

May 2, 2019

- Q1 2019 Results and FY 2019 Guidance Announced.
- SUBLOCADE™ Performance on Track.
- Cash Improves.

Quarter to March 31	2019 (in \$m)	2018 (in \$m)	% change at actual FX	% change at constant FX
Net Revenue	238	255	-6%	-5%
Operating Profit	75	116	-35%	-33%
Net Income	66	93	-29%	-27%
EPS (cents per share)	9	13	-31%	-27%
Adjusted Operating Profit*	102	99	+3%	+6%
Adjusted Net Income*	89	78	+14%	+16%
Adjusted EPS* (cents per share)	12	11	+9%	+16%

\* Adjusted basis excludes the impact of exceptional item as referenced in Notes 3 and 4.

### Q1 Financial Highlights

- Net revenue of \$238m declined 6% (5% at constant currency). U.S. net revenue grew 2% as SUBOXONE® Film share loss (at lower rates than analogues<sup>1</sup>) was more than offset by underlying market growth, strong initial sell-in of the Group’s authorized generic film product and net revenue from SUBLOCADE™ (Q1 2019: \$11m). Rest of World net revenue declined (-34%) primarily due to one-time net revenue gains in Canada in the prior period.
- Reported operating profit was \$75m (Q1 2018: \$116m). On an adjusted basis, operating profit was \$102m, an increase of 3% (Adj. Q1 2018: \$99m) primarily reflecting a decrease in operating expenses (SG&A and R&D expenses combined).
- Net income was \$66m (Q1 2018: \$93m). On an adjusted basis, net income increased 14% to \$89m (Q1 2019: \$78m), primarily reflecting increased operating profit and net financing income.
- Cash balance was \$1,054m (FY 2018: \$924m). Net cash was \$812m (FY 2018: \$681m).

### Q1 Operating Highlights

- U.S. buprenorphine market growth continued at low double-digit levels; growth continues to be driven primarily by Government channels.
- SUBOXONE® Film market share averaged 48% and exited at 40% (FY 2018 avg. and exit: 53%). Share erosion since the “at-risk” launch of generic buprenorphine/naloxone film products in February 2019 has been lower than historical industry analogues<sup>1</sup>.
- Sandoz Inc. launched an Indivior authorized generic buprenorphine/naloxone film and captured the leading position among all generic film products exiting Q1 19.
- SUBLOCADE™ dispense yield now exceeds initial target rate of 50%; other SUBLOCADE™ key performance indicators (KPIs) continue to improve (see page 4).
- Indivior reiterates SUBLOCADE FY 2019 net revenue guidance of \$50m-\$70m.
- PERSERIS™ (risperidone) extended release injection was launched with a field force of 50 representatives; modest initial net revenue was consistent with the Group’s expectations.

<sup>1</sup> IMS Institute Report, January 2016; “Price Declines after Branded Medicines Lose Exclusivity in the U.S.”

### FY 2019 Guidance

- Net revenue is expected to be in the range of \$525m to \$575m and a net (loss) / income range of approximately (\$40m) to \$10m (excluding exceptional items and at constant exchange rates).
- Net revenue guidance assumes share erosion of SUBOXONE<sup>®</sup> Film<sup>2</sup> and the authorized generic film product at rates of observed analogues for the remainder of 2019.
- Previously-stated guidance elements maintained, namely SUBLOCADE<sup>™</sup> net revenue of between \$50m-\$70m and operating expense (SG&A and R&D combined) in the range of \$440m-\$460mm, inclusive of the current Legal Proceedings as described in Note 10 on pages 20-23.

### Department of Justice Action

- A U.S. federal criminal grand jury investigation of Indivior was initiated in December 2013, and includes marketing and promotion practices, pediatric safety claims, and overprescribing of medication by certain physicians.
- The U.S. Attorney's Office for the Western District of Virginia served a number of subpoenas relating to SUBOXONE<sup>®</sup> Film, SUBOXONE<sup>®</sup> Tablet, SUBUTEX<sup>®</sup> Tablet, buprenorphine and our competitors, among other issues. The Group responded to the subpoenas and otherwise cooperated fully with the Department and prosecutors.
- The Group was in advanced discussions with the Department of Justice (DOJ) about a possible resolution to its investigation until recently.
- In December 2018, the company first learned from U.S. Health and Human Services/Office of Inspector General (HHS/OIG) that the proposed resolution could likely result, in HHS/OIG's view, in exclusion. This represented a change in HHS/OIG's interpretation of its exclusion authority. This change, and HHS/OIG's view that the proposed plea by Indivior could result in exclusion from US federal healthcare programs, was confirmed by HHS/OIG during a meeting in January. These programs are material to the Group's revenue.
- The Group continued in dialogue with DOJ and HHS/OIG and, at the time of the FY 2018 results, believed that a resolution was still possible.
- In early April, it became clear that an alternative resolution with DOJ and HHS/OIG would be necessary. DOJ then did not give the Group sufficient time to negotiate any alternative resolution that would work under the new HHS/OIG interpretation.
- On April 9th, Indivior Inc. and Indivior PLC were indicted by a grand jury in the Western District of Virginia. DOJ is seeking the forfeiture of all assets derived from the commission of the alleged offenses, including but not limited to \$3 billion. The Group's external counsel has advised it has strong defences to the government's charges with which the Group will vigorously defend itself. However, an adverse outcome at trial could also result in the Group's exclusion from participating in U.S. Federal Health Care Programs.
- Because the Group remains open to resolving the matter, it maintains a \$438m provision substantially related to that purpose. Should the matter go to trial, the Group has been advised by counsel that in their view the provision is materially in excess of the fine, forfeiture, and/or restitution that would likely be incurred in an adverse outcome at trial.
- Please see Notes 8, 9, and 10 beginning on page 20 for further details on provisions and legal proceeding.

The Group recognizes that its stakeholders now face additional uncertainty arising from the Department of Justice's action. The Indivior Board of Directors has been extensively advised by external legal counsel that it has strong defences to the Department of Justice's allegations.

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<sup>2</sup> IMS Institute Report, January 2016; "Price Declines after Branded Medicines Lose Exclusivity in the U.S."

## Comment by Shaun Thaxter, CEO of Indivior PLC

“We are maintaining the focus and energy of our organization on executing the key elements of our strategy that we believe will return Indivior to growth beyond the transition period.

Towards that end, looking at the underlying business, Indivior delivered a solid performance in the first quarter of 2019 despite the “at-risk” launch of generic film competition to SUBOXONE®. Our share loss to date has been lower than suggested by historic industry analogues<sup>3</sup> and we have also benefited from strong early shipments of our authorized generic. While this represents an encouraging operational start to the year, we continue to prudently assume that we will face an accelerated pace of share erosion in the coming quarters.

