

February 22nd, 2017

Full Year 2016 Adjusted Financial Results Ahead of Plan. Guidance for 2017.

Period to December 31st	Q4 2016 \$m	Q4 2016 Adj*	Q4 2015 \$m	% Δ Act FX	% Δ Cons FX	FY 2016 \$m	FY 2016 Adj*	FY 2015 \$m	% Δ Act FX	% Δ Cons FX
Net Revenue	259	259	248	+4	+6	1,058	1,058	1,014	+4	+5
Operating Profit	71	72	38	+87	+113	149	387	346	-57	-57
Net Income	78	49	37	+111	+65	35	254	228	-85	-86
EPS (cents)	11	7	5	+120	+65	5	35	32	-84	-86

* adjusted basis, excluding impact of exceptional SD&A items of \$1m in Q4 and \$238m in FY and exceptional tax items of \$30M in Q4 and \$19m in the FY.

This announcement contains inside information.

The Company recorded a charge of \$220m in the third quarter of 2016 for the investigative and antitrust litigation matters disclosed under Litigation Update on pages 8-9. The Company continues in discussions with the Department of Justice about a possible resolution to its investigation. The Company cannot predict with any certainty whether it will be able to reach ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this reserve.

Full Year Financial Highlights

- Net revenue at \$1,058m (2015: \$1,014m) increased 4%. Net revenue at constant FX was +5%.
- Operating profit of \$149m (2015: \$346m) after exceptional costs of \$238m. Adjusted operating profit of \$387m (2015: \$377m) +3%.
- Net income was \$35m (2015: \$228m) after net financing costs of \$51m (2015: \$61m). Adjusted tax rate of 25% (2015: 22%). Adjusted net income was \$254m (2015: \$246m) +3%.
- Cash balance at period end of \$692m. Net cash of \$131m (2015: net debt of \$174m).

Full Year Operating Highlights

- US market growth in FY 2016 improved during the year to high single digit percentage. Suboxone® Film average market share was 61% (2015: 60%).
- New product pipeline progress. Analysis of completed Phase III trials of Buprenorphine Monthly Depot and Risperidone Monthly Depot on track for filing of NDAs in 2017 on previously published timetable (see detail on page 7).
- ANDA Litigation. Trial in the Orange Book listed patent lawsuit against Dr Reddy's Laboratories and the process patent case against Dr Reddy's, Actavis & Par completed in November with ruling expected in Q2.

Guidance

- Full year preliminary 2017 guidance: net revenue of \$1,050m-\$1,080m and net income in a range of \$200m-\$220m excluding exceptionals and at constant exchange rates assuming no material change to current market conditions in the US. The guidance also reflects a strategic decision to reinvest an additional \$40m-\$60m in driving future organic growth priorities.
- Indivior has today updated projected peak annual net revenues for both its potential monthly depots assuming no material change in market circumstances:

- Buprenorphine Monthly Depot, peak annual net revenues now projected to be at least \$1,000m (previously \$400m-\$700m).
- Risperidone Monthly Depot, peak annual net revenues now projected to be in a range of \$200m-\$300m (previously \$100m-\$200m).

The majority of the \$40-\$60m of incremental investment will be focused on pre-launch preparation for these potential assets which require a different distribution and reimbursement model than the existing business.

Comment by Shaun Thaxter, CEO of Indivior PLC

“Indivior PLC had a strong second year as a public company.” commented **Shaun Thaxter, CEO of Indivior PLC**. “We outperformed our financial plan for the year and we made significant strategic progress against our objectives. The treatment market in the US grew by high single digits, with many new doctors certified, and more patients in treatment. Suboxone® Film share of 61% in the US demonstrated the resilience of our core business in the face a highly competitive market featuring multiple generic and branded competitors. This resilience was underlined by our ANDA trial success in June against Actavis and Par; we retain belief in the strength of the IP on Suboxone® Film, which will be tested again this year. We also took steps to further enhance our compliance capability to keep pace with the expected market growth. Our pipeline of potential treatments for addiction made progress. The potentially transformational Monthly Depot of Buprenorphine completed its Phase III trials and is on track to submit its NDA in Q2 this year while our Monthly Risperidone Depot completed its Phase III trials and is on track for filing later this year. We successfully filed our NDA for Suboxone® Tablets in China at the end of 2016.”

