Group's executives and Board members, and the implementation of a risk assessment and mitigation process. The CIA sets forth specified monetary penalties that may be imposed on a per day basis for failure to comply with the obligations specified in the CIA. The CIA also includes specific procedures under which the Group must notify HHS-OIG if it fails to meet the requirements under the CIA. In the event that HHS-OIG determines the Group to be in material breach of certain requirements of the CIA, the Group may be subject to exclusion from participation in the U.S. Federal health care programs, which would have a severe impact on the Group's ability to comply with the financial covenants in the Group's debt facility, maintain sufficient liquidity to fund its operations, pay off its debt in 2022, generate future revenue and ultimately impact the Group's viability.

The persistence of the COVID-19 pandemic and the ongoing government measures to address the global pandemic continue to create a very challenging business environment for companies across industries worldwide; and therefore related risks to the Group's business and operations. In response to COVID-19, the Group has implemented a number of mitigation and contingency actions to help maintain the supply of all products to our patients and the welfare of our employees (for more details, refer to the section "COVID-19 Response Update" of this press release). Given the remote working environment, the Group continues to closely monitor cybersecurity threats and the overall operating effectiveness of controls.

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

The Group had cash and cash equivalents of \$908 million (net cash of \$671 million). COVID-19 has not significantly impacted the Group's liquidity to date. The Group has, however, observed a continued decline in patient enrollments for both SUBLOCADE and PERSERIS injections since the end of the first quarter, though such decline appears to be stabilizing. The pandemic has resulted in overall fewer patient visits to healthcare provider offices for non-COVID-19 reasons or essential treatments, as patients become unable or unwilling to make visits due to overburdened healthcare systems or elect to have remote consultations (telehealth) with their providers. The pandemic has also resulted in safety concerns, quarantines or other travel restrictions for patients.

Furthermore, even though the Group has developed remote (digital) meeting capability with healthcare providers, the Group's commercial organization has only been able to engage in-person with a limited number of healthcare professionals (HCPs) and Organized Health Systems (OHS) – an important element of the Group's growth strategy. Therefore, a potential enduring and/or significant decline in patient enrollments and the inability to effectively engage with HCPs and OHS would have a negative impact on the Group's financial results in future periods.

Given the evolving and dynamic nature of the COVID-19 pandemic, and uncertainty surrounding the duration of measures designed to mitigate its spread, including the development of a vaccine or attainment of herd immunity, the impact on the Group's operations and financial position is highly uncertain and cannot be predicted with confidence. The developments in relation to COVID-19 are under constant review to ensure our mitigation and contingency actions are appropriate, proportionate and as effective as possible. However, despite the measures the Group has taken, if the pandemic adversely affects Indivior's operations and/or performance, it will have a heightened effect on many of the risks described beginning on page 41 of the Annual Report 2019, specifically those relating to business operations, the execution of the commercial strategy, the manufacturing and supply of products, as well as the delivery of and reliance on third-party products and services, including those related to clinical studies.

In preparation for the UK's exit from the European Union (Brexit), the Group continues to be proactive in taking necessary actions should a hard Brexit/no-deal occur. We are continuing to review our plans (e.g., increasing safety stocks) and potential impacts on our operations as negotiations and regulations develop, and to prepare for all foreseeable outcomes at the end of the expected transition period on December 31, 2020.

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 41 to 44 of the Annual Report 2019. These include:

Business Operations

The Group's operations rely on complex processes and systems, strategic partnerships, as well as specially-qualified and high-performing personnel to develop, manufacture and sell our products. Failure to continuously maintain operational processes and systems as well as to recruit and/or retain qualified personnel could adversely impact product availability and patient health, and ultimately the Group's performance and financials. Additionally, an ever-evolving regulatory, political and technological landscape requires that we have the right priorities, capabilities and structures in place to successfully execute on our business strategy and adapt to this changing environment. The finishing of our SUBOXONE and SUBUTEX tablets for all our European markets is manufactured by a third-party contract manufacturer located in the UK. The Group has been proactive in taking appropriate actions since the referendum should a hard Brexit/no-deal occur, including changes to logistics, shipping, and quality testing and release processes, as well as transfer of regulatory licenses and additional inventory builds. Uncertainties of the impact of Brexit on our operations remain a risk closely monitored as it impacts various areas of the Group, including Operations, Regulatory, Supply Chain, and Quality.

Product Pipeline, Regulatory & Safety

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

Commercialization

Successful commercialization of our products is a critical factor for the Group's sustained growth and robust financial position. Launch of a new product involves substantial investment in marketing, market access and sales activities, product stocks, and other investments. Certain factors, if different than anticipated, can significantly impact the Group's performance and position. These factors include: HCP/Patient adoption and adherence; generic and brand competition; pricing pressures; private and government reimbursement schemes and systems; negotiations with payors; erosion and/or infringement of intellectual property (IP) rights; and political and socioeconomic factors.

Economic & Financial

The nature of the pharmaceutical business is inherently risky and uncertain and requires that we make significant financial investments to develop and support the success of our product portfolio. Generating cash flow and external financing are key factors in sustaining our financial position, developing our product pipeline and, expanding our business growth. Our ability to realize value on those investments is often dependent upon regulatory approvals, market acceptance, strategic partnerships, competition, and legal developments. Unfavorable outcome from government resolutions and/or from legal proceedings (including the Western District of Virginia Indictment), as well as potential exclusion from participating in US Federal Health Care Programs may negatively impact our financial position and therefore, our ability to comply with our debt covenants. As a global business, we are also subject to political, economic, and capital markets changes.

Supply Chain

The manufacturing and supply of our products are highly complex and rely on a combination of internal manufacturing capabilities and third parties for the timely supply of our finished drug and combination drug products. The Group has a single source of supply for buprenorphine, an active pharmaceutical ingredient (API) in most of the Group's products and uses contract manufacturing organizations (CMOs) to manufacture, package and distribute our products. The manufacturing of non-sterile pharmaceutical and sterile filled, pharma/medical device combination drug products is subject to stringent global regulatory quality and safety standards, including Good Manufacturing Practice (GMP). Delays or interruptions in our supply chain, and/or product quality failures could significantly disrupt patient access, adversely impact the Group's financial performance; and to lead to product recalls, and/or potential regulatory actions against the Group, along with potential reputational damages.