Recognising the foregoing factors, we are introducing FY 2019 financial guidance. A key element of guidance is of course the performance of SUBLOCADE™, our new monthly buprenorphine extended-release injection, and here we made good progress in executing our plans: Q1 net revenue of \$11m puts us on track to meet our FY 2019 guidance for net revenue of \$50m-\$70m. We continue to believe SUBLOCADE™ to be a transformational treatment for opioid dependence and we will not be distracted in our efforts to bring this important new option to patients in the US. Separately, while not a material contributor to our full-year guidance, we are nonetheless encouraged by the initial market reception to PERSERIS™, our monthly risperidone injection for schizophrenia, which we launched towards the end of the first quarter.

Looking ahead, we do not underestimate the amount of work we still have to do. However, we remain undaunted in the pursuit of our Vision to improve the lives of patients suffering from addiction and its co-occurring disorders. We appreciate the continued resilience of our employees and their dedication to our Vision. Through the evolution of our business, we are continuing to invest in enhancing our already-strong capabilities and compliance.

Our first-quarter performance only strengthens our confidence that we are putting the building blocks in place for a return to sustained growth, led by SUBLOCADE™ and PERSERIS™, and I look forward to reporting our progress throughout the year.”

## Operating Review

### US Market Update

The market for buprenorphine products continued to grow at low double-digit rates in Q1 2019 versus the comparable quarter in 2018. The U.S. continues to benefit from legislative changes that have expanded OUD treatment funding and treatment capacity. In addition, there continues to be increased overall public awareness of the opioid epidemic. Both the number of physicians waived to administer medication-assisted treatment and those able to treat to the new permitted level of 275 patients (from 100 patients) continued to grow in Q1 2019. The number of waived nurse practitioners and physician assistants also continued to grow in Q1 2019.

On February 19, 2019, the market for generic buprenorphine/naloxone sublingual 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). There are currently four generic buprenorphine/naloxone sublingual film products in the market: “at-risk” launches from both DRL and Alvogen and two additional generic film offerings, Mylan N.V. and Indivior’s authorized generic buprenorphine/naloxone sublingual film product that was launched by its marketing partner, Sandoz Inc.

As a result of the launch of generic buprenorphine/naloxone sublingual film products, branded SUBOXONE® Film experienced significant market share loss in Q1 2019, albeit at a lower rate than suggested by industry

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<sup>3</sup> IMS Institute Report, January 2016; “Price Declines after Branded Medicines Lose Exclusivity in the U.S.

analogues<sup>4</sup>. SUBOXONE® Film market share exiting Q1 2019 was 40% versus Q1 2018 exit share of 55%. Overall commercial formulary access remains solid for SUBOXONE® Film. Looking ahead, the Group prudently assumes that the pace of market share loss will intensify for branded SUBOXONE® Film, ultimately resulting in a branded market share position in-line with industry analogues<sup>4</sup>. Industry analogues<sup>4</sup> suggest these levels could reach an erosion rate of 70% in the coming months and 90% by the end of FY 2019, however, the timing for reaching these levels is unknown at this point.

As the leader and innovator in the OUD category, Indivior has launched its monthly buprenorphine depot SUBLOCADE™. The Group is making good progress in the following KPIs that it believes will drive accelerated net revenue growth for SUBLOCADE™ in pursuit of its \$1 billion-plus peak net revenue goal:

SUBLOCADE™ Prescription Journey Timeline KPIs (3/31/19 vs. 12/31/18):

- Formulary Access – reached targeted levels, exiting Q1 at 85%.
- The Prescription Journey – reached targeted levels, exiting Q1 at 14 to 20 days.
- The Dispensing Yield Rate – increased to 51% (based on a 91% closed case rate) from 45%.

SUBLOCADE™ Demand KPIs (3/31/19 vs. 12/31/18):

- HCPs Initiating a Prescription Journey – increased to 2,930 versus 2,430.
- HCPs Administered SUBLOCADE™ – increased to 1,745 versus 1,325.
- HCPs Administered SUBLOCADE™ to 5-plus patients increased to 415 versus 232.

### Financial Performance in Q1 2019

Total net revenue in Q1 2019 decreased 6% to \$238m (Q1 2018: \$255m) at actual exchange rates (-5% at constant exchange rates).

U.S. net revenue increased 2% to \$200m (Q1 2018: \$197m). Overall volume was ahead of last year, reflecting low double-digit market growth, primarily from continued strength in government channels. Underlying market expansion, along with lower than expected share loss from SUBOXONE® Film, strong initial sell-in of the Group's authorized generic buprenorphine/naloxone film and growing SUBLOCADE™ net revenue (Q1 19: \$11m) were the principal drivers of the year-over-year increase in U.S. net revenue.

Rest of World net revenue decreased 34% at actual exchange rates (-27% at constant exchange rates) to \$38m (Q1 2018: \$58m). Growth in Australasia was more than offset by expected volume and pricing impacts from ongoing austerity measures in certain European markets. In addition, net revenue comparisons for Canada were impacted by one-time in nature benefits in the year-ago period related to a temporary unavailability of generic buprenorphine/naloxone tablets that resulted in higher SUBOXONE® Film net revenue.

Gross margin was 84% (Q1 2018: 91%). The decline in gross margin was principally due to unfavourable product mix related to initial sell-in of the Group's authorized generic buprenorphine/naloxone film.

SG&A expenses as reported were \$114m (Q1 2018: \$99m). Q1 2019 SG&A expenses included exceptional costs of \$27m. The exceptional costs comprised of \$19m primarily related to supply chain restructuring and \$8m related to potential redress for ongoing intellectual property litigation. Q1 2018 SG&A expenses included a \$17m exceptional gain from the out-licensing of the intranasal naloxone opioid overdose patents.

On an adjusted basis Q1 2019 SG&A expenses declined 25% to \$87m (Adj. Q1 2018: \$116m). The decline largely reflects savings from streamlining actions, including significant headcount reduction actions that have already been taken.

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<sup>4</sup> IMS Institute Report, January 2016; "Price Declines after Branded Medicines Lose Exclusivity in the U.S."

R&D expenses decreased by 25% to \$12m (Q1 2018: \$16m). The decrease primarily reflects lower clinical activity and the reprioritization of R&D activities principally to support SUBLOCADE™ Health Economics and Outcomes Research (HEOR) and post-marketing study commitments for SUBLOCADE™ and PERSERIS™.

Operating profit as reported was \$75m, 35% lower compared to the prior year (Q1 2018: \$116m). Exceptional costs of \$27m are included in the Q1 2019 results. An exceptional gain of \$17m is included in the Q1 2018 results. On an adjusted basis, Q1 2019 operating profit grew to \$102m (43% margin), a 3% increase versus \$99m (45% margin) in Q1 2018. The year-over-year increase primarily reflects benefits from cost saving initiatives.

EBITDA (operating profit plus depreciation and amortization) was \$80m (Q1 2018: \$119m). EBITDA margin was 34% (Q1 2018: 47%). On an adjusted basis (excluding exceptional costs and gains), EBITDA was \$107m (Q1 2018: \$102m). Adjusted EBITDA margin was 45% (Q1 2018: 40%).

