**July 31, 2019**

**Indivior Announces H1 2019 Results**

| Period to June 30th | Q2 2019 $m | Q2 2018 $m | % Δ Actual FX | % Δ Constant FX | H1 2019 $m | H1 2018 $m | % Δ Actual FX | % Δ Constant FX |
|---|---|---|---|---|---|---|---|---|
| Net Revenue | **215** | 268 | -20 | -19 | **454** | 524 | -13 | -12 |
| Operating Profit | **88** | 84 | 5 | 6 | **163** | 200 | -18 | -17 |
| Net Income | **75** | 70 | 7 | 9 | **141** | 162 | -13 | -12 |
| EPS (cents/share) | **10** | 10 | - | 9 | **19** | 22 | -14 | -12 |
| | | | | | | | | |
| Adj. Operating Profit | **89** | 84 | 6 | 7 | **191** | 183 | 4 | 6 |
| Adj. Net Income | **76** | 70 | 9 | 10 | **165** | 147 | 12 | 14 |
| Adj. EPS | **10** | 10 | - | 10 | **23** | 20 | 15 | 14 |

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

## H1 2019 Financial Highlights

- Net revenue of $454m declined 13% (12% at constant currency). U.S. net revenue declined 12% primarily due to SUBOXONE® (buprenorphine and naloxone) Film share loss to generic competitors, albeit at a lower rate than suggested by historical industry analogues[1]. The impact of share loss was partially offset by good underlying market growth for buprenorphine medication-assisted treatment (BMAT), strong performance of the authorized generic buprenorphine/naloxone film product marketed by Sandoz Inc. (including a one-time gross to net revenue benefit related to the launch of the product) and net revenue from SUBLOCADE™ (buprenorphine extended-release) Injection of $28m in H1 2019 (H1 2018: $2m). Rest of World net revenue declined 19% primarily due to continued austerity measures in EU markets and one-time in nature items in Canada that impacted comparability in Q1 2019.
- Reported operating profit was $163m (H1 2018: $200m). On an adjusted basis, operating profit was $191m, an increase of 4% (Adj. H1 2018: $183m) primarily reflecting lower overall net revenue that was more than offset by a significant decrease in operating expenses (SG&A and R&D expenses combined).
- Reported net income was $141m (H1 2018: $162m). On an adjusted basis, net income increased 12% to $165m (Adj. H1 2018: $147m), primarily reflecting the increase in operating profit and finance income.
- Ending H1 2019 cash balance was $988m (FY 2018: $924m). Net cash was $747m (FY 2018: $681m).

## H1 2019 Operating Highlights

- U.S. BMAT market growth continued at low double-digit levels; growth continues to be driven primarily by government channels.
- SUBOXONE® Film market share during H1 2019 averaged 38% (H1 2018: 54%) and exited at 27% (H1 2018: 52%). Share erosion since the “at-risk“ launch of generic buprenorphine/naloxone film products in February 2019 has been lower than historical industry analogues[1].
- The authorized generic buprenorphine/naloxone film, launched and marketed by Sandoz Inc., continues to lead all generic film products with a 49% share of the total generic buprenorphine/naloxone film market exiting H1 2019.
- SUBLOCADE™ dispense yield of 58% showed further expansion beyond the initial target of 50%; SUBLOCADE™ key performance indicators (KPIs) continued to improve (see page 3).
- PERSERIS™ (risperidone) extended-release injection achieved net revenue consistent with the Group‘s expectations.

[1] IMS Institute Report, January 2016; “Price Declines after Branded Medicines Lose Exclusivity in the U.S.

## FY 2019 Guidance

- On July 11, 2019 Indivior announced revised expectations for FY 2019 net revenue and net income following the stronger than expected H1 2019 net revenue performance.
- Consistent with the update, FY 2019 net revenue is expected to be in the range of $670m to $720m (previously: $525m to $575m) and net income in the range of $80m to $130m (previously: a loss of $40m to net income of $10m), excluding exceptional items and at constant exchange rates.
- Net revenue guidance assumes that share erosion of SUBOXONE® Film[2] and the authorized generic film product trend toward the rates of historical industry analogues over the remainder of FY 2019.
- All other key FY 2019 guidance elements are maintained, including:
  - SUBLOCADE™ net revenue of $50m to $70m;
  - Modest net revenue contribution from PERSERIS™;
  - Authorized generic buprenorphine/naloxone film contribution to net revenue in the tens of $-millions;
  - Operating expense (SG&A and R&D combined) of $440m to $460m (before exceptional costs), inclusive of costs relating to the current Legal Proceedings as described in Note 11 on pages 21-23; and,
  - A tax rate in the high-single to low double-digit range.

## Department of Justice Action

- On April 9, 2019, a federal grand jury in the Western District of Virginia indicted Indivior PLC and Indivior Inc. on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE® Film and/or SUBOXONE® Tablet by certain physicians. DOJ is seeking to recover $3 billion in monetary forfeitures and all assets derived from the commission of the alleged offenses. Indivior believes it has strong defences to the government's charges and will vigorously defend itself. On July 19, 2019, Indivior filed a Motion to Dismiss the indictment. It is not possible to predict with any certainty the potential impact of this litigation or to quantify the ultimate cost of a verdict or resolution, but it could have a material impact on the Group.
- Please see Notes 9, 10 and 11 beginning on page 20 for further details on Provisions, Contingent Liabilities and Legal Proceedings.

## Comment by Shaun Thaxter, CEO of Indivior PLC

"2019 has been a uniquely complex and challenging year for Indivior, which has impacted all of our stakeholders. Set against this backdrop, I am pleased to report another quarter of strong execution and delivery against our strategic priorities. We have recently increased our FY 2019 guidance based on the outperformance of SUBOXONE® Film versus historical industry analogues[2] in the first half of the year, while at the same time continuing to make important strides in growing SUBLOCADE™ and PERSERIS™, the future value drivers of Indivior. We have also maintained our cost discipline resulting in a continued financial position that helps fortify against expected accelerated share loss of SUBOXONE® Film.