Legal & Intellectual Property

Our pharmaceutical operations, which include controlled substances, are subject to a wide range of laws and regulations from various governmental and non-governmental bodies. Perceived noncompliance with these applicable laws and regulations may result in investigations or proceedings leading the Group to become subject to civil or criminal sanctions and/or pay fines and/or damages, as well as reputational damages. Intellectual Property (IP) rights protecting our products may be challenged by external parties, including generic manufacturers. Although we have developed robust patent protection for our products, we are exposed to the risk that courts may decide that our IP rights are invalid and/or that third parties do not infringe our asserted IP rights. Unfavorable outcome from government investigations and/or resolutions from legal proceedings (including the Western District of Virginia Indictment), expiry and/or loss of IP rights could have a material adverse impact on the Group's prospects, results of operations and financial condition, including potential exclusion from participating in US Federal health care programs. As previously disclosed in the Prospectus dated November 17, 2014, Indivior has indemnification obligations in favor of Reckitt Benckiser (RB) (page 43). Some of these indemnities are unlimited in terms of amount and duration and amounts potentially payable by the Group pursuant to such indemnity obligations could be significant and could have a material adverse effect on the Group's business, financial condition and/or operating results. Requests for indemnification may be subject to legal challenge.

Compliance

Our Group operates on a global basis and the pharmaceutical industry is both highly competitive and regulated.

Complying with all applicable laws and regulations, including engaging in activities that are consistent with legal and industry standards, and our Group’s Code of Conduct are core to the Group’s mission, culture, and practices. Failure to comply with applicable laws and regulations may subject the Group to civil, criminal and administrative liability, including the imposition of substantial monetary penalties, fines, damages and restructuring the Group’s operations through the imposition of compliance or integrity obligations and have a potential adverse impact on the Group’s prospects, reputation, results of operations and financial condition.

The Group’s Annual Report for the 2019 financial year contains additional details on these principal business risks.

Exchange Rates

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

	6 Months to June 30, 2020	6 Months to June 30, 2019
GB £ period end	1.2336	1.2698
GB £ average rate	1.2617	1.2940
€ Euro period end	1.1219	1.1382
€ Euro average	1.1014	1.1297

Webcast Details

There will be a live webcast presentation at 12:00 BST (7:00 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.

Webcast link: <https://edge.media-server.com/mmc/p/ot3s33jj>

Confirmation Code: 6735858

Participants, Local - London, United Kingdom: +44 (0) 207 1928000

Participants, Local - New York, United States of America: +1 631 510 7495

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.

Forward-Looking Statements

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

things, statements regarding the Indivior Group's financial guidance for 2020, if any, and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

Various factors may cause differences between Indivior's expectations and actual results, including, among others (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases): factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing and in the supply chain; disruptions in or failure of information technology systems; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; challenges in the commercial execution; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including settlement with the U.S. Department of Justice, potential exclusion from participating in U.S. Federal health care programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; risks related to the evolving COVID-19 pandemic and the potential impact of COVID-19 on the Indivior Group's operations and financial condition, which cannot be predicted with confidence; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

Consequently, forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

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

Indication

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

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

Important Safety Information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE) INJECTION FOR SUBCUTANEOUS USE (CIII)

INDICATION AND HIGHLIGHTED SAFETY INFORMATION

INDICATION

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

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

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

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

HIGHLIGHTED SAFETY INFORMATION

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

ADVERSE REACTIONS

Adverse reactions commonly associated with SUBLOCADE (in $\geq 5\%$ 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 and six months ended June 30	Notes	Unaudited	Unaudited	Unaudited	Unaudited
		Q2 2020 \$m	Q2 2019 \$m	H1 2020 \$m	H1 2019 \$m
Net Revenues	2	150	215	303	454
Cost of Sales		(18)	(27)	(41)	(64)
Gross Profit		132	188	262	390
Gross profit before exceptional items	4	131	188	268	390
Exceptional items	3	1	-	(6)	-
Selling, general and administrative expenses	3	(99)	(87)	(408)	(202)
Research and development expenses	3	(8)	(13)	(19)	(25)
Operating Profit/(Loss)		25	88	(165)	163
Operating profit before exceptional items	4	24	89	26	191
Exceptional items	3	1	(1)	(191)	(28)
Finance income		2	6	6	13
Finance expense		(7)	(5)	(12)	(10)
Net finance (expense)/income		(5)	1	(6)	3
Profit/(Loss) before Taxation		20	89	(171)	166
Income tax (expense)/benefit		(2)	(14)	26	(25)
Taxation before exceptional items	5	(2)	(14)	(6)	(29)
Exceptional items within taxation	3,5	-	-	32	4
Net Income/(Loss)		18	75	(145)	141

Earnings per ordinary share (cents)

Basic earnings per share	6	2	10	(20)	19
Diluted earnings per share	6	2	10	(20)	19

Condensed consolidated interim statement of comprehensive income

For the three and six months ended June 30	Unaudited	Unaudited	Unaudited	Unaudited
	Q2 2020 \$m	Q2 2019 \$m	H1 2020 \$m	H1 2019 \$m
Net income/(loss)	18	75	(145)	141
Other comprehensive (loss)/income				
<i>Items that may be reclassified to profit or loss in subsequent years:</i>				
Net exchange adjustments on foreign currency translation	(3)	(5)	(13)	1
Other comprehensive (loss)/income	(3)	(5)	(13)	1
Total comprehensive income/(loss)	15	70	(158)	142

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

Condensed consolidated interim balance sheet

	Notes	Unaudited Jun 30, 2020 \$m	Audited Dec 31, 2019 \$m
ASSETS			
Non-current assets			
Intangible assets		63	72
Property, plant and equipment		54	60
Right-of-use assets		41	47
Deferred tax assets	5	87	40
Other assets	7	128	73
		373	292
Current assets			
Inventories		90	73
Trade and other receivables		178	227
Current tax receivable	5	2	-
Cash and cash equivalents	8	908	1,060
		1,178	1,360
Total assets		1,551	1,652
LIABILITIES			
Current liabilities			
Borrowings	8	(4)	(4)
Provisions	9	(139)	(71)
Trade and other payables	12	(480)	(623)
Lease liabilities		(6)	(5)
Current tax liabilities	5	(55)	(39)
		(684)	(742)
Non-current liabilities			
Borrowings	8	(232)	(233)
Provisions	9	(535)	(417)
Lease liabilities		(42)	(51)
		(809)	(701)
Total liabilities		(1,493)	(1,443)
Net assets		58	209
EQUITY			
Capital and reserves			
Share capital	13	73	73
Share premium		6	5
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(36)	(23)
Retained Earnings		1,310	1,449
Total equity		58	209