Net finance income in the quarter was \$2m (Q1 2018: \$5m expense). The net improvement reflects lower interest and amortization of financing costs due to the voluntary debt repayments of \$235m of the principal term loan balance in FY 2018, and higher interest income earned from the Group's increased cash balance.

The tax charge was \$11m at a rate of 14% (Q1 2018: \$18m, 16%), and \$15m at a rate of 14% on an adjusted basis which excludes the \$27m exceptional costs (Q1 2018: \$16m, 17%). The rate decreased in the current year due to earnings mix in the quarter versus the prior year.

Net income was \$66m (Q1 2018: \$93m), and \$89m on an adjusted basis excluding the \$23m after-tax impact from exceptional items (Q1 2018: \$78m). Lower net revenue was more than offset by a decline in operating expenses (SG&A and R&D combined) and financing income.

EPS on a diluted basis was 9 cents and 12 cents on an adjusted diluted basis (Q1 2018: 12 cents on a diluted and 10 cents adjusted diluted basis).

### **Balance Sheet & Cash Flow**

Cash and cash equivalents at the end of Q1 2019 were \$1,054m, an increase of \$130m versus the \$924m position at FY 2018. Borrowings, net of issuance costs, were \$240m at the end of Q1 2019 (FY 2018: \$241m). As a result, net cash stood at \$812m at Q1 2019 (FY 2018: \$681), a \$131m improvement.

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative \$361m at the end of Q1 2019 versus negative \$356m at the end of FY 2018. The \$5m improvement was primarily driven by lower inventory and receivables balances from year end that were partially offset by lower rebate and accrual balances from the timing of payments and the cost reduction measures initiated in Q4 18.

Cash generated from operating activities in Q1 2019 was \$101m (Q1 2018: \$41m), an increase of \$60m primarily due to the decline in operating profit being more than offset by decreases in receivables and inventory. Net cash flow from operations was \$135m in the quarter (Q1 2018: \$25m) primarily reflecting the higher cash from operating activities and tax refunds received in the quarter.

Q1 2019 cash outflow from investing activities was \$2m (Q1 2018: \$6m cash inflow). The prior year inflow primarily reflected the proceeds from the disposal of the nasal naloxone intangible asset.

Q1 2019 cash outflow from financing activities was \$3m (Q1 2018: nil), reflecting the new classification adopted under IFRS 16 *Leases*, and the quarterly amortisation on the term loan facility.

### **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 Directors have reviewed the principal risks and uncertainties for the remainder of 2019 financial year. The principal risks and uncertainties affecting the business activities of the Group are much in line with those detailed on pages 30 to 34 of the Indivior PLC Annual Report 2018. The Group utilizes a formal process to identify, evaluate and manage significant risks. During the period, changes to the company's environment have occurred, specifically impacting the Principal Risks of *Economic and Financial* and *Legal and Intellectual Property*.

On April 9th, a federal grand jury sitting in Abingdon, Virginia, indicted Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) and Indivior PLC (Indivior) on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the Company's marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE® Film and/or SUBOXONE® Tablet by certain physicians. DOJ is seeking the forfeiture of all assets derived from the commission of the alleged offenses, including but not limited to \$3 billion. (refer to the Legal Update section on pages 20 to 23 for additional information). The potential unfavorable impact of this legal proceeding could result in significant monetary penalties and/or exclusion from participating in U.S. Federal Health Care Programs which would have a severe impact on the Group's ability to comply with the financial covenant in the Group's debt facility, maintain sufficient liquidity to fund its operations, pay off the debt in 2022, future revenue, and ultimately impact the Group's viability. In addition, class action lawsuits in relation to alleged US securities law breaches for disclosure have been filed in U.S. District Courts on behalf of all persons or entities who acquired Indivior PLC securities between 10 March 2015 and 9 April 2019 (specifically Indivior sponsored ADRs publicly traded on the OTC market, which comprise approximately less than 1% of Indivior's market capitalization) which may result in the payment of financial damages.

Other than in respect to the update explained 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 remain the same as described on pages 30 and 34 of the Indivior PLC Annual Report 2018. 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 products availability and patient health, and ultimately the Group's performance and financials. Additionally, an ever evolving regulatory, political and technological landscape requires that we have the right priorities, capabilities and structures in place to successfully execute on our business strategy and adapt to this changing environment. An example of this evolving landscape is Brexit (decision for the UK to leave the EU), which creates uncertainties and 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 to the benefit/risk profiles of our products. Deviations from these quality and safety practices can impact patient safety and market access, which can have a material effect on our 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 new product involves substantial investment in marketing, market access and sales activities, product stocks, and other investments. 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, political and socioeconomic factors and HCP/Patient adoption and adherence, if different than anticipated, also can significantly impact the Group's performance and position.

## Economic & Financial

- 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. Our ability to realize value on those investments is often dependent upon regulatory approvals, market acceptance, strategic partnerships, competition, and legal developments. As a global business, we are also subject to political, economic, and capital markets changes. External financing is a key factor in sustaining our financial position and expanding our business growth.

## Supply Chain

- The manufacture 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 product ingredient (API) in 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/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, lead to product recalls, and/or potential regulatory actions against the company, along with reputational damage.

## 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.
- Unfavourable outcome from government investigations and/or resolutions from legal proceedings, expiry and/or loss of IP rights could have a material adverse impact on the Group's prospects, results of operations and financial condition.
- As previously disclosed in the Prospectus dated November 17, 2014, Indivior has indemnification obligations in favor of Reckitt Benckiser. Some indemnities are unlimited in terms of amount and duration and amounts potentially payable by the Indivior Group pursuant to such indemnity obligations could be significant and could have a material adverse effect on the Indivior 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 commercial 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.

## Exchange Rates

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

	Q1 2019	Q1 2018
GB £ period end	1.3219	1.4157
GB £ average rate	1.3019	1.3910
€ Euro period end	1.1254	1.2403
€ Euro average rate	1.1360	1.2288

## [Webcast Details](#)

There will be a conference call and webcast presentation at 1:00 BST (8:00 am Eastern in the USA) hosted by Shaun Thaxter, CEO. This presentation will also be webcast live. The details are below and are available on the Indivior's website at [www.indivior.com](http://www.indivior.com).

Webcast link: <https://edge.media-server.com/m6/p/o2rwc9e>

<b>Confirmation Code:</b>	<b>1175404</b>
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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 2019 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 this release): factors affecting sales of Indivior Group's products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; 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; 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; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including the ongoing investigative and antitrust litigation matters and the DOJ indictment; 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; 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](http://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](http://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](http://www.suboxoneREMS.com).