Consistent with our stated priorities for SUBLOCADE™, further improvements were achieved in the overall prescription journey and in healthcare provider trial and adoption through our Addiction Sciences salesforce, which is now exclusively focused on SUBLOCADE™. Based on net revenues of $28m in the first half (including $17m in Q2), we are tracking comfortably towards our FY 2019 guidance of $50m-$70m. We are also pleased with continued positive anecdotal treatment provider feedback on PERSERIS™, our monthly risperidone injection for schizophrenia.

Finally, I am incredibly proud of the way our employees have responded to Indivior's challenges. The strong business execution we are reporting today reflects our organization's resilience and dedication to delivering our Vision to improve the lives of patients suffering from addiction and its co-occurring disorders."

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

## Operating Review

### US Market Update

The market for buprenorphine medication-assisted treatment (BMAT) products continued to grow at low double-digit rates in H1 2019 versus the comparable period in 2018. Market volume growth is benefiting both from increased overall public awareness of the opioid epidemic and approved treatments, and from regulatory and legislative changes that have expanded Opioid Use Disorder (OUD) treatment funding and treatment capacity. States are also realizing that providing treatment brings substantial value to both patients and society, but BMAT remains underutilized[3].

In response, both the number of physicians waivered to administer medication-assisted treatment and those able to treat to the permitted level of 275 patients (from 100 patients) continued to grow in H1 2019. The number of waivered nurse practitioners and physician assistants also continued to grow in H1 2019. Indivior supports efforts to encourage more eligible healthcare practitioners to provide treatment, and the Group continues to invest in expanding its compliance program to meet the growing number of BMAT prescribers and patients.

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 now four generic buprenorphine/naloxone sublingual film products in the market: "at-risk" launches from DRL and Alvogen and additional generic film offerings, including Indivior's authorized generic buprenorphine/naloxone sublingual film product and one from Mylan N.V. The presence of these generics is not impacted by the recent ruling by Court of Appeals for the Federal Circuit (CAFC) on the '514, '150, and '832 patents. The CAFC upheld the decisions of the U.S. District Court for the District of Delaware finding that the asserted claims of the '514 Patent are valid but not infringed by DRL and Alvogen, and that the '150 Patent is valid but not infringed by DRL. The Court also upheld The District Court's decision that Actavis infringes the '514 patent.

As a result of the launch of generic buprenorphine/naloxone sublingual film products, branded SUBOXONE® Film experienced significant market share loss in H1 2019, albeit at a lower rate than suggested by historical industry analogues[4]. SUBOXONE® Film market share exiting H1 2019 was 27% versus H1 2018 exit share of 52%. Overall commercial formulary access remains solid for SUBOXONE® Film. However, Indivior prudently assumes 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[4] which suggests SUBOXONE® Film share loss could approach 90% in the coming 12 months. However, the timing for reaching this level is unknown at this point.

Indivior 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 (as of 6/30/19):

- Formulary Access – reached targeted levels, exiting H1 2019 at 85%.
- The Prescription Journey – reached targeted levels, exiting H1 2019 at 12 to 17 days.
- The Dispensing Yield Rate – improved to 58% (based on a 93% closed case rate) from 51% at 3/31/19.

SUBLOCADE™ Demand KPIs (6/30/19 vs. 3/31/19):

- HCPs Initiating a Prescription Journey – increased to 3,463 versus 2,930.
- HCPs Administered SUBLOCADE™ – increased to 2,249 versus 1,745.
- HCPs Administered SUBLOCADE™ to 5-plus patients increased to 569 versus 415.

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[3] *Source: JAMA Network Open. 2019;2(6):e196373. doi:10.1001/jamanetworkopen.2019.6373*

[4] IMS Institute Report, January 2016; "Price Declines after Branded Medicines Lose Exclusivity in the U.S.

## Financial Performance in H1 2019

Total net revenue in H1 2019 decreased 13% to $454m (H1 2018: $524m) at actual exchange rates (-12% at constant exchange rates). In Q2 2019, total net revenue decreased 20% at actual exchange rates (-19% at constant exchange rates) to $215m (Q2 2018: $268m)

U.S. net revenue decreased 12% in H1 2019 to $362m (H1 2018: $411m) and by 24% in Q2 2019 to $163m (Q2 2018: $214m). U.S. market growth continued at low double-digit rates, primarily from continued strength in government channels. Underlying market strength, benefits from the authorized generic buprenorphine/naloxone film (including a one-time gross to net revenue benefit related to the launch of the product) and growing SUBLOCADE™ net revenue of $28m at H1 2019 (H1 2018: $2m) were, however, more than offset by SUBOXONE® Film share loss due to the introduction of generic buprenorphine/naloxone sublingual film alternatives in Q1 2019. U.S. net revenue dynamics in the second quarter were substantially the same as those for H1 2019.

Rest of World net revenue decreased 19% at actual exchange rates in H1 2019 to $92m (H1 2018: $113m) (-13% at constant exchange rates). In Q2 2019, Rest of World net revenue decreased 4% at actual exchange rates to $52m (Q2 2018: $54m) (+4% at constant exchange rates). Continued 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 in H1 2019 were impacted by one-time in nature net revenue benefits in the year-ago period in the Canadian market related to temporary unavailability of generic buprenorphine/naloxone tablets that resulted in higher SUBOXONE® Film net revenue in the prior year period.

Gross margin in H1 2019 was 86% (H1 2018: 89%) and 87% in Q2 2019 (Q2 2018: 87%), respectively. The decline in gross margin in the half year was principally due to unfavourable product mix related to sell-in of the Group's authorized generic buprenorphine/naloxone film and the reduction in sales of branded SUBOXONE® Film.

SG&A expenses as reported in H1 2019 were $202m (H1 2018: $231m) and $87m as reported in Q2 2019 (Q2 2018: $131m). H1 2019 SG&A expenses included exceptional costs of $28m. The exceptional costs comprised of $20m primarily related to supply chain restructuring and redundancy costs, and $8m related to potential redress for ongoing intellectual property related litigation. H1 2018 SG&A expenses included a $17m exceptional gain from the out-licensing of the intranasal naloxone opioid overdose patents.