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

Condensed consolidated interim statement of changes in equity

Unaudited	Notes	Share	Share	Other	Foreign	Retained	Total
		capital	Premium	reserve	translation	earnings	
		\$m	\$m	\$m	reserve	\$m	\$m
Balance at January 1, 2020		73	5	(1,295)	(23)	1,449	209
Comprehensive loss							
Net loss		-	-	-	-	(145)	(145)
Other comprehensive loss		-	-	-	(13)	-	(13)
Total comprehensive loss		-	-	-	(13)	(145)	(158)
Transactions recognised directly in equity							
Share-based payments		-	1	-	-	6	7
Balance at June 30, 2020		73	6	(1,295)	(36)	1,310	58
Balance at January 1, 2019		73	5	(1,295)	(32)	1,315	66
Comprehensive income							
Net income		-	-	-	-	141	141
Other comprehensive income		-	-	-	1	-	1
Total comprehensive income		-	-	-	1	141	142
Transactions recognised directly in equity							
IFRS 16 impact (adjustment to opening balance)		-	-	-	-	(2)	(2)
Share-based payments		-	-	-	-	1	1
Deferred taxation on share-based plans and IFRS 16		-	-	-	-	(2)	(2)
Balance at June 30, 2019		73	5	(1,295)	(31)	1,453	205

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

Condensed consolidated interim cash flow statement

For the six months ended June 30	Unaudited 2020 \$m	Unaudited 2019 \$m
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating (Loss)/Profit	(165)	163
Depreciation and amortization	10	9
Gain on disposal of right-of-use assets	(2)	-
Depreciation and impairment of right-of-use assets	4	4
Share-based payments	6	1
Impact from foreign exchange movements	1	(1)
Decrease in trade and other receivables	46	75
Increase in other assets	(57)	(39)
(Increase)/Decrease in inventories	(20)	8
Decrease in trade and other payables	(139)	(167)
Increase/(Decrease) in provisions	184	(8)
Cash (used in)/generated from operations	(132)	45
Interest paid	(9)	(9)
Interest received	6	11
Taxes (paid)/refunded	(13)	25
Net cash (outflow)/inflow from operating activities	(148)	72
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	-	(2)
Net cash outflow from investing activities	-	(2)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of borrowings	(2)	(2)
Payment of lease liabilities	(3)	(4)
Proceeds from the issuance of ordinary shares	1	-
Net cash outflow from financing activities	(4)	(6)
Net (decrease)/increase in cash and cash equivalents	(152)	64
Cash and cash equivalents at beginning of the period	1,060	924
Cash and cash equivalents at end of the period	908	988

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 and domiciled in the United Kingdom on September 26, 2014. 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 IAS 34, Interim Financial Reporting. The financial information herein has been prepared in the basis of the accounting policies set out in the annual accounts of the Group for the year ended December 31, 2019 and should be read in conjunction with those annual accounts. The Group prepares its annual accounts in accordance with International Financial Reporting Standards (IFRS) and IFRS Interpretations Committee (IFRIC) interpretations as adopted by the European Union and the Companies Act 2006 (the Act) applicable to companies reporting under IFRS. In preparing these Condensed Financial Statements, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were applied in a consistent manner to the consolidated financial statements for the year ended December 31, 2019, with the exception of changes in estimates that are required in determining the provision for income taxes. Additionally, the Group reviewed the impact of COVID-19 on key business practices and further evaluated estimates used in judgmental accounting positions as a result of the Pandemic. The Group's review focused on disruptions to the supply chain, inventory obsolescence, impact on cash flows (Going Concern), impairment of finite-lived intangible assets, impairment of fixed assets and expected credit loss provisions for trade receivables.

The Group has adopted the following standards as of January 1, 2020, which had no material impact on the Condensed Financial Statements. The IASB issued amendments to IFRS 9 *Financial Instruments*, IAS 39 *Financial Instruments: Recognition and Measurement* and IFRS 7 *Financial Instruments: Disclosures*. These standards relate to interbank offered rates (IBORs) reform. The replacement of benchmark interest rates such as LIBOR and other IBORs is a priority of global regulators. The amendments provide relief from applying specific hedge accounting requirements to hedge relationships directly affected by IBOR reform and have the effect that IBOR reform should generally not cause hedge accounting to terminate. As discussed in Note 8, the Group's term Loan matures after publication of LIBOR is expected to end. The Group has engaged with the administrative agent and expect to work with other market participants in the transition to a reasonable substitute base rate. Other standards were issued and adopted by the Group on January 1, 2020 which had no impact on the Condensed Financial Statements.

The Condensed Financial Statements do not include all the information and disclosures required in the annual financial statements and should be read in conjunction with the Group's annual financial statements as at December 31, 2019. These Condensed Financial Statements have been reviewed and not audited. These Condensed Financial Statements were approved for issue on July 29, 2020.

As disclosed in Notes 9 and 11, the Group carries a provision of \$624m (FY19: \$438m) for Department of Justice (DOJ) and related matters. Substantially all of this amount relates to the agreement with the DOJ and the Federal Trade Commission to resolve the Group's criminal and civil liability in connection with the indictment and related matters, which is pending final judicial approval in the Western District of Virginia scheduled for October 2020. In the very remote instance the agreement is not approved and a trial ensues, the potential of an unfavorable outcome in combination with potential exclusion from participating in US federal healthcare programs, would negatively impact the financial position and long-term viability of the Group including the ability to comply with debt covenants. Therefore, this remains a risk to the Group until the agreement is formally accepted by the Court in October. Reasonably possible impacts on the Group from the COVID-19 pandemic, failure of SUBLOCADE® and PERSERIS® to meet revenue growth expectations and/or lower than forecast revenue of SUBOXONE® Film have also been considered as part of the Group's adoption of the going concern basis. A combination of the above risks, specifically the status of the DOJ agreement, indicate the existence of a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern. However, the Directors believe the Group has sufficient liquidity and the ability to carry out any further measures that may be necessary for the Group to continue as a going concern for at least the next twelve months. The Condensed Financial Statements do not include the adjustments that would result if the Group were unable to continue as a going concern.

The financial information contained in this document does not constitute statutory accounts as defined in section 434 and 435 of the Act. For the Group's financial statements for the year ended December 31, 2019, the auditors issued (1) an emphasis of matter dealing with the outcome of litigation matters, details of which are included above and in Notes 9 and 11; and (2) a material uncertainty related to going concern dealing with the existence of a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern in relation to the Group's litigation matters, which may be further adversely affected by the failure of SUBLOCADE and PERSERIS to meet revenue growth expectations and/or lower than forecast revenue of SUBOXONE Film. The Group's statutory financial statements for the year ended December 31, 2019 were approved by the Board of Directors on March 5, 2020 and delivered to the Registrar of Companies House on June 29, 2020.

2. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker ('CODM'). The CODM, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer (CEO). The Group is predominantly engaged in a single business activity, which is the development, manufacture and sale of buprenorphine-based prescription drugs for treatment of opioid dependence and related disorders. The CEO reviews net revenues to third parties, operating expenses by function, and financial results on a consolidated basis for evaluating financial performance and allocating resources. Accordingly, the Group operates in a single reportable segment.

Net revenues

Revenues are attributed to countries based on the country where the sale originates. The following table represents net revenues from continuing operations and non-current assets, net of accumulated depreciation and amortization, by region. Non-current assets for this purpose consist of intangible assets, property, plant and equipment, right-of-use assets and other assets. Net revenues and non-current assets for the three and six months to June 30, 2020 and 2019 were as follows:

Net revenues from sale of goods:

	Q2 2020	Q2 2019	H1 2020	H1 2019
	\$m	\$m	\$m	\$m
For the three and six months ended June 30				
United States	107	163	211	362
ROW	43	52	92	92
Total	150	215	303	454

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

	Q2 2020	Q2 2019	H1 2020	H1 2019
	\$m	\$m	\$m	\$m
For the three and six months ended June 30				
SUBLOCADE	29	17	58	28
Sublingual/Other	121	198	245	426
Total	150	215	303	454

Non-current assets:

	Jun 30, 2020 \$m	Dec 31, 2019 (restated) \$m
United States	168	118
ROW	118	134
Total	286	252

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

3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

	Q2 2020	Q2 2019	H1 2020	H1 2019
	\$m	\$m	\$m	\$m
For the three and six months ended June 30				
Research and development expenses	(8)	(13)	(19)	(25)
Marketing, selling and general expenses	(36)	(43)	(110)	(86)
Administrative expenses ¹	(59)	(41)	(288)	(107)
Depreciation and amortization	(4)	(3)	(10)	(9)
Total	(99)	(87)	(408)	(202)

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

Exceptional Items

Where significant expenses or income that do not reflect the Groups, ongoing operations are incurred during the year, these items are disclosed as exceptional items in the income statement. Examples of such items could include restructuring and 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 operating costs and expenses information:

	Q2 2020	Q2 2019	H1 2020	H1 2019
For the three and six months ended June 30	\$m	\$m	\$m	\$m
Cost of sales ¹	1	-	(6)	-
Restructuring costs ²	-	(1)	(2)	(20)
Legal Expenses/Provision ³	-	-	(183)	(8)
Total exceptional items before taxes	1	(1)	(191)	(28)
Tax on exceptional items	-	-	32	4
Total exceptional items	1	(1)	(159)	(24)

¹\$6m of exceptional cost of sales relate to inventory provisions due to the adverse impact of COVID-19 on the business in H1 2020. \$1m of exceptional benefit recorded in Q2 2020 relates to the release of inventory provisions previously established in Q1 2020.

²Restructuring costs in H1 2020 and H1 2019 relate to the cost saving initiatives to offset the financial impact of recent adverse U.S. market developments. These consist primarily of lease disposals and termination costs (in H1 2020) and supply chain restructuring (in H1 2019). These are included in SG&A.

³\$183m of legal provision recognized in H1 2020 relates predominantly to the DOJ. \$8m of legal expenses in the H1 2019 relate to potential redress for ongoing intellectual property related litigation with DRL and Alvogen Pharmaceuticals. These are included within SG&A.

4. ADJUSTED RESULTS

The board and management team use adjusted results and measures to give greater insight to the financial results of the Group and the way it is managed. The tables below show the list of adjustments between the reported and adjusted gross profit, operating profit and net income for both Q2/H1 2020 and Q2/H1 2019. Refer to Note 3 for more information on exceptional items.

Reconciliation of gross profit to adjusted gross profit

	Q2 2020	Q2 2019	H1 2020	H1 2019
For the three and six months ended June 30	\$m	\$m	\$m	\$m
Gross profit	132	188	262	390
Exceptional cost of sales	(1)	-	6	-
Adjusted gross profit	131	188	268	390

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

	Q2 2020	Q2 2019	H1 2020	H1 2019
For the three and six months ended June 30	\$m	\$m	\$m	\$m
Operating profit/(loss)	25	88	(165)	163
Exceptional cost of sales	(1)	-	6	-
Exceptional selling, general and administrative expenses	-	1	185	28
Adjusted operating profit	24	89	26	191

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

	Q2 2020	Q2 2019	H1 2020	H1 2019
For the three and six months ended June 30	\$m	\$m	\$m	\$m
Profit/(loss) before taxation	20	89	(171)	166
Exceptional cost of sales	(1)	-	6	-
Exceptional selling, general and administrative expenses	-	1	185	28
Adjusted profit before taxation	19	90	20	194

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

	Q2 2020	Q2 2019	H1 2020	H1 2019
For the three and six months ended June 30	\$m	\$m	\$m	\$m
Net income/(loss)	18	75	(145)	141
Exceptional cost of sales	(1)	-	6	-
Exceptional selling, general and administrative expenses	-	1	185	28
Tax benefit on exceptional items	-	-	(32)	(4)
Adjusted net income	17	76	14	165

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. Where appropriate, permanent items are not included in determining the annual effective tax rate, but instead are dealt with in the interim periods in which they arise. The resulting expense is allocated between current and deferred taxes based upon the forecasted full year ratio.

In the six months ended June 30, 2020, the reported total tax benefit was \$26m, or a rate of 15% (H1 2019 tax charge: \$25m, 15%). The tax expense on adjusted profits amounted to \$6m excluding exceptionals (H1 2019: \$29m) and represented a year to date effective tax rate of 27% (H1 2019: 15%).

The current year tax benefit on exceptional items of \$32m (H1 2019 \$4m) reflects the portion of future provision payments that are expected to be deductible, using the currently enacted income tax rates for the jurisdiction. The amount of deductibility and possible filing positions will be clarified upon sentencing and as related matters are settled.

The increase in the adjusted effective tax rate was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the quarter. The full year rate is expected to be in line with guidance in the mid to upper teens.

The Group's balance sheet at June 30, 2020 included a current tax receivable of \$2m, current tax payable of \$55m (FY 2019: \$39m), and deferred tax asset of \$87m (FY 2019: \$40m). The increase in the current tax payable is partly due to deferral on timing of tax payments due to US Government temporary stimulus measures. The increase in the deferred tax asset is due to current year activity, including the tax benefit on the exceptional provision.