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

### INDICATION AND HIGHLIGHTED SAFETY INFORMATION

#### INDICATION

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

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

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

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

#### HIGHLIGHTED SAFETY INFORMATION

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

#### CONTRAINDICATIONS

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

#### WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

#### ADVERSE REACTIONS

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

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

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

## INDICATION AND HIGHLIGHTED SAFETY INFORMATION

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

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

See full prescribing information for complete boxed warning.

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

## CONTRAINDICATIONS

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

## WARNINGS AND PRECAUTIONS

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

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

Tardive Dyskinesia: Discontinue treatment if clinically appropriate.

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

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

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

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

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

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

## ADVERSE REACTIONS

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

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

## Condensed consolidated interim income statement

For the three months ended March 31	Notes	Unaudited 2019 \$m	Unaudited 2018 \$m
<b>Net Revenues</b>	2	<b>238</b>	255
Cost of sales		<b>(37)</b>	(24)
<b>Gross Profit</b>		<b>201</b>	231
Selling, general and administrative expenses	3	<b>(114)</b>	(99)
Research and development expenses	3	<b>(12)</b>	(16)
<b>Operating Profit</b>		<b>75</b>	116
Operating profit before exceptional items		<b>102</b>	99
Exceptional items	3	<b>(27)</b>	17
Finance income		<b>7</b>	2
Finance expense		<b>(5)</b>	(7)
Net finance income/(expense)		<b>2</b>	(5)
<b>Profit Before Taxation</b>		<b>77</b>	111
Income tax expense		<b>(11)</b>	(18)
Taxation before exceptional items	5	<b>(15)</b>	(16)
Taxation on exceptional items	3,5	<b>4</b>	(2)
<b>Net Income</b>		<b>66</b>	93
<b>Earnings per ordinary share (cents)</b>			
Basic earnings per share	6	<b>9</b>	13
Diluted earnings per share	6	<b>9</b>	12

## Condensed consolidated interim statement of comprehensive income

For the three months ended March 31	Unaudited 2019 \$m	Unaudited 2018 \$m
Net income	<b>66</b>	93
<b>Other comprehensive income</b>		
<i>Items that may be reclassified to profit or loss in subsequent years:</i>		
Net exchange adjustments on foreign currency translation	<b>6</b>	6
Other comprehensive income	<b>6</b>	6
<b>Total comprehensive income</b>	<b>72</b>	99

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

## Condensed consolidated interim balance sheet

	Notes	Unaudited Mar 31, 2019 \$m	Audited Dec 31, 2018 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		82	84
Property, plant and equipment		59	57
Right-of-use assets	1	50	-
Deferred tax assets	5	41	44
Other assets		22	33
		<b>254</b>	<b>218</b>
<b>Current assets</b>			
Inventories		71	78
Trade and other receivables		226	287
Current tax receivable		-	40
Cash and cash equivalents		1,054	924
		<b>1,351</b>	<b>1,329</b>
<b>Total assets</b>		<b>1,605</b>	<b>1,547</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	7	(4)	(4)
Provisions	8	(62)	(69)
Trade and other payables	11	(658)	(721)
Lease liabilities	1	(6)	-
Current tax liabilities	5	(23)	(24)
		<b>(753)</b>	<b>(818)</b>
<b>Non-current liabilities</b>			
Borrowings	7	(236)	(237)
Provisions	8	(432)	(424)
Lease liabilities	1	(51)	-
Other non-current liabilities		-	(2)
		<b>(719)</b>	<b>(663)</b>
<b>Total liabilities</b>		<b>(1,472)</b>	<b>(1,481)</b>
<b>Net assets</b>		<b>133</b>	<b>66</b>
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	12	73	73
Share premium		5	5
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(26)	(32)
Retained Earnings		1,376	1,315
<b>Total equity</b>		<b>133</b>	<b>66</b>

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

## Condensed consolidated interim statement of changes in equity

	Share Notes	Share capital	Share Premium	Other reserve	Foreign Currency Translation reserve	Retained earnings	Total equity
		\$m	\$m	\$m	\$m	\$m	\$m
<b>Unaudited</b>							
<b>Balance at January 1, 2019</b>		<b>73</b>	<b>5</b>	<b>(1,295)</b>	<b>(32)</b>	<b>1,315</b>	<b>66</b>
<b>Comprehensive income</b>							
Net income		-	-	-	-	66	66
Other comprehensive income		-	-	-	6	-	6
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>6</b>	<b>66</b>	<b>72</b>
<b>Transactions recognised directly in equity</b>							
IFRS 16 impact (adjustment to opening balance)		-	-	-	-	(2)	(2)
Share-based plans		-	-	-	-	(3)	(3)
Deferred taxation on share-based plans and IFRS 16		-	-	-	-	-	-
<b>Balance at March 31, 2019</b>		<b>73</b>	<b>5</b>	<b>(1,295)</b>	<b>(26)</b>	<b>1,376</b>	<b>133</b>
<b>Balance at January 1, 2018</b>		<b>72</b>	<b>2</b>	<b>(1,295)</b>	<b>(14)</b>	<b>1,032</b>	<b>(203)</b>
<b>Comprehensive income</b>							
Net income		-	-	-	-	93	93
Other comprehensive income		-	-	-	6	-	6
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>6</b>	<b>93</b>	<b>99</b>
<b>Transactions recognised directly in equity</b>							
Share-based plans		<b>1</b>	<b>1</b>	-	-	2	4
Deferred taxation on share-based plans		-	-	-	-	(1)	(1)
<b>Balance at March 31, 2018</b>		<b>73</b>	<b>3</b>	<b>(1,295)</b>	<b>(8)</b>	<b>1,126</b>	<b>(101)</b>

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

## Condensed consolidated interim cash flow statement

For the three months ended March 31	Unaudited 2019 \$m	Unaudited 2018 \$m
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit	75	116
Depreciation and amortization	5	3
Gain on disposal of intangible assets	-	(17)
Depreciation of right-of-use assets	2	-
Share-based payments	(4)	1
Impact from foreign exchange movements	1	1
Decrease in trade and other receivables	75	17
Decrease/(Increase) in inventories	8	(15)
Decrease in trade and other payables	(60)	(59)
Decrease in provisions	(1)	(6)
<b>Cash generated from operations</b>	<b>101</b>	<b>41</b>
Interest paid	(4)	(7)
Interest received	5	2
Taxes refunded/(paid)	33	(11)
<b>Net cash inflow from operating activities</b>	<b>135</b>	<b>25</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(2)	(2)
Purchase of intangible assets	-	(5)
Proceeds from disposal of intangible assets	-	13
<b>Net cash outflow from investing activities</b>	<b>(2)</b>	<b>6</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Repayment of borrowings	(1)	(1)
Payment of lease liabilities	(2)	-
Proceeds from the issuance of ordinary shares	-	1
<b>Net cash outflow from financing activities</b>	<b>(3)</b>	<b>-</b>
<b>Net increase in cash and cash equivalents</b>	<b>130</b>	<b>31</b>
Cash and cash equivalents at beginning of the period	924	863
<b>Exchange differences</b>	<b>-</b>	<b>1</b>
<b>Cash and cash equivalents at end of the period</b>	<b>1,054</b>	<b>895</b>

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 consolidated interim 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, 2018 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 consolidated interim financial statements, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the consolidated financial statements for the year ended December 31, 2018, with the exception of changes in estimates that are required in determining the provision for income taxes.