On an adjusted basis (ex.-exceptionals) H1 2019 SG&A expenses declined 30% to $173m (Adj. H1 2018: $248m) and in Q2 2019 SG&A expenses declined 34% to $86m (Adj. Q2 2019: $131m). The decline in both periods largely reflects savings from streamlining actions, including significant headcount reduction actions that have already taken place.

H1 2019 and Q2 2019 R&D expenses decreased by 26% to $25m and by 28% to $13m, respectively (H1 2018: $34m; Q2 2018: $18m). The decrease in both periods 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™.

H1 2019 operating profit as reported was $163m, 18% lower compared to the prior year (H1 2018: $200m). Exceptional costs of $28m are included in the H1 2019 reported results. An exceptional gain of $17m is included in the H1 2018 reported results. On an adjusted basis (ex.-exceptionals), H1 2019 operating profit was $191m (41% margin), a 4% increase versus $183m (35% margin) in H1 2018. Q2 2019 operating profit as reported was $88m, 5% lower compared to the prior year (Q2 2018: $84m). Exceptional costs of $1m are included in the Q2 reported 2019 results. On an adjusted basis, Q2 2019 operating profit was $89m (41% margin), a 6% increase versus $84m (31% margin) in the year-ago quarter on the same basis. The increase in both periods on an adjusted basis primarily reflects lower net revenue that was more than offset by benefits from cost saving initiatives.

H1 2019 net finance income was $3m (H1 2018: $11m 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.

H1 2019 reported tax charge was $25m, or a rate of 15% (H1 2018: $27m, 14%). Excluding the $4m tax benefit on exceptional items in H1 2019, the effective tax rate was 15% (H1 2018 adj. tax charge: $25m; 15% rate). Q2 2019 reported tax charge was $14m, or a rate of 16% (Q2 2018: $8m, 10%), with no tax exceptionals for the quarter or prior year. The rate increased both for Q2 2019 and H1 2019 due to the change in earnings mix versus the prior year.

H1 2019 net income was $141m (H1 2018: $162m), and $165m on an adjusted basis excluding the $24m after-tax impact from exceptional items (Adj. H1 2018: $147m). Q2 2019 net income was $75m (Q2 2018: $70m), and $76m on an adjusted basis excluding the $1m after-tax impact from exceptional items (Adj. Q2 2018: $70m). Lower net revenue in each period was more than offset by a decline in operating expenses (SG&A and R&D combined) and by net finance income.

EPS on a diluted basis in H1 2019 was 19 cents and 22 cents on an adjusted diluted basis (H1 2018: 22 cents on a diluted and 20 cents adjusted diluted basis). In Q2 2019, EPS on both a diluted and adjusted diluted basis was 10 cents (Q2 2018: 10 cents on a diluted and 9 cents adjusted diluted basis).

## Balance Sheet & Cash Flow

Cash and cash equivalents at the end of H1 2019 were $988m, an increase of $64m versus the $924m position at FY 2018. Borrowings, net of issuance costs, were $241m at the end of H1 2019 (FY 2018: $243m). As a result, net cash stood at $747m at H1 2019 (FY 2018: $681), a $66m improvement over the half year.

Net working capital (inventory plus trade and other receivables, less trade and other payables) was negative $271m at the end of H1 2019 versus negative $356m at the end of FY 2018. The $85m change over the period was primarily driven by lower rebate, trade payables, and accrual balances resulting from lower revenues and the cost reduction measures initiated in Q4 2018.

Cash generated from operating activities in H1 2019 was $45m (H1 2018: $119m), a decrease of $74m primarily due to the decline in operating profit and trade and other payables. Net cash flow from operations was $72m in the half year (H1 2018: $100m) primarily reflecting the lower cash from operating activities partially offset by tax refunds received.

H1 2019 cash outflow from investing activities was $2m (H1 2018: $12m). The prior year outflow primarily reflected the upfront payments for the licensing arrangements with Addex and C4X, capitalized development costs, and investments in facilities partially offset by proceeds received from the disposal of the nasal naloxone intangible asset.

H1 2019 cash outflow from financing activities was $6m (H1 2018: $1m inflow), 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 first half of the year, changes to the company's environment have occurred, specifically impacting the Principal Risks of Economic and Financial and Legal and Intellectual Property.

On April 9, 2019, a federal grand jury in the Western District of Virginia indicted Indivior PLC and Indivior Inc. on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the Company's marketing and promotion practices, paediatric 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 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, generate future revenue, and ultimately impact the Group's viability. In addition, class action lawsuits in relation to alleged U.S. 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. (Refer to Note 10 "Contingent Liabilities" on page 20).

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 U.S. dollars that have most significant impact on the Group's results were:

| | **6 Months to June 30, 2019** | **6 Months to June 30, 2018** |
|---|---|---|
| GB £ period end | 1.2698 | 1.3113 |
| GB £ average rate | 1.2940 | 1.3771 |
| | | |
| € Euro period end | 1.1382 | 1.1553 |
| € Euro average | 1.1297 | 1.2115 |

## Webcast Details

**There will be a presentation at 11:30 am BST (6:30 am EDT) hosted by Shaun Thaxter, CEO. This presentation will also be webcast live. The details are below. All pertinent materials are available on the Group's website at www.indivior.com.**

*Webcast link:* https://edge.media-server.com/mmc/p/k4988h75

| | |
|---|---|
| **Confirmation Code:** | 5287734 |
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## For Further Information

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

## 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 subsequent releases): factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing and in the supply chain; disruptions in or failure of information technology systems; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; challenges in the commercial execution; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including the indictment by the U.S. Department of Justice, potential exclusion from participating in U.S. Federal Health Care Programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

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

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

### Indication

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII) is a prescription medicine indicated for treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.
**Treatment should be initiated under the direction of healthcare providers qualified under the Drug Addiction Treatment Act.**

### Important Safety Information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE) INJECTION FOR SUBCUTANEOUS USE (CIII)
## INDICATION AND HIGHLIGHTED SAFETY INFORMATION

### INDICATION

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

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

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

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

### HIGHLIGHTED SAFETY INFORMATION

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

### CONTRAINDICATIONS

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

### WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

### ADVERSE REACTIONS

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

**For more information about SUBLOCADE, the full Prescribing Information including BOXED WARNING, and Medication Guide visit** www.sublocade.com**.**

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

## INDICATION AND HIGHLIGHTED SAFETY INFORMATION

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

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

**See full prescribing information for complete boxed warning.**

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

## CONTRAINDICATIONS

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

## WARNINGS AND PRECAUTIONS

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

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

Tardive Dyskinesia: Discontinue treatment if clinically appropriate.