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 UK decision to withdraw from the European Union ('EU') may have a material effect on our taxes. Whilst the UK left the EU on January 31, 2020, the impact of the withdrawal will not be known until both the EU and the UK develop the exit plan and the related changes in tax laws are enacted. The UK has entered into a transition period and has until December 31, 2020 to negotiate and conclude additional arrangements. We will adjust our current and deferred income taxes when tax law changes related to the UK withdrawal are substantively enacted and/or when EU law ceases to apply in the UK.

The main rate of UK corporation tax was reduced to 19% from 1 April 2017. Further reductions were enacted by Finance Act 2016 to reduce the corporation tax rate to 17% from 1 April 2020. On 11 March 2020, the Chancellor announced that from 1 April 2020 the corporation tax rate will remain at 19%. This new law was substantively enacted on 17 March 2020.

6. EARNINGS PER SHARE

	Q2 2020	Q2 2019	H1 2020	H1 2019
	cents	cents	cents	cents
For the three and six months ended June 30				
Basic earnings per share	2	10	(20)	19
Diluted earnings per share	2	10	(20)	19
Adjusted basic earnings per share	2	10	2	23
Adjusted diluted earnings per share	2	10	2	22

Basic

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

Diluted

Diluted earnings per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. The Company has dilutive potential ordinary shares in the form of stock options and awards. The weighted average number of shares is adjusted for the number of shares granted assuming the exercise of stock options.

	2020 thousands	2019 thousands
Weighted average number of shares		
On a basic basis	732,208	729,724
Dilution from share awards and options	40,968	26,504
On a diluted basis	773,176	756,228

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. OTHER ASSETS

	Jun 30 2020 \$m	Dec 31 2019 \$m
Long-term prepaid expenses	20	23
Other non-current assets	108	50
Total	128	73

Long-term prepaid expenses relate primarily to payments for contract manufacturing capacity and other non-current assets relate to surety bonds. The increase in other non-current assets relates to surety bond underwriting (see Note 11).

8. FINANCIAL LIABILITIES – BORROWINGS

	Jun 30 2020 \$m	Dec 31 2019 \$m
Current		
Bank loans	(4)	(4)
	(4)	(4)
Non-current		
Bank loans	(232)	(233)
	(232)	(233)
Analysis of net cash		
Cash and cash equivalents	908	1,060
Borrowings*	(237)	(239)
	671	821

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

	Jun 30 2020 \$m	Dec 31 2019 \$m
Reconciliation of net cash		
The movements in the period were as follows:		
Net cash at beginning of period	821	681
Net (decrease)/increase in cash and cash equivalents	(152)	136
Net repayment of borrowings	2	4
Net cash at end of period	671	821

Net cash is presented as it is relevant to our Term Loan maximum leverage ratio. These do not include lease liabilities of \$48m (FY 2019: \$56m).

At June 30, 2020, the term loan was trading at approximately 87% 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 June 30, 2020 are as follows:

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

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

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

9. PROVISIONS

	Jun 30 2020 \$m	Dec 31 2019 \$m
DOJ and related matters	(624)	(438)
Intellectual property related matters	(46)	(45)
Restructuring costs	(1)	(2)
Other	(3)	(3)
Total	(674)	(488)

The Group is involved in legal and intellectual property disputes as described in Note 11, “Legal Proceedings.” On July 24, 2020, the Group reached an agreement with the DOJ and other litigants, subject to approval by a federal judge, described in Note 11 under “DOJ and Related Matters” to resolve the investigation of alleged charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE Film and/or SUBOXONE Tablet by certain physicians. Under the agreement, the Group will make a payment of \$100 million the week the plea is finalized and approved by a judge. Subsequently, six annual instalments of \$50 million will be due every January 15 from 2022 to 2027. The final instalment of \$200 million will be due on December 15, 2027. Provisions have also been made for other related matters. The provision has been recorded at the net present value of the estimated payments.

The Group also carries provisions totaling \$46m (FY19: \$45m) for intellectual property related matters, all of which relate to potential redress for ongoing intellectual property litigation with DRL and Alvogen.

10. CONTINGENT LIABILITIES

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

11. LEGAL PROCEEDINGS

DOJ and Related Matters

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

- The Group has reached an agreement with the United States Department of Justice (Justice Department), the Federal Trade Commission (“FTC”), and U.S. state attorneys general to resolve the criminal and civil liability in connection with a multi-count indictment brought in April 2019 by a grand jury in the Western District of Virginia, a civil lawsuit joined by the Justice Department in 2018, and an FTC investigation. Under the terms of the agreement, Indivior Solutions Inc. (“Solutions Inc.”), a wholly owned subsidiary of Indivior PLC, has pleaded guilty to a single count of making a false statement relating to health care matters in 2012 in violation of 18 U.S.C. Section 1035. Indivior will make payments to federal and state authorities totalling \$600 million (plus applicable interest of 1.25 %) over a period of seven years, has agreed to a stipulated injunction with the FTC, and entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services (HHS). Under the terms of the agreement, the Justice Department will move to dismiss all other charges upon judicial approval of the agreements and sentencing.
- Under the terms of a related agreement with the HHS, Solutions Inc. will be excluded from participating in government health programs. This exclusion will not apply to any other entities within the Group. The Group does not anticipate the exclusion of Solutions Inc. will have any material impact on the Group’s ability to continue to participate in government health programs.
- Under the agreement, the Group will make a payment of \$100 million the week the plea is finalized and approved by a judge. Subsequently, six annual instalments of \$50 million will be due every January 15 from 2022 to 2027. The final instalment of \$200 million will be due on December 15, 2027. The Group carries a provision of \$624 million (FY19: \$438 million) for Department of Justice and related matters.
- 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 and annual Board and CEO certifications submitted to the U.S. Attorney’s Office. In addition, the Group will be subject to monitoring by an Independent Review Organization, who will submit audit findings to HHS-OIG, and review by a Board Compliance Expert, who will prepare two compliance assessment reports in the first and third reporting periods of the Corporate Integrity Agreement. See Risk Factors on page 7.
- The agreement is subject to approval by a federal judge.

- Prior to the settlement, the parties reached agreement on an Agreed First Protective Order, which was entered by the court on February 26, 2020. The Agreed First Protective Order requires Indivior to seek court approval prior to engaging in various transactions outside in the ordinary course of business with a value of more than \$5m or that would reduce cash and cash equivalents below \$600m, as well as other relief. Indivior is authorized to continue engaging in ordinary course transactions related to intercompany obligations, payments made in accordance with its secured credit obligations, payments to goods and service vendors, payments of employee and related costs, and other similar transactions consistent with Indivior's ordinary past practices. The Agreed First Protective Order is expected to be in place until judicial approval of the agreements and sentencing.