These condensed consolidated interim financial statements reflect the Group's adoption of IFRS 16 *Leases*. On adoption of IFRS 16, the Group recognized lease liabilities in relation to all leases, including those which had previously been classified as 'operating leases' under the principles of IAS 17 *Leases*. Assets and liabilities arising from a lease are initially measured at the net present value of lease payments which are discounted using the group's incremental borrowing rate. Leases executed prior to adoption were discounted at the January 1, 2019 incremental borrowing rate. The Group applied the modified retrospective approach, which requires recognition of the cumulative effect of initially applying IFRS 16, as of January 1, 2019, to retained earnings.

As at January 1, 2019, the Group recognized \$27 million of right-of-use assets and \$33 million of lease liabilities and an impact to beginning retained earnings of \$2 million. The remaining \$4m was for deferred tax and straight-line lease liability. Having adopted IFRS 16 in the year, we will recognise interest payments within the profit and loss and lease liability payments in the cashflow; both of which we expect to be immaterial.

The Group is using one or more practical expedients permitted by the standard on transition; including the reliance on a previous assessment of whether a lease is onerous, the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application, application of a single discount rate to leases with similar characteristics, the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease, and the accounting for operating leases with a remaining lease term of less than 12 months as at January 1, 2018 as short-term leases.

The condensed consolidated interim 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, 2018. These condensed consolidated interim financial Statements have been reviewed and not audited. These condensed consolidated interim financial statements were approved for issue on May 1, 2019.

As disclosed in Notes 8 and 10, the Group carries a provision of \$438m substantially all relating to the Department of Justice litigation matters. While the Directors believe the Group has strong defences to the government's charges and will vigorously defend itself, they will still endeavour to pursue a settlement. Even if a settlement cannot be reached, the outcome from the DOJ indictment is not expected to impact the Group during the going concern period over the next 12 months. However, an unfavorable verdict may impact the long-term viability of the Group. The final resolution of the Group's legal proceedings as disclosed in Note 10 may be materially higher than the amount provided which, together with higher than expected loss of revenue following the 'at-risk' launch of generic buprenorphine/naloxone sublingual film products or the failure for new products to meet revenue growth expectations, could impact the Group's ability to operate. The Directors have already taken significant steps to reduce the cost base of the business and manage its capital structure. A combination of the above risks may require additional measures to be taken such as further cost reductions. The above factors 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, 2018, the auditors issued (1) an emphasis of matter dealing with the outcome of the Department of Justice and Federal Trade Commission investigations and antitrust litigation details of which are included above and in Notes 8 and 10; 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 involvement in investigations by the Department of Justice and the Federal Trade Commissions as well as antitrust litigation, which will be adversely affected by the significant decline in revenue in 2019 and beyond following the "at-risk" launch of the generic buprenorphine/naloxone of sublingual film products and potential risk of failure for new products to meet revenue growth expectations. The Group's statutory financial statements for the year ended December 31, 2018 were approved by the Board of Directors on March 1, 2019 and will be delivered to the Registrar of Companies.

### 2. SEGMENT INFORMATION

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



operating segments, has been identified as the Chief Executive Officer (CEO). The Indivior Group is predominately engaged in a single business activity, which is the development, manufacture and sale of buprenorphine-based prescription drugs for treatment of opioid dependence. 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 country. Non-current assets for this purpose consist of property, plant and equipment, right-of-use assets, intangible assets, and other receivables. Net revenues and non-current assets for the three months to March 31, 2019 and 2018 were as follows:

Net revenues from sale of goods:

	2019	2018
For the three months ended March 31	\$m	\$m
United States	200	197
ROW	38	58
<b>Total</b>	<b>238</b>	<b>255</b>

Included in Q1 2019 US revenue is \$11m of SUBLOCADE net revenues (Q1 2018: nil)

Non-current assets:

	Mar 31, 2019 \$m	Dec 31, 2018 \$m
United States	73	62
ROW	140	112
<b>Total</b>	<b>213</b>	<b>174</b>

### 3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

	2019	2018
For the three months ended March 31	\$m	\$m
Research and development expenses	(12)	(16)
Marketing, selling and general expenses	(43)	(45)
Administrative expenses <sup>1</sup>	(67)	(50)
Depreciation and amortization	(4)	(3)
Operating lease rentals <sup>2</sup>	-	(1)
<b>Total</b>	<b>(114)</b>	<b>(99)</b>

<sup>1</sup>Administrative expenses include exceptional costs in the current and prior year as outlined in table below. Prior year administrative expenses also included non-exceptional expenses of \$4m related to the ongoing protection of the company's intellectual property. These costs were not classified as exceptionals as they primarily related to non-litigation expenses for the ongoing protection of the Group's prospective revenues.

<sup>2</sup>Following the group's adoption of IFRS 16, *Leases* on January 1, 2019, operating lease rentals have been reclassified to the balance sheet as lease liabilities with a portion being recorded as interest on the P&L.

### Exceptional Items

	2019	2018
For the three months ended March 31	\$m	\$m
Other operating income <sup>1</sup>	-	17
Restructuring costs <sup>2</sup>	(19)	-
Legal Expenses/Provision <sup>3</sup>	(8)	-
<b>Total exceptional items before taxes</b>	<b>(27)</b>	<b>17</b>
Tax on exceptional items	4	(2)
<b>Total exceptional items</b>	<b>(23)</b>	<b>15</b>

<sup>1</sup>\$17m of exceptional income in FY 2018 relates to the proceeds received from the out-licensing of nasal naloxone opioid overdose patents which are included within SG&A.

<sup>2</sup>Restructuring costs relate to the cost saving initiative announced in the HY 2018 results to offset the financial impact of recent adverse U.S. market developments. These consist primarily of supply chain restructuring, redundancy and related costs.

<sup>3</sup>\$8m of legal expenses in the current year and quarter relate to potential redress for ongoing intellectual property related litigation with DRL and Alvogen Pharmaceuticals. These are included within administrative expenses.

#### 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 operating profit and net income for both Q1 2019 and 2018. Refer to Note 3 for more information on exceptional items.