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

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

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

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

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

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

## ADVERSE REACTIONS

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

**For more information about PERSERIS, the full Prescribing Information including BOXED WARNING, and Medication Guide visit** www.perseris.com**.**

# Condensed consolidated interim income statement

| For the three and six months ended June 30 | Notes | **Unaudited Q2 2019 $m** | Unaudited Q2 2018 $m | **Unaudited H1 2019 $m** | Unaudited H1 2018 $m |
|---|---|---|---|---|---|
| **Net Revenues** | 2 | **215** | 268 | **454** | 524 |
| Cost of Sales | | **(27)** | (35) | **(64)** | (59) |
| **Gross Profit** | | **188** | 233 | **390** | 465 |
| Selling, general and administrative expenses | 3 | **(87)** | (131) | **(202)** | (231) |
| Research and development expenses | 3 | **(13)** | (18) | **(25)** | (34) |
| **Operating Profit** | | **88** | 84 | **163** | 200 |
| Operating profit before exceptional items | | **89** | 84 | **191** | 183 |
| Exceptional items | 3 | **(1)** | - | **(28)** | 17 |
| Finance income | | **6** | 4 | **13** | 6 |
| Finance expense | | **(5)** | (10) | **(10)** | (17) |
| Net finance income/(expense) | | **1** | (6) | **3** | (11) |
| **Profit before Taxation** | | **89** | 78 | **166** | 189 |
| Income tax expense | | **(14)** | (8) | **(25)** | (27) |
| Taxation before exceptional items | 5 | **(14)** | (8) | **(29)** | (25) |
| Exceptional items within taxation | 5 | **-** | - | **4** | (2) |
| **Net income** | | **75** | 70 | **141** | 162 |
| | | | | | |
| **Earnings per ordinary share (cents)** | | | | | |
| Basic earnings per share | 6 | **10** | 10 | **19** | 22 |
| Diluted earnings per share | 6 | **10** | 9 | **19** | 22 |

# Condensed consolidated interim statement of comprehensive income

| For the three and six months ended June 30 | **Unaudited Q2 2019 $m** | Unaudited Q2 2018 $m | **Unaudited H1 2019 $m** | Unaudited H1 2018 $m |
|---|---|---|---|---|
| Net income | **75** | 70 | **141** | 162 |
| **Other comprehensive income** | | | | |
| *Items that may be reclassified to profit or loss in subsequent years:* | | | | |
| Net exchange adjustments on foreign currency translation | **(5)** | (16) | **1** | (10) |
| Other comprehensive (loss)/income | **(5)** | (16) | **1** | (10) |
| **Total comprehensive income** | **70** | 54 | **142** | 152 |

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

# Condensed consolidated interim balance sheet

| | Notes | **Unaudited Jun 30, 2019 $m** | Audited Dec 31, 2018 $m |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible assets | | **77** | 84 |
| Property, plant and equipment | | **57** | 57 |
| Right-of-use assets | 1 | **49** | - |
| Deferred tax assets | 5 | **42** | 44 |
| Other assets | 8 | **72** | 33 |
| | | **297** | 218 |
| **Current assets** | | | |
| Inventories | | **69** | 78 |
| Trade and other receivables | | **213** | 287 |
| Current tax receivable | | **1** | 40 |
| Cash and cash equivalents | | **988** | 924 |
| | | **1,271** | 1,329 |
| **Total assets** | | **1,568** | 1,547 |
| | | | |
| **LIABILITIES** | | | |
| **Current liabilities** | | | |
| Borrowings | 7 | **(4)** | (4) |
| Provisions | 9 | **(54)** | (69) |
| Trade and other payables | 12 | **(553)** | (721) |
| Lease liabilities | 1 | **(6)** | - |
| Current tax liabilities | 5 | **(28)** | (24) |
| | | **(645)** | (818) |
| **Non-current liabilities** | | | |
| Borrowings | 7 | **(235)** | (237) |
| Provisions | 9 | **(433)** | (424) |
| Lease liabilities | 1 | **(50)** | - |
| Other non-current liabilities | | **-** | (2) |
| | | **(718)** | (663) |
| **Total liabilities** | | **(1,363)** | (1,481) |
| **Net assets** | | **205** | 66 |
| | | | |
| **EQUITY** | | | |
| **Capital and reserves** | | | |
| Share capital | 13 | **73** | 73 |
| Share premium | | **5** | 5 |
| Other Reserves | | **(1,295)** | (1,295) |
| Foreign currency translation reserve | | **(31)** | (32) |
| Retained Earnings | | **1,453** | 1,315 |
| **Total equity** | | **205** | 66 |