Federal FCA Qui Tam Suits

- On August 2, 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, with some of the cases also alleging retaliation claims. Indivior believes it has strong defenses to the government's charges and will vigorously defend itself. Indivior is aware of additional claims regarding similar allegations.

State and Local Matters

- On October 12, 2016, Indivior was served with a subpoena for records from the State of Connecticut Office of the Attorney General under its Connecticut civil false claims act authority. The subpoena requests documents related to the Group's marketing and promotion of SUBOXONE products and its interactions with a non-profit third-party organization. The Group has fully cooperated in this civil investigation.
- On November 16, 2016, Indivior was served with a subpoena for records from the State of California Department of Insurance under its civil California insurance code authority. The subpoena requests documents related to SUBOXONE® Film, SUBOXONE® Tablet, and SUBUTEX® Tablet. The State of California served additional deposition subpoenas on Indivior in 2017 and served a subpoena in 2018 requesting documents relating to the bioavailability / bioequivalency of SUBOXONE Film, manufacturing records for the product and its components, and the potential to develop dependency on SUBOXONE Film. The Group has fully cooperated in this civil investigation and is in discussions aimed toward resolving the matter.
- In June 2019, the Group learned that the State of Illinois Insurance Department is investigating potential violations of its civil Insurance Claims Fraud Prevention Act with respect to sales and marketing activity by the Company. The Group is in discussions aimed toward resolving this matter.
- 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.

FTC investigation

- Indivior Inc. and the U.S. Federal Trade Commission (FTC) have agreed to resolve the FTC's pending investigation, contingent upon judicial approval by the U.S. District Court for the Western District of Virginia of the agreements to resolve 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 the FTC investigation. The FTC has filed a complaint against Indivior Inc. alleging monopolization in violation of 15 U.S.C. § 45(a). FTC and Indivior Inc. then filed a joint motion asking the Court (subject to the above contingency) to enter a stipulated injunction. Under the injunction, if entered by the Court, among other terms (as detailed in the text of the proposed injunction on file with the U.S. District Court for the Western District of Virginia): (a) Indivior Inc. will be required to make specified disclosures to the FTC and will be prohibited from certain conduct, (b) the FTC will receive \$10 million from the payments required by the agreement with the Department of Justice, and (c) the FTC's complaint will be dismissed with prejudice. The joint motion also asks — if the Court does not accept and implement the agreement with the Department of Justice — that the Court reject the injunction and dismiss the FTC's complaint without prejudice.

False Claims Act Allegations

- On August 2, 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 the Company, and other entities, 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 Company has not been served with the complaint. We are in discussions regarding this matter with the plaintiff-relator.

Securities Class Action Litigation

- On April 23, 2019, Michael Van Dorp filed a putative class action lawsuit in the United States District Court for the District of New Jersey on behalf of holders of publicly traded Indivior securities alleging violations of U.S. federal securities laws under the Securities Exchange Act of 1934. The complaint names Indivior PLC, Shaun Thaxter, Mark

Crossley and Cary J. Claiborne as defendants. On July 30, 2019, the Court granted Mr. Van Dorp's motion for appointment as lead plaintiff on behalf of the putative class. On September 30, 2019, following his appointment as lead plaintiff on behalf of the putative class, Mr. Van Dorp filed an amended complaint on behalf of the putative class. On November 29, 2019, the Defendants filed a motion to dismiss the amended complaint. Plaintiff filed its opposition to the motion on January 28, 2020, and Defendants' filed their reply on February 27, 2020. A decision on the motion is still pending.

The Group carries a provision for DOJ and related matters of \$624m (FY19: \$438m). This provision was determined based upon the terms of the agreement and the Group's best estimate related to others matters in accordance with IFRS. The Group cannot predict with any certainty whether it will reach an ultimate resolution with all of the parties to the other matters discussed above.

Intellectual Property Related Matters

ANDA Litigation

- On August 31, 2017, the United States District Court for the District of Delaware found that asserted claims of the '150 Patent, U.S. Patent No. 8,900,497 ("the '497 Patent") and the '514 Patent are valid but not infringed by Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories Inc. (collectively, "DRL"). Indivior appealed the rulings as to the '514 and '150 patents, and on July 12, 2019, the CAFC upheld the District Court ruling, finding the patents not invalid but also not infringed by DRL. DRL requested that the District of Delaware award its attorneys' fees and costs, and Indivior opposed that request. A hearing on DRL's request took place on February 12, 2020. On April 23, 2020, the court issued an opinion denying DRL's motion for attorneys' fees, and on April 27, 2020, the clerk of court denied DRL's request for costs.
- Litigation against DRL is currently pending in the District of New Jersey regarding the '454 and '305 Patents. DRL received final FDA approval for all four strengths of its generic buprenorphine/naloxone film product on June 14, 2018, and immediately launched its generic buprenorphine/naloxone film product "at-risk." On July 13, 2018, the District Court issued a ruling granting Indivior a Preliminary Injunction (PI) pending the outcome of a trial on the merits of the '305 Patent. Indivior was required to post a surety bond for \$72 million in connection with the PI. On November 20, 2018, the CAFC issued a decision vacating the PI against DRL. Indivior's motion for rehearing and rehearing en banc was denied on February 4, 2019, and the mandate issued on February 19, 2019. DRL is no longer prevented from selling, offering to sell, or importing their generic buprenorphine/naloxone sublingual film products. DRL has re-launched its generic product, and any sales in the U.S. are on an "at-risk" basis, subject to the outcome of the ongoing litigation in the District of New Jersey. On June 18, 2019, DRL filed a motion for leave to file their first amended Answer, Affirmative Defenses, and Counterclaims to add counterclaims for anticompetitive conduct by Indivior in violation of federal antitrust laws and for recovery against Indivior's sureties for damages resulting from the injunction that was issued against DRL. The motion was granted by the Magistrate Judge on November 20, 2019. Indivior appealed that ruling to the District Court Judge on December 4, 2019 and a decision is pending with the court. On July 24, 2020, Indivior submitted a letter to the District Court seeking leave to file a motion for summary judgment on the antitrust counterclaims, which if granted, would moot the appeal. The Court held a claim construction hearing on October 17, 2019, and entered its ruling on November 5, 2019. In light of the claim construction, the parties filed a Stipulated Order and Judgment of non-infringement on the '305 Patent, which was entered by the Court on January 7, 2020. On January 21, 2020, DRL filed a motion requesting the entry of final partial judgment of noninfringement of the '305 Patent pursuant to Federal Rule of Civil Procedure 54(b), which Indivior opposed. That motion is pending with the court.
- On November 13, 2018, DRL filed two separate petitions for inter partes review ("IPR") of the '454 Patent with the USPTO. The USPTO denied institution of one of the IPR petitions but granted institution for the second IPR petition. Oral argument took place on March 3, 2020. The Patent Trial and Appeal Board (USPTO) issued a decision on June 2, 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 filed a Notice of Appeal to the Court of Appeals for the Federal Circuit on July 24, 2020.
- Teva Pharmaceuticals USA, Inc. ("Teva") filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of buprenorphine/naloxone film (CASSIPA™). Indivior, Aquestive Pharmaceuticals (formerly known as MonoSol Rx) and Teva agreed that infringement of the '514, '497, and '150 patents by Teva's 16mg/4mg dosage strength would be governed by the infringement ruling as to DRL's 8mg/2mg dosage strength that was the subject of the trial in November 2016. Accordingly, the non-infringement ruling by the District of Delaware in the DRL case means that the Teva 16mg/4mg dosage strength has been found not to infringe those patents. Indivior appealed the November 2016 DRL ruling as to the '514 and '150 patents, and on July 12, 2019, the CAFC upheld the District Court finding of noninfringement. Teva received final approval from the FDA for CASSIPA on September 7, 2018 and has agreed to be bound by the decision in the District of New Jersey DRL case for the '454 and '305 Patents. Teva was therefore able to launch CASSIPA at-risk as of February 19, 2019, when the CAFC issued a mandate vacating the PI against DRL. Any sales of CASSIPA in the U.S. would be on an "at-risk" basis, subject to the outcome of the ongoing litigation against Teva and DRL in the District of New Jersey.