##### Reconciliation of operating profit to adjusted operating profit

For the three months ended March 31	2019 \$m	2018 \$m
<b>Operating profit</b>	<b>75</b>	<b>116</b>
Exceptional selling, general and administrative expenses	<b>27</b>	<b>(17)</b>
<b>Adjusted operating profit</b>	<b>102</b>	<b>99</b>

##### Reconciliation of net income to adjusted net income

For the three months ended March 31	2019 \$m	2018 \$m
<b>Net Income</b>	<b>66</b>	<b>93</b>
Exceptional selling, general and administrative expenses	<b>27</b>	<b>(17)</b>
Tax on exceptional items	<b>(4)</b>	<b>2</b>
<b>Adjusted net income</b>	<b>89</b>	<b>78</b>

#### 5. TAXATION

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

In the three months ended March 31, 2019, the tax expense on adjusted profits amounted to \$15m excluding exceptionals (Q1 2018: \$16m) and represented a quarterly effective tax rate of 14% (Q1 2018: 17% excluding exceptionals). The Group's balance sheet at March 31, 2019 included a current tax payable of \$23m (FY 2018: \$24m), current tax receivable of \$0m (FY 2018: \$40m), and deferred tax asset of \$41m (FY 2018: \$44m). The current tax asset decreased due the receipt of refunds during the quarter.

The decrease in the effective tax rate to 14% was primarily driven by the relative contribution to pre-tax income by taxing jurisdiction in the quarter. While there may be fluctuations in the rate from quarter to quarter, this rate reduction is expected to be materially sustained for the full year.

##### Other tax matters

The European Commission has issued a press release on 2 April 2019 announcing its conclusion that the UK Finance Company Partial Exemption Rules are partly justified. The UK government is now required to initiate recovery of the alleged State Aid irrespective of any appeal against the decision. The Group is currently reviewing the detailed decision published on 25 April 2019 and continue to believe there is significant uncertainty at this stage to quantify any potential future liability that may arise, so no provision has been made at this time.

At 31 March 2019, the Group has benefited from the UK controlled foreign company financing exemption by approximately \$26 million.

The United Kingdom ('UK') decision to withdraw from the European Union ('EU') could have a material effect on our taxes. 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. 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.

#### 6. EARNINGS PER SHARE

For the three months ended March 31	2019 cents	2018 cents
Basic earnings per share	<b>9</b>	<b>13</b>
Diluted earnings per share	<b>9</b>	<b>12</b>
Adjusted basic earnings per share	<b>12</b>	<b>11</b>
Adjusted diluted earnings per share	<b>12</b>	<b>10</b>

### 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.

	2019 thousands	2018 thousands
Weighted average number of shares		
On a basic basis	729,411	723,933
Dilution from share awards and options	27,120	24,779
On a diluted basis	756,531	748,712

### 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. FINANCIAL LIABILITIES – BORROWINGS

	Mar 31 2019 \$m	Dec 31 2018 \$m
<b>Current</b>		
Bank loans	(4)	(4)
	(4)	(4)
<b>Non-current</b>		
Bank loans	(236)	(237)
	(236)	(237)
<b>Analysis of net debt</b>		
Cash and cash equivalents	1,054	924
Borrowings*	(242)	(243)
	812	681

\*Borrowings reflects the principal amount drawn before debt issuance costs of \$2m (FY 2018: \$2m). These do not include lease liabilities.

	Mar 31 2019 \$m	Dec 31 2018 \$m
<b>Reconciliation of net debt</b>		
The movements in the period were as follows:		
Net cash at beginning of period	681	376
Net increase in cash and cash equivalents	130	61
Net repayment of borrowings	1	240
Exchange adjustments	-	4
Net cash at end of period	812	681

The net carrying value of current borrowings before issuance costs and cash at bank, as well as trade receivables and trade payables are assumed to approximate their fair values. The terms of the loan in effect at March 31, 2019 are as follows:

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

- Nominal interest margin is calculated over three-month LIBOR subject to the LIBOR floor.
- 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; which remained undrawn at the balance sheet date.

## 8. PROVISIONS

	Mar 31 2019 \$m	Dec 31 2018 \$m
Litigation/Investigative matters	(438)	(438)
Intellectual property related matters	(48)	(44)
Restructuring costs	(5)	(8)
Other	(3)	(3)
Total	(494)	(493)

The Group is involved in legal and intellectual property disputes as described in Note 10, "Legal Proceedings."

The Group carries a provision for investigative and antitrust litigation matters of \$438m. Substantially all of the provision relates to the U.S. Department of Justice ("DOJ") litigation, described in Note 10 under "Western District of Virginia Indictment." The Group remains open to resolving the matter, although it cannot predict with any certainty whether, when, or at what cost it will reach an ultimate resolution.

The final resolution may be materially higher than this provision which, together with higher than expected loss of revenue following the 'at-risk' launch of generic buprenorphine/naloxone sublingual film products or the failure for new products to meet revenue growth expectations, could impact the Group's ability to operate. The Directors have already taken significant steps to reduce the cost base of the business and manage its capital structure. A combination of the above risks may require additional measures to be taken such as further cost reductions.

The Group also carries provisions totalling \$48m for intellectual property related matters, all of which relate to potential redress for ongoing intellectual property related litigation with DRL, Alvogen, and Rhodes Pharmaceuticals and have been classified as exceptional costs (see Note 3).

The final aggregate cost of these matters may be materially higher than the amount provided.

The Group believes that it has strong defences in the antitrust and other litigations and is actively litigating these matters. Indivior cannot predict with any certainty whether, when, or at what cost it will reach ultimate resolution of the antitrust and other litigation matters.

## 9. CONTINGENT LIABILITIES

Other than the disputes for which provisions have been taken as disclosed in Note 8, 'Provisions' or as separately disclosed in Note 5, 'Taxation', reliable estimates could not be made of the potential range of cost required to settle legal or intellectual property disputes where the possibility of losses is more than remote. Descriptions of the significant tax, legal and other disputes to which the Group is a party are set out in Note 5, 'Taxation' and Note 10, 'Legal Proceedings.'

## 10. LEGAL PROCEEDINGS

### Litigation/Investigative Matters

#### *Western District of Virginia Indictment*

- On April 9, 2019, a federal grand jury in the Western District of Virginia indicted the Company on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the Company's marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE® Film and/or SUBOXONE® Tablet by certain physicians. DOJ is seeking to recover \$3 billion in monetary forfeitures and all assets derived from the commission of the alleged offenses. The Company believes it has strong defences to the government's charges and will vigorously defend itself. It is not possible to predict with any certainty the potential impact of this litigation on the Group or to quantify the ultimate cost of a verdict or resolution.

#### *State Subpoenas*

- 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. 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 is fully cooperating in these civil investigations.

#### *FTC investigation and Antitrust Litigation*

- The U.S. Federal Trade Commission's investigation remains pending. Litigation regarding privilege claims has now been resolved. Indivior has produced certain documents that it had previously withheld as privileged; other such documents have not been produced.
- Civil antitrust claims have been filed by (a) a putative class of direct purchasers, (b) a putative class of end payor purchasers, (c) Amneal Pharmaceuticals LLC (Amneal), a manufacturer of generic buprenorphine/naloxone tablets,

and (d) 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. The Group has settled the dispute with Amneal, and Amneal has dismissed its claims against the Group with prejudice. The other antitrust cases are pending in federal court in the Eastern District of Pennsylvania. Pre-trial proceedings were coordinated. The fact discovery period has closed. Class certification motions are briefed and pending. Expert discovery is ongoing.