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

# Condensed consolidated interim statement of changes in equity

| Unaudited | Notes | Share capital $m | Share Premium $m | Other reserve $m | Foreign currency translation reserve $m | Retained earnings $m | **Total equity $m** |
|---|---|---|---|---|---|---|---|
| **Balance at January 1, 2019** | | **73** | **5** | **(1,295)** | **(32)** | **1,315** | **66** |
| **Comprehensive income** | | | | | | | |
| Net income | | **-** | **-** | - | - | 141 | 141 |
| Other comprehensive income | | **-** | **-** | **-** | 1 | - | 1 |
| **Total comprehensive income** | | **-** | **-** | **-** | **1** | **141** | **142** |
| **Transactions recognised directly in equity** | | | | | | | |
| IFRS 16 impact (adjustment to opening balance) | | **-** | **-** | - | - | (2) | (2) |
| Share-based plans | | **-** | **-** | - | - | 1 | 1 |
| Deferred taxation on share-based plans and IFRS 16 | | **-** | **-** | - | - | (2) | (2) |
| **Balance at June 30, 2019** | | **73** | **5** | **(1,295)** | **(31)** | **1,453** | **205** |
| | | | | | | | |
| **Balance at January 1, 2018** | | 72 | 2 | (1,295) | (14) | 1,032 | (203) |
| **Comprehensive income** | | | | | | | |
| Net income | | **-** | **-** | - | - | 162 | 162 |
| Other comprehensive income | | **-** | **-** | **-** | (10) | - | (10) |
| **Total comprehensive income** | | **-** | **-** | **-** | **(10)** | **162** | **152** |
| **Transactions recognised directly in equity** | | | | | | | |
| Share-based plans | | **1** | 2 | - | - | 5 | 8 |
| Deferred taxation on share-based plans | | **-** | **-** | - | - | - | - |
| **Balance at June 30, 2018** | | **73** | **4** | **(1,295)** | **(24)** | **1,199** | **(43)** |

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

# Condensed consolidated interim cash flow statement

| For the six months ended June 30 | **Unaudited 2019 $m** | Unaudited 2018 $m |
|---|---|---|
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | |
| Operating Profit | **163** | 200 |
| Depreciation and amortization | **9** | 7 |
| Gain on disposal of intangible assets | **-** | (17) |
| Depreciation of right-of-use assets | **4** | - |
| Share-based payments | **1** | 5 |
| Impact from foreign exchange movements | **(1)** | (4) |
| Decrease in trade and other receivables | **75** | (4) |
| Increase in other assets | **(39)** | (7) |
| Decrease/(Increase) in inventories | **8** | (24) |
| Decrease in trade and other payables | **(167)** | (30) |
| Decrease in provisions | **(8)** | (7) |
| **Cash generated from operations** | **45** | 119 |
| Interest paid | **(9)** | (10) |
| Interest received | **11** | 6 |
| Taxes refunded/(paid) | **25** | (15) |
| **Net cash inflow from operating activities** | **72** | 100 |
| | | |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | |
| Purchase of property, plant and equipment | **(2)** | (5) |
| Purchase of intangible assets | **-** | (20) |
| Proceeds from disposal of intangible assets | **-** | 13 |
| **Net cash outflow from investing activities** | **(2)** | (12) |
| | | |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | |
| Repayment of borrowings | **(2)** | (2) |
| Payment of lease liabilities | **(4)** | - |
| Proceeds from the issuance of ordinary shares | **-** | 3 |
| **Net cash outflow from financing activities** | **(6)** | 1 |
| | | |
| **Net increase in cash and cash equivalents** | **64** | 89 |
| Cash and cash equivalents at beginning of the period | **924** | 863 |
| **Exchange differences** | **-** | (1) |
| **Cash and cash equivalents at end of the period** | **988** | 951 |

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 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 sales rebates and income taxes.

The Condensed 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 related to deferred tax and previously recognized straight-line lease liability. Having adopted IFRS 16, the Group will recognise interest payments within the profit and loss and lease liability payments in cashflow from financing activities; both of which are expected 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 July 30, 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 have been delivered to the Registrar of Companies.

## 2. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker ('CODM'). The CODM, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer (CEO). The Group is 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 and six months to June 30, 2019 and 2018 were as follows:

Net revenues from sale of goods:

| For the three and six months ended June 30 | **Q2 2019 $m** | Q2 2018 $m | **H1 2019 $m** | H1 2018 $m |
|---|---|---|---|---|
| United States | **163** | 214 | **362** | 411 |
| ROW | **52** | 54 | **92** | 113 |
| **Total** | **215** | 268 | **454** | 524 |

Revenue disaggregation:

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

| For the three and six months ended June 30 | **Q2 2019 $m** | Q2 2018 $m | **H1 2019 $m** | H1 2018 $m |
|---|---|---|---|---|
| SUBLOCADE™ | **17** | 2 | **28** | 2 |
| Sublingual/Other | **198** | 266 | **426** | 522 |
| **Total** | **215** | 268 | **454** | 524 |

Non-current assets:

| | **Jun 30, 2019 $m** | **Dec 31, 2018 $m** |
|---|---|---|
| United States | **122** | 62 |
| ROW | **133** | 112 |
| Total | **255** | 174 |

## 3. OPERATING EXPENSES

The table below sets out selected operating expenses information:

| For the three and six months ended June 30 | **Q2 2019 $m** | Q2 2018 $m | **H1 2019 $m** | H1 2018 $m |
|---|---|---|---|---|
| Research and development expenses | **(13)** | (18) | **(25)** | (34) |
| Marketing, selling and general expenses | **(43)** | (56) | **(86)** | (102) |
| Administrative expenses[1] | **(41)** | (71) | **(107)** | (121) |
| Depreciation and amortization | **(3)** | (3) | **(9)** | (6) |
| Operating lease rentals[2] | **-** | (1) | **-** | (2) |
| **Total** | **(87)** | (131) | **(202)** | (231) |

[1]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 considered exceptional as they primarily related to non-litigation expenses for the ongoing protection of the Group's prospective revenues.

[2]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**

| For the three and six months ended June 30 | **Q2 2019 $m** | Q2 2018 $m | **H1 2019 $m** | H1 2018 $m |
|---|---|---|---|---|
| Other operating income[1] | **-** | - | **-** | 17 |
| Restructuring costs[2] | **(1)** | | **(20)** | |
| Legal Expenses/Provision[3] | **-** | - | **(8)** | - |
| **Total exceptional items before taxes** | **(1)** | - | **(28)** | **17** |
| Tax on exceptional items | **-** | - | **4** | **(2)** |
| **Total exceptional items** | **(1)** | - | **(24)** | **15** |

[1]$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.
[2]Restructuring costs in the quarter and HY 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.
[3]$8m of legal expenses in the current year 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 Q2/H1 2019 and Q2/H1 2018. Refer to Note 3 for more information on exceptional items.