- Trial against Alvogen Pine Brook, Inc. (“Alvogen”) in the lawsuit involving the ’514 and ’497 Patents took place in September 2017. The trial was limited to the issue of infringement because Alvogen did not challenge the validity of either patent. On March 22, 2018, the United States District Court for the District of Delaware ruled both patents were not infringed by Alvogen. Indivior appealed this ruling, and on July 12, 2019, the CAFC upheld the noninfringement judgments. Alvogen requested that the District of Delaware award it attorneys’ fees and costs. Indivior opposed Alvogen’s request for fees but agreed to pay a portion of Alvogen’s costs. A hearing on Alvogen’s request for fees took place on February 12, 2020. On April 23, 2020, the court issued an opinion denying Alvogen’s motion for attorneys’ fees.
- Litigation against Alvogen is pending in the United States District Court for the District of New Jersey regarding the ’454 and ’305 Patents. On January 22, 2019, Indivior filed a motion for a temporary restraining order (“TRO”) and preliminary injunction in the District of New Jersey, requesting that the Court restrain the launch of Alvogen’s generic buprenorphine/naloxone film product until a trial on the merits of the ’305 Patent. Alvogen received approval for its generic product on January 24, 2019. The same day, the District of New Jersey granted a TRO until February 7, 2019. On January 31, 2019, Indivior and Alvogen entered in to an agreement whereby Alvogen was enjoined from the use, offer to sell, or sale within the United States, or importation into the United States, of its generic buprenorphine and naloxone sublingual film product unless and until the CAFC issued a mandate vacating the PI against DRL. The mandate vacating the DRL PI issued on February 19, 2019, and Alvogen launched its generic product. Any sales in the US are on an “at-risk” basis, subject to the ongoing litigation against Alvogen in the District of New Jersey. On June 21, 2019, Alvogen filed a motion for recovery on the bond for improper restraints and asked that the court set a schedule for an accounting of damages. This motion was denied on November 5, 2019. On August 9, 2019, Alvogen filed a motion for leave to file an amended Answer to Complaint and Separate Defenses and Counterclaims to add counter claims alleging anticompetitive conduct by Indivior in violation of federal and state antitrust laws. The motion was granted by the Magistrate Judge on November 20, 2019. Indivior appealed that ruling to the District Court Judge on December 4, 2019, and a decision is pending with the court. The Court held a claim construction hearing on October 17, 2019, and the Court entered its ruling on November 5, 2019. In light of the claim construction, the parties filed a Stipulated Order and Judgment of non-infringement on the ’305 Patent, which was signed by the Court on January 9, 2020. On January 24, 2020, Alvogen filed a motion requesting the entry of final partial judgment of noninfringement of the ’305 Patent pursuant to Federal Rule of Civil Procedure 54(b). Indivior and Alvogen subsequently agreed that they would be bound by the ruling on DRL’s similar motion, which Indivior opposed. That motion is pending with the court.

Teva Opposition to SUBLOCADE European Patent

- On October 10, 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. Teva alleges the claims of EP 874 lack novelty and inventive step, and extend beyond the content of the application as originally filed. Oral hearings originally scheduled for March 2020 were postponed due to the coronavirus pandemic. A new hearing date has now been set for November 2, 2020.

Antitrust Litigation and Consumer Protection

- Civil antitrust claims have been filed by (a) a class of direct purchasers, (b) a class of end payor plaintiffs, and (c) a group of states, now numbering 41, and the District of Columbia. Each set of plaintiffs filed generally similar claims alleging, among other things, that Indivior violated U.S. federal and/or state antitrust and consumer protection laws in attempting to delay generic entry of alternatives to SUBOXONE Tablets. Plaintiffs further allege that Indivior unlawfully acted to lower the market share of these products. These antitrust cases are pending in federal court in the Eastern District of Pennsylvania. Pre-trial proceedings were coordinated. The fact and expert discovery periods have closed. On September 27, 2019, the court certified a class of direct purchasers of branded SUBOXONE Tablets. The same day, the court also certified, with respect to specified issues, a class of end-payor plaintiffs. The court denied certification of a putative “nationwide injunctive class” of end-payor plaintiffs. On November 4, 2019, the Court of Appeals for the Third Circuit granted Indivior’s petition for permission to appeal the certification of the direct purchaser class, but affirmed the certification of the direct purchaser class on July 28, 2020. Scheduling for submissions of summary judgment motions and for trial have not yet 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 In re Suboxone, MDL No. 2445 (E.D. Pa.). The Carefirst case remains pending.
- On May 29, 2018, the Company 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.

- On July 1, 2019, the Indiana Attorney General issued a Civil Investigative Demand investigating potential violations of Indiana's Civil Deceptive Consumer Sales Act with respect to sales and marketing activity by the Company. The Group is cooperating fully in this civil investigation.
- On June 30, 2020, Blue Cross and Blue Shield of Massachusetts, Inc., and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. ("BCBSMA") sent a demand letter to Indivior Inc. and Indivior PLC. The demand letter alleges that Indivior violated M.G.L. ch93A, § 9 by, among other things, initiating a "product hop" from Suboxone Tablets to Suboxone Film, engaging in illegal marketing tactics, causing a delay in the approval of generic alternatives to Suboxone, illegally marketing off-label doses and uses of Suboxone, and engaging in unlawful kickbacks with physicians. BCBSMA has threatened to file a lawsuit if its demand is not met.