#### ***Opioid Class Action Litigation***

- In February 2019, Indivior, along with other manufacturers of opioid products, was first named in one of the national multi-district litigation cases brought by state and local governments and public health agencies, alleging misleading marketing messages. At present, Indivior has been named in slightly more than 160 such lawsuits. Indivior has been voluntarily dismissed with prejudice from one of these lawsuits and has been voluntarily dismissed without prejudice in eight others. The Company is in discussions with other plaintiffs' counsel in an effort to achieve additional voluntary dismissals during the period of a stay in this national multi-district litigation.

#### ***Securities Class Action Litigation***

- On April 23, 2019, Michael van Dorp filed a 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. The Company has not yet been served with the complaint.

### **Intellectual property related matters**

#### ***ANDA Litigation***

- On February 7, 2019, Indivior received a letter from Aveva Drug Delivery Systems, Inc. (Aveva) notifying Indivior that Aveva had filed an ANDA with the U.S. Food and Drug Administration for generic buprenorphine and naloxone film, which had included a PIV certification. On March 22, 2019, Indivior sued Aveva in the United States District Court for the Southern District of Florida on U.S. Patent Nos. 8,017,150 ("the '150 patent"); 8,603,514 ("the '514 patent"); 9,687,454 ("the '454 patent"); and 9,931,305 ("the '305 patent"). Aveva's ANDA is subject to an automatic stay of approval which will expire on the earlier of: August 7, 2021, or a District Court ruling in Aveva's favor.
- On October 24, 2017, Actavis received tentative approval from FDA for at least its 8mg/2mg generic product under its Abbreviated New Drug Application (ANDA) No. 204383 and on November 15, 2017, it received tentative approval for its 12mg/3mg generic product under ANDA No. 207087. Actavis is currently enjoined from launching a generic buprenorphine/naloxone film product until April 2024 based on a June 3, 2016 ruling by the United States District Court for the District of Delaware finding the asserted claims of the '514 Patent valid and infringed. Actavis has appealed this ruling, and the Court of Appeals for the Federal Circuit (CAFC) heard oral arguments on April 1, 2019. Litigation against Actavis is also pending in the District of Delaware on Indivior's more recently listed Orange Book Patents: U.S. Patent Nos. 9,687,454 (the '454 Patent), and 9,931,305 (the '305 Patent).
- On August 31, 2017, the United States District Court for the District of Delaware found that asserted claims of U.S. Patent No. 8,017,150 (the '150 Patent), U.S. Patent No. 8,900,497 (the '497 Patent), and the '514 Patent are valid but not infringed by DRL. Indivior has appealed this ruling. Litigation against DRL is currently pending in the District of New Jersey on 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 June 15, 2018, Indivior filed a motion with the United States District Court for the District of New Jersey seeking a Temporary Restraining Order (TRO) and Preliminary Injunction (PI) pending the outcome of a trial on the merits of the '305 Patent. The court granted Indivior a two-week TRO, preventing DRL from continuing to sell or offer to sell its generic product. Indivior was required to post an \$18 million surety bond to cover DRL's damages in the event of an Indivior loss of its patent case against DRL. On June 28, 2018, the court heard oral argument in support of Indivior's motion for a PI against DRL and, at the conclusion of this hearing, extended the TRO for an additional 14 days in order to rule on the PI motion and required Indivior to post another \$18 million surety bond. On July 13, 2018, the District Court issued its ruling granting Indivior a PI against DRL. On July 18, 2018, the District Court ordered Indivior to post a surety bond for \$72 million (that total figure being inclusive of the \$36 million surety bond already posted) in connection with the PI. DRL appealed to the United States Court of Appeals for the Federal Circuit (CAFC) on the same day. On November 20, 2018, the CAFC issued a decision vacating the PI against DRL. Indivior filed a timely petition for rehearing and rehearing en banc on December 20, 2018. The CAFC denied the petition on February 4, 2019. On February 5, 2019, Indivior filed an emergency motion to stay the issuance of mandate pending the resolution of the appeal of the District of Delaware decision with respect to the '514 patent and pending Indivior's forthcoming petition for a writ of certiorari to the Supreme Court of the United States in the PI matter. The CAFC denied that motion on February 11, 2019, and Indivior filed a second emergency motion to stay the mandate pending resolution of its forthcoming application for an administrative stay to the Supreme Court of the United States. The CAFC denied that motion and ordered issuance of the mandate on February

19, 2019. Indivior filed an application to the Supreme Court of the United States requesting a stay of the mandate pending resolution of its forthcoming petition for certiorari seeking to overturn the CAFC's PI vacatur. On February 19, the Supreme Court of the United States denied Indivior's motion to stay issuance of the CAFC's mandate vacating the PI granted against DRL. The CAFC subsequently issued the mandate vacating the PI granted against DRL. The U.S. District Court for the District of New Jersey then confirmed the PI against DRL had been vacated.