**Reconciliation of operating profit to adjusted operating profit**

| For the three and six months ended June 30 | **Q2 2019 $m** | Q2 2018 $m | **H1 2019 $m** | H1 2018 $m |
|---|---|---|---|---|
| **Operating profit** | **88** | **84** | **163** | 200 |
| Exceptional selling, general and administrative expenses | **1** | - | **28** | - |
| Exceptional operating (income)/expense | **-** | - | **-** | (17) |
| **Adjusted operating profit** | **89** | **84** | **191** | 183 |

**Reconciliation of net income to adjusted net income**

| For the three and six months ended June 30 | **Q2 2019 $m** | Q2 2018 $m | **H1 2019 $m** | H1 2018 $m |
|---|---|---|---|---|
| **Net Income** | **75** | 70 | **141** | 162 |
| Exceptional selling, general and administrative expenses | **1** | - | **28** | - |
| Exceptional operating (income)/expense | **-** | - | **-** | (17) |
| Tax on exceptional items | **-** | - | **(4)** | 2 |
| **Adjusted net income** | **76** | 70 | **165** | 147 |

## 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 six months ended June 30, 2019, the reported tax expense was $25m, or a rate of 15% (H1 2018: $27m, 14%). The tax expense on adjusted profits amounted to $29m excluding exceptionals (H1 2018: $25m) and represented a quarterly effective tax rate of 15% (H1 2018: 15% excluding exceptionals). The Group's balance sheet at June 30, 2019 included a current tax payable of $28m (FY 2018: $24m), current tax receivable of $1m (FY 2018: $40m), and deferred tax asset of $42m (FY 2018: $44m).The current tax asset decreased due the receipt of refunds during the first half of the year.

The effective tax rate to 15% 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 UK government has made an annulment application to the General Court against this 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. HMRC have sent an information request (dated 12 July) and the Group is in the process of gathering the information requested to compile a response.

The Group has benefited from the UK controlled foreign company financing exemption and the tax thereon is approximately $24 million including interest.

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 and six months ended June 30 | **Q2 2019 cents** | Q2 2018 cents | **H1 2019 cents** | H1 2018 cents |
|---|---|---|---|---|
| Basic earnings per share | **10** | 10 | **19** | 22 |
| Diluted earnings per share | **10** | 9 | **19** | 22 |
| Adjusted basic earnings per share | **10** | 10 | **23** | 20 |
| Adjusted diluted earnings per share | **10** | 9 | **22** | 20 |

### 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.

| Weighted average number of shares | **2019 thousands** | 2018 thousands |
|---|---|---|
| On a basic basis | **729,724** | 725,917 |
| Dilution from share awards and options | **26,504** | 24,190 |
| On a diluted basis | **756,228** | 750,107 |

### 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

| Current | **Jun 30 2019 $m** | Dec 31 2018 $m |
|---|---|---|
| Bank loans | **(4)** | (4) |
| | **(4)** | (4) |

| Non-current | **Jun 30 2019 $m** | Dec 31 2018 $m |
|---|---|---|
| Bank loans | **(235)** | (237) |
| | **(235)** | (237) |

| Analysis of net cash | **Jun 30 2019 $m** | Dec 31 2018 $m |
|---|---|---|
| Cash and cash equivalents | **988** | 924 |
| Borrowings* | **(241)** | (243) |
| | **747** | 681 |

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

| Reconciliation of net cash | Jun 30 2019 $m | Dec 31 2018 $m |
|---|---|---|
| The movements in the period were as follows: | | |
| Net cash at beginning of period | **681** | 376 |
| Net increase in cash and cash equivalents | **64** | 61 |
| Net repayment of borrowings | **2** | 240 |
| Exchange adjustments | **-** | 4 |
| Net cash at end of period | **747** | 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 June 30, 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. OTHER ASSETS

| | Jun 30 2019 $m | Dec 31 2018 $m |
|---|---|---|
| Long-term prepaid expenses | **22** | 33 |
| Other non-current assets | **50** | - |
| Total | **72** | 33 |

Long-term prepaid expenses relate primarily to payments for contract manufacturing capacity and Other non-current assets relate to surety bond funding.

## 9. PROVISIONS

| | Jun 30 2019 $m | Dec 31 2018 $m |
|---|---|---|
| Litigation/Investigative matters | **(438)** | (438) |
| Intellectual property related matters | **(43)** | (44) |
| Restructuring costs | **(3)** | (8) |
| Other | **(3)** | (3) |
| Total | **(487)** | (493) |

The Group is involved in legal and intellectual property disputes as described in Note 11, “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 11 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 $43m for intellectual property related matters, all of which relate to potential redress for ongoing intellectual property related litigation with DRL and Alvogen, and have been recognized 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.

## 10. CONTINGENT LIABILITIES

Other than the disputes for which provisions have been taken as disclosed in Note 9, '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 11, 'Legal Proceedings.'

## 11. 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 Indivior PLC and Indivior Inc. on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the marketing and promotion practices, pediatric safety claims, and overprescribing of SUBOXONE® Film and/or SUBOXONE® Tablet by certain physicians. DOJ is seeking to recover $3 billion in monetary forfeitures and all assets derived from the commission of the alleged offenses. Indivior believes it has strong defences to the government's charges and will vigorously defend itself. On July 19, 2019, Indivior filed a Motion to Dismiss the indictment. It is not possible to predict with any certainty the potential impact of this litigation or to quantify the ultimate cost of a verdict or resolution, but it could have a material impact on the Group.