“Our guidance for 2017, if delivered, would represent another year of progress for the Company building on the growth achieved in 2016, albeit it assumes no material change in the US market. We are looking for a second year of net revenue growth in a growing marketplace, and for profit to be resilient taking account of a more ambitious investment plan to drive longer-term organic opportunities. The promise of our pipeline on top of the scale of the opioid crisis in the USA suggests there is room for sustained long-term growth in the business. At the same time, we continue to work intensively to manage the risks to the business. We hope for further success in defending our IP in the ANDA litigation. The Board has recorded a \$220m charge in connection with the investigative and antitrust litigation matters although the Company cannot predict with any certainty whether we will be able to reach ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this reserve.”

“Indivior PLC is focused on empowering patients and striving to improve their quality of life by pioneering innovative, high-quality, accessible and cost effective treatments,” **Shaun Thaxter** continued. “I am pleased with our progress towards realizing our vision and achieving key strategic priorities for 2016. We strongly welcome recent regulatory and legislative change in the USA which recognizes the scale of the opioid crisis. It can only be good news that 2016 saw record numbers of physicians qualifying to treat addiction with medication assisted treatment, that many have already qualified for the higher patient cap of 275, and that training is now developed for nurse practitioners and physician assistants to allow them to start treating patients. The medical societies, addiction treatment experts, regulators and the industry need to co-operate further in 2017 to ensure that this progress continues for the sake of the more than 2.4m Americans who suffer from this chronic, relapsing condition. Every step of progress at Indivior should help address the crisis by bringing more patients into treatment and by improving the range and quality of treatments available to them and their physicians. That is our mission and our commitment.”

Full Year Operating Review

US Market Update

The market for buprenorphine products showed modest acceleration in growth in 2016, with volume growth of high single digit percentage in line with expectation. A key driver of growth remains the certification of new physicians to practice addiction medicine as patients look to find treatment. Such certification was at record levels in 2016. In addition, over 2,400 physicians have now been waived to treat up to 275 patients, the higher patient cap approved in August 2016 although the impact of this has been small so far.

Suboxone® Film had a market share of 61% on average in 2016, compared to 60% in the same period in 2015 (on a restated database). This was slightly ahead of the exit share at the end of 2015, so market share has been maintained. The Company has taken steps to enhance its compliance capability to handle this growth.

Guidance for Full Year 2017

The Company today issued its preliminary financial guidance for 2017; net revenue in a range of \$1,050m to \$1,080m, and net income in a range of \$200m to \$220m all at constant exchange. This guidance is based on the assumption of no material change to current US market conditions - no disruption to US generic tablet pricing, no generic film entry, and limited impact of branded competition in 2017. The net income guidance excludes exceptional items.

The guidance also reflects a strategic decision to reinvest an additional \$40m to \$60m in driving organic growth opportunities in the long-term.

Investment in launch preparation of RBP-6000, assuming the product is approved, will include:

- New medical affairs capacity to enhance scientific exchange and education with physicians on the science related to receptor occupancy and blockade.
- New field based team with capability to address the new mechanisms of reimbursement that will be required.
- New specialty pharmaceutical distribution architecture.

In addition, investment will also be directed at increasing access to treatment for patients with opioid use disorder in the USA, particularly in the light of recent legislative and regulatory changes which are expected to expand the number of medical professionals eligible to treat the condition.

While the final launch strategy for the monthly Risperidone depot (RBP-7000) for the treatment of schizophrenia remains under consideration, we will invest in planning activities in preparation for launch, assuming approval. This is necessary whatever the final decision on route-to-market, either Indivior alone or in conjunction with a third-party.