- DRL is therefore 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 CAFC appeal of the judgments related to U.S. Patent No. 8,603,514, and U.S. 8,017,150, as well as ongoing litigation in the District of New Jersey asserting Orange Book-listed U.S. Patent Nos. 9,931,305 and 9,687,454. On April 15, 2019, DRL requested that the District Court of New Jersey allow them to file a motion for summary judgment of noninfringement of the '305 patent. That request remains pending.
- On February 12, 2019, the CAFC granted Indivior's request to expedite the appeal of the non-infringement judgment in the '514 patent case to the extent it placed the case on the next available oral argument calendar. The CAFC heard oral argument in the appeal of the '514 patent case on April 1, 2019. A decision by the CAFC is pending.
- On November 13, 2018, DRL filed two separate petitions for inter partes review of the '454 Patent with the USPTO. Indivior filed its preliminary responses on March 6, 2019 and March 7, 2019. DRL was authorized to file a reply to Indivior's preliminary responses by April 24, 2019, and did so. Indivior has been authorized to file a sur-reply by May 2, 2019. A decision from the USPTO on whether to institute the IPRs is expected on or about June 6, 2019.
- 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 by Teva's 16mg/4mg dosage strength would be governed by the infringement ruling as to Dr. Reddy's 8mg/2mg dosage strength that was the subject of the trial in November 2016. Accordingly, the non-infringement ruling in the Dr. Reddy's case means that the Teva 16mg/4mg dosage strength has been found not to infringe. Indivior has appealed this November 2016 ruling. Litigation is ongoing against Teva in the District of New Jersey on the '454 patent and '305 patent. Teva received final approval from the FDA for CASSIPA on September 7, 2018 and has agreed to be bound by the decision in the DRL PI case. 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 appeal of the non-infringement judgment related to the '514 patent, as well as the ongoing litigation against Teva and DRL in the District of New Jersey.
- Trial against Alvogen in the lawsuit involving the '514 and '497 Patents for SUBOXONE® Film 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 issued its ruling finding both patents not infringed by Alvogen. Indivior has appealed this ruling. Litigation against Alvogen is also pending in the United States District Court for the District of New Jersey on the '454 Patent and the '305 Patent. 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, with a PI hearing scheduled for 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. Alvogen has launched its generic product, and any sales in the US are on an "at-risk" basis, subject to the outcome of the appeal of the non-infringement judgment related the '514 patent, as well as the ongoing litigation against Alvogen in the District of New Jersey. On February 12, 2019, the CAFC granted Indivior's request to expedite the appeal of the non-infringement judgment in the '514 patent case to the extent it placed the case on the next available oral argument calendar. The CAFC heard oral argument in the appeal of the non-infringement judgment in the '514 patent case on April 1, 2019. On April 10, 2019, Alvogen requested that the District Court of New Jersey allow them to file a motion for Summary Judgment of noninfringement of the '305 patent. That request was granted on April 15, 2019. No motion for summary judgment has been filed to date.
- By a Court order dated August 22, 2016, Indivior's SUBOXONE® Film patent litigation against Sandoz was dismissed without prejudice because Sandoz is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE® Film. Sandoz launched an authorized generic version of SUBOXONE® Film on February 19, 2019.
- On September 25, 2017, Indivior settled its SUBOXONE® Film patent litigation against Mylan, the terms of which are confidential. Mylan received final FDA approval for its generic version of the 8mg buprenorphine/naloxone film product on June 14, 2018. Mylan launched its generic versions of the 8mg and 12 mg buprenorphine and naloxone film product on or about February 22, 2019.
- On May 11, 2018, Indivior settled its SUBOXONE® Film patent litigation against Par. Under the terms of the settlement agreement, Par can launch its generic buprenorphine/naloxone film product on January 1, 2023, or earlier under

certain circumstances. Other terms of the settlement agreement are confidential. So far as Indivior is aware, FDA to date has not granted tentative or final approval for Par's generic buprenorphine/naloxone film product.

#### **Rhodes Pharmaceuticals**

- On December 23, 2016, Rhodes Pharmaceuticals filed a complaint against Indivior in the United States District Court for the District of Delaware, alleging that Indivior's sale of SUBOXONE® Film in the U.S. infringes one or more claims of U.S. Patent No. 9,370,512 (the '512 Patent). The asserted patent, which was issued in June 2016, claims priority to an application filed in August 2007.
- On March 16, 2018, Indivior filed a petition for inter partes review (IPR) with the United States Patent and Trademark Office (USPTO) asserting that all claims of the '512 Patent are invalid.
- On October 4, 2018, the USPTO declined to institute an IPR on the challenged claims of the '512 patent.

### **11. TRADE AND OTHER PAYABLES**

	Mar 31 2019 \$m	Dec 31 2018 \$m
Sales returns and rebates	(468)	(510)
Trade payables	(52)	(47)
Accruals	(121)	(149)
Other tax and social security payables	(17)	(15)
<b>Total</b>	<b>(658)</b>	<b>(721)</b>

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

### **12. SHARE CAPITAL**

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
<b>At January 1, 2019</b>	<b>728,441,653</b>	<b>\$0.10</b>	<b>73</b>
Allotments	1,588,935	\$0.10	-
<b>At March 31, 2019</b>	<b>730,030,588</b>		<b>73</b>

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2018	721,462,733	\$0.10	72
Allotments	5,999,688	\$0.10	1
At March 31, 2018	727,462,421		73

#### **Allotment of ordinary shares**

During the period, 1,588,935 ordinary shares (2018: 5,999,688) were allotted to satisfy vestings/exercises under the Group's Long-Term Incentive Plan and U.S. Employee Stock Purchase Plan.

### **13. POST BALANCE SHEET EVENTS**

There have been no material post balance sheet events.

## 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.

Indivior's PLC's Directors are listed in the Annual Report and Accounts for 2018.

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

By order of the Board

Shaun Thaxter  
Chief Executive Officer

Mark Crossley  
Chief Financial Officer

May 1, 2019



# **Independent review report to Indivior PLC**

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

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### **Our conclusion**

We have reviewed Indivior PLC's condensed consolidated interim financial statements (the "interim financial statements") in the Q1 Financial Results Release of Indivior PLC for the three-month period ended 31 March 2019. 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.

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### **Emphasis of matter – Outcome of litigation**

Without modifying our conclusion on the interim financial statements, which is not modified, we draw your attention to Notes 8 and 10 that describe the uncertain outcome of the ongoing litigation by the Department of Justice, Federal Trade Commission and other antitrust matters. While the Directors believe the Group has strong defences to the government's charges and will vigorously defend itself, they will still endeavour to pursue a settlement. There is a provision of \$438 million for potential settlement for these matters. The final outcome of the DoJ litigation and the aggregate settlement amount for all of the other outstanding matters referred to may be materially higher than this provision.

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### **Emphasis of matter – Going Concern**

In forming our conclusion on the Interim Financial Statements, which is not modified, we have considered the adequacy of the disclosure made in Notes 8 and 10 that describe the uncertain outcome of the ongoing litigations by the Department of Justice, Federal Trade Commission and other antitrust matters. This could impact the Group's ability to operate, which would be further adversely impacted in the event of:

- higher than expected loss of revenue following the 'at-risk' launch of generic buprenorphine/naloxone sublingual film products; and/or
- the failure of SUBLOCADE™ and PERSERIS™ to meet revenue growth expectations.

The Directors have already taken significant steps to reduce the cost base of the business and manage its capital structure. A combination of the above risks may require additional measures to be taken, such as further cost savings. The Directors believe the Group has sufficient liquidity and ability to carry out further measures that may be necessary for the Group to continue as a going concern for at least the next 12 months. As explained in Note 1 to the interim financial statements, the above factors indicate the existence of a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern. The interim financial statements do not include the adjustments that would result if the Group were unable to continue as a going concern.

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### **What we have reviewed**

The interim financial statements comprise:

- the Condensed consolidated interim balance sheet as at 31 March 2019;
- the Condensed consolidated interim income statement and Condensed consolidated statement of comprehensive income for the period then ended;
- the Condensed consolidated interim cash flow statement for the period then ended;
- the Condensed consolidated interim statement of changes in equity for the period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the Q1 Financial Results Release 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.

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## Responsibilities for the interim financial statements and the review

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### Our responsibilities and those of the directors

The Q1 Financial Results Release, including the interim financial statements, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the Q1 Financial Results Release 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 Q1 Financial Results Release 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.

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### What a review of interim financial statements involves

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

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

We have read the other information contained in the Q1 Financial Results Release and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP  
Chartered Accountants  
London  
1 May 2019