***State Subpoenas and Civil Investigative Demands***

- On October 12, 2016, Indivior was served with a subpoena for records from the State of Connecticut Office of the Attorney General under its Connecticut civil false claims act authority. The subpoena requests documents related to the Group's marketing and promotion of SUBOXONE® products and its interactions with a non-profit third-party organization. The Group is fully cooperating in this civil investigation.
- On November 16, 2016, Indivior was served with a subpoena for records from the State of California Department of Insurance under its civil California insurance code authority. The subpoena requests documents related to SUBOXONE® Film, SUBOXONE® Tablet, and SUBUTEX® Tablet. The State of California served additional deposition subpoenas on Indivior in 2017 and served a subpoena in 2018 requesting documents relating to the bioavailability / bioequivalency of SUBOXONE® Film, manufacturing records for the product and its components, and the potential to develop dependency on SUBOXONE Film. The Group is fully cooperating in this civil investigation.
- In June 2019, the Group learned that the State of Illinois Insurance Department is investigating potential violations of its Insurance Claims Fraud Prevention Act with respect to sales and marketing activity by the Company. The Group is fully cooperating in this civil investigation.
- On July 1, 2019, the Indiana Attorney General issued a Civil Investigative Demand investigating potential violations of Indiana's Deceptive Consumer Sales Act with respect to sales and marketing activity by the Company. The Group is cooperating fully in this civil investigation.

***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 largely complete.

***Opioid Class Action Litigation***

- In February 2019, Indivior, along with other manufacturers of opioid products, was first named but not served in one of the national multi-district litigation cases brought by state and local governments and public health agencies in the Northern District of Ohio, alleging misleading marketing messages. At present, Indivior has been named by other state and local governments and in other multi-district cases brought by individual plaintiffs. To date, Indivior has been

named in slightly more than 246 such lawsuits in federal court. Indivior has been voluntarily dismissed with prejudice from one of these lawsuits and has been voluntarily dismissed without prejudice in eight others, leaving 237 active cases as of July 24, 2019. In addition, Indivior has been named in one opioid-related case in the Court of Common Pleas in the Commonwealth of Pennsylvania and three cases in the Twenty-Second Judicial District, Parish of St. Tammany in the State of Louisiana. All proceedings in the multi-district litigation pending in the Northern District of Ohio and in Pennsylvania state court with respect to Indivior have been stayed.

***Securities Class Action Litigation***

- On April 23, 2019, Michael Van Dorp filed a putative class action lawsuit in the United States District Court for the District of New Jersey on behalf of holders of publicly traded Indivior securities alleging violations of U.S. federal securities laws under the Securities Exchange Act of 1934. The complaint names Indivior PLC, Shaun Thaxter, Mark Crossley and Cary J. Claiborne as defendants. On June 24, 2019, Mr. Van Dorp filed a motion to be appointed as lead plaintiff on behalf of the putative class. On July 15, 2019, the parties entered into a stipulation extending the defendants time to respond to any complaint in the action until after the Court appoints a lead plaintiff.

**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, as well as Apotex Corp. and Apotex Inc. (collectively, "Apotex") 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 and Apotex have filed counterclaims on these patents, as well as U.S. Patent Nos. 9,855,221 and 8,475,832. 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 Laboratories UT, Inc. ("Actavis," formerly known as Watson Laboratories Inc.) received tentative approval from FDA for 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. That ruling was affirmed by the Court of Appeals for the Federal Circuit ("CAFC") on July 12, 2019. Litigation against Actavis is also pending in the District of Delaware on the '305 and '454 patents.
- On August 31, 2017, the United States District Court for the District of Delaware found that asserted claims of the '150 Patent, U.S. Patent No. 8,900,497 ("the '497 Patent") and the '514 Patent are valid but not infringed by Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories Inc. (collectively, "DRL"). Indivior appealed the rulings as to the '514 and '150 patents, and on July 12, 2019, the CAFC upheld the District Court ruling, finding the patents not invalid but also not infringed by DRL.
- 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 July 13, 2018, the District Court issued a ruling granting Indivior a Preliminary Injunction (PI) pending the outcome of a trial on the merits of the '305 Patent. Indivior was required to post a surety bond for $72 million in connection with the PI. On November 20, 2018, the CAFC issued a decision vacating the PI against DRL. Indivior's motion for rehearing and rehearing en banc was denied on February 4, 2019, and the mandate issued on February 19, 2019. DRL is no longer prevented from selling, offering to sell, or importing their generic buprenorphine/naloxone sublingual film products. DRL has re-launched its generic product, and any sales in the U.S. are on an "at-risk" basis, subject to the outcome of the ongoing litigation in the District of New Jersey asserting Orange Book-listed U.S. Patent Nos. 9,931,305 and 9,687,454.
- On November 13, 2018, DRL filed two separate petitions for inter partes review ("IPR") 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. The USPTO denied institution of one of the IPR petitions but granted institution for the second IPR petition. A final decision on the IPR is expected in June of 2020.
- Teva Pharmaceuticals USA, Inc. ("Teva") filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of buprenorphine/naloxone film (CASSIPA™). Indivior, Aquestive Pharmaceuticals (formerly known as MonoSol Rx) and Teva agreed that infringement of the '514, '497, and '150 patents by Teva's 16mg/4mg dosage strength would be governed by the infringement ruling as to DRL's 8mg/2mg dosage strength that was the subject of the trial in November 2016. Accordingly, the non-infringement ruling by the District of Delaware in the DRL case means that the Teva 16mg/4mg dosage strength has been found not to infringe those patents. Indivior appealed the November 2016 DRL ruling as to the '514 and '150 patents, and on July 12, 2019, the CAFC upheld the District Court finding of noninfringement. 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 District of New Jersey DRL case for the ’454 and ’305 Patents. Teva was therefore able to launch CASSIPA at-risk as of February 19, 2019, when the CAFC issued a mandate vacating the PI against DRL. Any sales of CASSIPA in the U.S. would be on an “at-risk” basis, subject to the outcome of the ongoing litigation against Teva and DRL in the District of New Jersey.