As the market for buprenorphine products continues to grow and we invest in our pipeline, the Company is committed to continuing to enhance its compliance capability to keep up with expected growth on a continuing basis in 2017.

Cost savings

Indivior has completed its benchmarking study relative to an appropriate peer group of multinational specialty pharmaceutical companies. The data shows Indivior's operating expenses compared to net revenue are broadly average or better excluding unusual legal costs and the cost of separation/set-up as an independent company. The study has shown some opportunity in indirect procurement costs which will result in savings of around \$10m spread across 2016 and 2017. Management has also used the study findings to challenge operating expenses across the business with a target to hold operating expenses flat in 2017 excluding the additional investment highlighted above.

Peak Annual Net Revenue Estimates

The Company today revised its estimates for potential peak annual net revenues (previously reviewed in 2014) for two of its pipeline projects assuming they are approved.

- Buprenorphine Monthly Depot (RBP-6000), peak annual net revenues now projected to be at least \$1,000m (previously \$400m-\$700m). This increased estimate is based on more research findings on the potential market opportunity for the Buprenorphine Monthly Depot following completion of its Phase III trials as well as a revised estimate of potential market size, reflecting faster market growth historically and anticipated following regulatory and legislative change in the USA.

However, the introduction of the once a month buprenorphine depot will be more complex than the launch of Suboxone® Film, as there are a number of key challenges which need to be overcome which will likely result in a slower initial rate of uptake albeit with a higher peak net revenue.

- Risperidone Monthly Depot (RBP-7000), peak annual net revenues now projected to be in a range of \$200m-\$300m (previously \$100m-\$200m). This higher estimate reflects continuing growth in the market for long-acting treatments for schizophrenia and the successful outcome of the product's Phase III trials combined with research findings on the potential niche market opportunity for RBP-7000.

Both of these revised peak net revenue estimates are based on no material change in market circumstances.

Financial Performance for twelve months to December 31st, 2016

The analysis below shows the financial performance both as reported and on an adjusted basis, excluding the exceptional items. A full profit and loss account on an adjusted basis for both Q4 and FY 2016 (and 2015) is shown on page 25.

For full year, total net revenue increased 4% to \$1,058m (2015: \$1,014m) at actual exchange rates reflecting improving US market growth, increased list price and slightly increased market share offset by the higher rebates in connection with maintained formulary access and negative channel mix. At constant exchange rates, net revenues increased 5%.

In Q4, total net revenue increased 4% at actual exchange rates to \$259m (Q4 2015: \$248m). At constant exchange rates the increase in Q4 was 6%.

US net revenue increased in the full year by 6% to \$857m (2015: \$807m). Volume was ahead of last year reflecting market growth and slightly increased average market share compared to prior year. Pricing reflected a combination of increased list price, offset by adverse channel mix, with lower margin Medicaid sales growing faster than total market, and tactical rebates, in connection with formulary access in both commercial managed care and Medicaid in the face of aggressive discounting by branded competitors.

In Q4, net revenue increased 6% in the US to \$206m (Q4 2015: \$194m) reflecting a slight increase in market growth towards the end of the year, maintained market share and pricing offset by channel mix and tactical rebates.

For the full year, Rest of World net revenue declined by 3% to \$201m (2015: \$207m) as reported in USDs but this decline was due to translation out of a weak GBP and weaker Euro. At constant exchange, net revenue increased 1%, reflecting growth for Suboxone in Europe and further steady growth in Australia.

In Q4, Rest of World net revenue declined 2% to \$53m (Q4 2015: \$54m); at constant exchange rates net revenue increased 4% reflecting growth in both Europe and Australia plus some one-off exports revenue in Europe.

Gross margin for the full year was 90%, unchanged from last year (2015: 90%). Excluding the exceptional item of \$11m included in Cost of Sales, the gross margin was 91% benefitting slightly from the devaluation of GBP. The exceptional items were in respect of the exploration of strategic initiatives for the event of a potential negative ANDA ruling.