The Group has re-evaluated the antitrust and consumer protection 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.

Opioid Class Action Litigation

- As of July 15, 2020, Indivior has been named as a defendant in 333 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 (321) have been consolidated and are pending in a federal multi-district litigation ("MDL") in U.S. District Court for the Northern District of Ohio. Six (6) cases are pending before the Joint Panel on Multidistrict Litigation for anticipated transfer to the MDL. At the present time, litigation against Indivior in the MDL is stayed. There remain six (6) cases against Indivior pending in state courts located in Arizona, Missouri, Pennsylvania and Virginia. As it concerns these state court cases, litigation is currently proceeding against Indivior only in the Arizona and Virginia state courts. The Group is vigorously defending against these cases and has already filed Motions to Dismiss the complaints in both Arizona and Virginia. Oral arguments on the Motions to Dismiss are expected to take place sometime in late August-early September 2020. Given the status and preliminary stage of litigation in both the MDL and state courts, no estimate of a possible loss in these cases can be made at this time.

12. TRADE AND OTHER PAYABLES

	Jun 30 2020 \$m	Dec 31 2019 \$m
Sales returns and rebates	(365)	(460)
Trade payables	(23)	(39)
Accruals	(83)	(113)
Other tax and social security payables	(9)	(11)
Total	(480)	(623)

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

13. SHARE CAPITAL

	Equity Ordinary Shares	Nominal value paid per share	Aggregate nominal value \$m
Issued and fully paid			
At January 1, 2020	730,787,719	\$0.10	73
Allotments	1,648,454	\$0.10	-
At June 30, 2020	732,436,173		73

	Equity Ordinary Shares	Nominal value paid per share	Aggregate nominal value \$m
Issued and fully paid			
At January 1, 2019	728,441,653	\$0.10	73
Allotments	1,601,495	\$0.10	-
At June 30, 2019	730,043,148		73

Allotment of ordinary shares

During the period, 1,648,454 ordinary shares (2019: 1,601,495) 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 July 24, 2020, the Group announced it had reached an agreement with the DOJ and the FTC, and U.S. state attorneys general to resolve the Company's liability in connection with the Western District of Virginia indictment. The Group will make payments totaling \$600m over a period of seven years and entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services (HHS). Under the terms of the agreement, the Justice Department will move to dismiss all charges returned by a grand jury in April 2019. Under the agreement, the Group will make a payment of \$100 million the week the plea is finalized and approved by a judge. Subsequently, six annual instalments of \$50 million will be due every January 15 from 2022 to 2027. The final instalment of \$200 million will be due on December 15, 2027. The Group carries a provision of \$624m (FY19: \$438m) for Department of Justice and related matters (see Notes 9 and 11).

DIRECTORS' RESPONSIBILITY STATEMENT

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

- This condensed set of Interim Financial Statements, which have been prepared in accordance with IAS 34 "Interim Financial Reporting" as adopted by the European Union, 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 required pursuant to 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

By order of the Board

Mark Crossley
Chief Executive Officer

July 29, 2020

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 H1 2020 Results of Indivior PLC for the three and six month periods ended 30 June 2020. 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 adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Emphasis of matter – Outcome of litigation

Without modifying our conclusion on the interim financial statements, we draw your attention to Notes 9 and 11 that describe the litigation status with the U.S. Department of Justice (DoJ), Federal Trade Commission (FTC), and U.S. state attorneys general. On 24 July 2020, management reached a settlement agreement with these parties to resolve the Group's criminal and civil liability in connection with the indictment and related matters, which is subject to final judicial approval in the Western District of Virginia scheduled for October 2020. The Group carries a provision of \$624 million, substantially all of which relates to these matters. Until final approval is obtained, there remains a risk that, in the instance the agreement is not approved, and a trial ensues, the Group could face potential exclusion from participating in US federal healthcare programs or the final outcome of the settlement amount may be materially higher.

Emphasis of matter – Going Concern

In forming our conclusion on the interim financial statements, which is not modified, we have also considered the adequacy of the disclosure made in Notes 1, 9 and 11 that describe the litigation status of the ongoing negotiations with the DoJ, FTC and U.S. state attorneys general and other matters. The agreement with the DoJ, the FTC and U.S. state attorneys general to resolve the Group's criminal and civil liability in connection with the indictment and related matters is pending final judicial approval in the Western District of Virginia scheduled for October 2020.

In the instance the agreement is not approved, and a trial ensues, the outcome from the DoJ indictment is not expected to impact the Group during the going concern period over the next 12 months. However, the potential of an unfavourable outcome in combination with potential exclusion from participating in US federal healthcare programs would negatively impact the financial position and long-term viability of the Group including the ability to comply with debt covenants. Therefore, this remains a risk to the Group until the agreement is formally accepted by the Court in October 2020.

Reasonably possible impacts on the Group from the COVID-19 pandemic, failure of SUBLOCADE and PERSERIS to meet revenue growth expectations and/or lower than forecast revenue of SUBOXONE Film have also been considered as part of the Group's adoption of the going concern basis.

As explained in Note 1 to the interim financial statements, a combination of the above risks, specifically the status of the DoJ agreement, indicate the existence of a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern. However, the Directors believe the Group has sufficient liquidity and the ability to carry out any further measures that may be necessary for the Group to continue as a going concern for at least the next 12 months. The interim financial statements do not include the adjustments that would result if the Group were unable to continue as a going concern.

What we have reviewed

The interim financial statements comprise:

- the Condensed consolidated interim balance sheet as at 30 June 2020;
- the Condensed consolidated interim income statement and Condensed consolidated interim statement of comprehensive income for the three and six month periods then ended;
- the Condensed consolidated interim cash flow statement for the six month period then ended;
- the Condensed consolidated interim statement of changes in equity for the six month period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the H1 2020 Results have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

As disclosed in Note 1 to the interim financial statements, the financial reporting framework that has been applied in the preparation of the full annual financial statements of the Group is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union.

Responsibilities for the interim financial statements and the review

Our responsibilities and those of the Directors

The H1 2020 Results, including the interim financial statements, is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the H1 2020 Results in accordance with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express a conclusion on the interim financial statements in the H1 2020 Results based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority and for no other purpose. 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 H1 2020 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
29 July 2020