- Trial against Alvogen Pine Brook, Inc. (“Alvogen”) in the lawsuit involving the ’514 and ’497 Patents took place in September 2017. The trial was limited to the issue of infringement because Alvogen did not challenge the validity of either patent. On March 22, 2018, the United States District Court for the District of Delaware ruled both patents were not infringed by Alvogen. Indivior appealed this ruling, and on July 12, 2019, the CAFC upheld the noninfringement judgments. Litigation against Alvogen is also pending in the United States District Court for the District of New Jersey on the ’454 and ’305 patents. On January 22, 2019, Indivior filed a motion for a temporary restraining order (“TRO”) and preliminary injunction in the District of New Jersey, requesting that the Court restrain the launch of Alvogen’s generic buprenorphine/naloxone film product until a trial on the merits of the ’305 patent. Alvogen received approval for its generic product on January 24, 2019. The same day, the District of New Jersey granted a TRO until February 7, 2019. On January 31, 2019, Indivior and Alvogen entered in to an agreement whereby Alvogen was enjoined from the use, offer to sell, or sale within the United Sates, or importation into the United States, of its generic buprenorphine and naloxone sublingual film product unless and until the CAFC issued a mandate vacating the PI against DRL. The mandate vacating the DRL PI issued on February 19, 2019, and Alvogen launched its generic product. Any sales in the US are on an “at-risk” basis, subject to the ongoing litigation against Alvogen on the ’454 and ’305 patents in the District of New Jersey.
- 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 Technologies Inc.; Mylan Pharmaceutics Inc.; and Mylan N.V. (“Mylan”), the terms of which are confidential. Mylan received final FDA approval for its generic version of the 8mg/2mg buprenorphine/naloxone film product on June 14, 2018. Mylan launched its generic version on or about February 22, 2019.
- On May 11, 2018, Indivior settled its SUBOXONE® Film patent litigation against Par Pharmaceutical, Inc. (“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 litigation was dismissed with prejudice on May 22, 2019.

**Regulatory exclusivity related matters**

***Braeburn Inc. v. FDA and Indivior Inc.***

- On December 21, 2018, Braeburn Inc. received tentative approval for its injectable depot buprenorphine product, Brixadi™. FDA did not grant final approval to Braeburn because it determined that the monthly version of Brixadi™ was blocked until November 30, 2020 by Indivior’s three-year exclusivity period for injectable depot buprenorphine products that are approved to treat moderate to severe opioid use disorder.

- On April 9, 2019, Braeburn Inc. sued the FDA in the United States District Court for the District of Columbia, asking the Court for an order holding unlawful, vacating, and setting aside FDA’s decision that Sublocade’s three-year exclusivity period bars approval of its monthly Brixadi product. Indivior moved to intervene on April 11, 2019, and that motion was granted on April 12, 2019. Braeburn moved for summary judgment on May 13, 2019, and both the FDA and Indivior filed cross-motions for summary judgment on June 3, 2019. The court heard oral argument on the parties’ cross-motions on July 15, 2019.

- On July 22, 2019, the U.S. District Court for the District of Columbia granted Braeburn’s motion for summary judgment, and vacated FDA’s initial three-year exclusivity decision. The Court remanded the issue for FDA “to reconsider, with deliberate speed, Braeburn’s application for final approval of Brixadi Monthly.”

***Braeburn Citizen Petition***

On April 5, 2019, Braeburn submitted a Citizen Petition to the FDA asking that FDA revoke the Orphan Drug Designation that previously was granted to Indivior and applied to SUBLOCADE™, and that the FDA further refuse to grant Orphan Drug

Exclusivity to SUBLOCADE™. Indivior submited a response to this Citizen Petition on July 24, 2019. The FDA's decision remains pending at this time.

## 12. TRADE AND OTHER PAYABLES

| | **Jun 30 2019 $m** | Dec 31 2018 $m |
|---|---|---|
| Sales returns and rebates | **(396)** | (510) |
| Trade payables | **(25)** | (47) |
| Accruals | **(121)** | (149) |
| Other tax and social security payables | **(11)** | (15) |
| Total | **(553)** | (721) |

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

## 13. SHARE CAPITAL

| | **Equity Ordinary Shares** | **Issue price** | **Nominal value $m** |
|---|---|---|---|
| Issued and fully paid | | | |
| **At January 1, 2019** | **728,441,653** | **$0.10** | **73** |
| Allotments | **1,601,495** | **$0.10** | **-** |
| **At June 30, 2019** | **730,043,148** | | **73** |

| | Equity Ordinary Shares | Issue price | Nominal value $m |
|---|---|---|---|
| Issued and fully paid | | | |
| At January 1, 2018 | 721,462,733 | $0.10 | 72 |
| Allotments | 6,641,420 | $0.10 | 1 |
| At June 30, 2018 | 728,104,153 | | 73 |

### Allotment of ordinary shares

During the period, 1,601,495 ordinary shares (2018: 6,641,420) were allotted to satisfy vestings/exercises under the Group's Long-Term Incentive Plan and U.S. Employee Stock Purchase Plan.

## 14. POST BALANCE SHEET EVENTS

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**

By order of the Board

Shaun Thaxter
Chief Executive Officer

Mark Crossley
Chief Financial and Operations Officer

July 30, 2019

# *Independent review report to Indivior PLC*

## Report on the condensed consolidated interim financial statements

### Our conclusion

We have reviewed Indivior PLC's condensed consolidated interim financial statements (the "interim financial statements") in the H1 2019 Results of Indivior PLC for the three and six month periods ended 30 June 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.

### 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 9 and 11 that describe the uncertain outcome of the ongoing litigation by the Department of Justice (DoJ), 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.

### 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 9 and 11 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 for 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.

### What we have reviewed

The interim financial statements comprise:

- the Condensed consolidated interim balance sheet as at 30 June 2019;
- the Condensed consolidated interim income statement and Condensed consolidated interim statement of comprehensive income for the three and six month periods then ended;
- the Condensed consolidated interim cash flow statement for the six month period then ended;
- the Condensed consolidated interim statement of changes in equity for the six month period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the H1 2019 Results have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and

the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

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

## Responsibilities for the interim financial statements and the review

### Our responsibilities and those of the directors

The H1 2019 Results, including the interim financial statements, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the H1 2019 Results in accordance with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express a conclusion on the interim financial statements in the H1 2019 Results based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

### What a review of interim financial statements involves

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

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

We have read the other information contained in the H1 2019 Results and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP
Chartered Accountants
London
30 July 2019