SD&A expenses for the full year increased 61% to \$683m (2015: \$423m). The increase mainly reflects the exceptional items included in SD&A of \$227m (2015: \$15m). The exceptional costs include write offs of manufacturing costs and legal and advisory costs related to the exploration of strategic initiatives for the event of a negative ANDA ruling plus ongoing legal costs and the provision of \$220m in the third quarter of the year for the investigative and antitrust litigation matters set out on pages 8-9 below.

On an adjusted basis, the SD&A expenses for the year were \$456m, an increase of 12% (2015: \$408m) reflecting increased legal expenses, annualisation of the full PLC standalone costs of \$55m plus investment of additional \$30m in launch planning activities ahead of the expected approval of RBP-6000, the monthly depot of Buprenorphine, in 2017/18 partially offset by cost savings.

R&D expenses for the year decreased by 20% to \$119m (2015: \$148m), reflecting the lower level of activity in the Company's clinical development pipeline, which has advanced compared to prior year, and in particular to fewer pipeline projects in development plus the fact that the pivotal Phase III trials running in 2015 are now largely complete. On an adjusted basis, excluding the exceptional \$16m write-off included in R&D in 2015, the decrease in R&D expenses was 10%.

Operating profit for the year was \$149m, 57% below prior year (2015: \$346m). On an adjusted basis, operating profit was \$387m, 3% ahead of the prior year (2015: \$377m).

EBITDA for the full year was \$163m (2015: \$370m), and excluding the exceptional costs was \$401m (2015: \$401m).

Operating margin was 14% as reported (2015: 34%). Excluding the exceptional costs, the operating margin was 37% (2015: 37%).

Finance expenses for the full year were \$51m (2015: \$61m) being the full all-in cost of interest and amortisation for the \$750m borrowing facility as reduced by the repurchase of debt in the open market in 2015-16 and the repayment of debt on schedule. Borrowings over the year reduced by \$78m.

The underlying tax rate on the pretax profit for the period was 25% (2015: 22%) in line with expectations. The reported tax charge for the full year was \$63m, an effective rate of 64% (2015: 20%) including \$19m exceptional tax credit. The exceptional tax credit consists of \$13m of exceptional tax effects on the movement of assets within the Group, additional provisions for unresolved tax matters and prior year adjustments and Patent Box claim benefits, and \$6m relating to the the effect of exceptional items within SD&A and Cost of Sales.

Net income for the year was therefore \$35m (2015: \$228m), excluding exceptional costs, the adjusted net income was \$254m, an increase of 3% (2015: \$246m).

EPS for the full year was 5 cents (2015: 32 cents) basic and 5 cents (2015: 31 cents) on a fully diluted basis. On an adjusted basis, excluding the effect of exceptional costs, basic EPS was 35 cents (2015: 34 cents) and fully diluted EPS was 34 cents (2015: 34 cents).

Cash Flow

Cash generated from operations in the full year was \$512m (2015: \$518m), a decrease of \$6m reflecting an improvement in net working capital reflecting trade payables dynamic on working capital with a release of cash of \$119m (2015: \$127m). Depreciation, amortization and impairment (non cash items) decreased to \$14m (2015: \$40m) as there were no impairment charges in 2016 and

amortization of the cost of acquisition of the ROW rights in 2010 was completed in the first half of the year.

In the full year net cash inflow from operating activities was \$407m (2015: \$320m) reflecting the slight decrease in cash from operating activities plus significantly lower tax payments in the period of \$63m (2015: \$131m), interest paid of \$42m (2015: \$44m) and transaction costs relating to the loan facility of nil (2015: \$23m).

Full Year investment in property, plant and equipment, primarily related to the new R&D laboratory in Hull and redevelopment of the facility in Fort Collins, plus building refits was \$20m (2015: \$27m). Investments in intangible assets of \$15m related to the development of the Company's standalone ERP system.

In the full year, the Group repaid \$78m (2015: \$112m) of its term loan as part of its commitment under the syndicated debt facility. The final dividend for 2015 was \$69m, paid in July 2016 (2015: interim dividend of \$23m). The Board has determined that it does not expect to pay further dividends in the foreseeable future.

The net increase in cash and cash equivalents in the period therefore was \$225m (2015: \$145m), being the sum of the cash inflow from operating activities of \$407m, less net cash outflows from investing and financing activities of \$35m and \$147m respectively. Added to the cash and cash equivalents at the beginning of the period of \$467m, that gave the Group a total cash and cash equivalents balance of \$692m at the period end.

The increase in cash and cash equivalents in Q4 was \$106m.

Balance Sheet at December 31st, 2016

Non-current assets increased to \$219m at the year end (2015: \$216m) primarily due to increases in property, plant and equipment mostly offset by a decrease in intangible assets from the amortisation of the ROW rights and deferred tax assets. \$20m of costs related to the development of the ERP system, within PPE in 2015, were reclassified to Intangibles in the period.

Inventories decreased to \$41m (2015: \$48m). Trade and other receivables were \$227m (2015: \$206m). The overall increase in current assets was primarily due to the \$225m increase in cash and cash equivalents in the year and \$30m increase in current tax receivable.

Trade and other payables increased to \$658m (2015: \$528m), reflecting higher sales combined with higher levels of rebates in the US in connection with formulary access and in response to heightened branded competition.

Current tax liabilities increased to \$52m (2015: \$41m) following significant tax accruals in the year.

Net working capital (inventory plus trade and other receivables, less trade and other payables) was minus \$390m at the year end, an improvement of \$116m on December 2015 reflecting the trade payables dynamic in the US. This represents a ratio of minus 37% of annual total net revenue.

Cash and cash equivalents at the period end was \$692m, reflecting a net cash increase of \$225m in the year. Cash and cash equivalents increased \$106m in Q4.

Borrowings, net of issuance costs, were \$535m at the year end (2015: \$605m).

The net cash of the Group was \$131m at the year end (2015: net debt of \$174m) including the unamortised cost of the debt facility. In Q4, net cash increased by \$120m.

At the period end, therefore, the Group had net liabilities of \$295m (2015: \$279m), consisting of assets of \$1,209m (2015: \$937m), and liabilities of \$1,504m (2015: \$1,216m).

R&D / Pipeline Update

Developments since Half-Year 2016 results announcement: -

Treatment of Opioid Use Disorder

- **SUBOXONE® Tablet.** NDA submitted to Chinese FDA December 27th, 2016. sNDS submitted to Health Canada for two additional dosage strengths (12mg & 16mg) December 6th, 2016.
- **RBP-6000, Monthly Depot Buprenorphine:** Phase III Efficacy study (RB-US-13-0001); top line results published on August 17th, 2016 showing RBP-6000 achieved both primary and secondary endpoints. Phase III Safety Extension Study (RB-US-13-0003) completed with database lock achieved October 31st, 2016.

US Fast Track Designation granted May 23rd, 2016.

Pre-NDA meeting held December 2016. Target NDA submission to FDA Q2-2017.

Meetings with Regulatory Agencies ex-USA held in Q4-2016: TGA (Australia); HC (Canada); ANSM (France); MHRA (United Kingdom); MPA (Sweden); BfArM (Germany).

Overdose Rescue Products

- **Intranasal Naloxone for treatment of opioid overdose.** NALSCUE® launched in France under Temporary Authorisation for Use (ATU) in July 2016. MAA submitted November 2016.
- **RBP-8000 Cocaine Esterase for treatment of Cocaine Intoxication.** Second type B meeting with FDA held March 2016. Per agreement with FDA, work has continued with the development of a lyophilized product and first test batch has been manufactured in October 2016.

Treatment of Alcohol Use Disorder

- **Arbaclofen Placarbil for alcohol use disorder:** Phase IIa study (RB-US-14-0001) reported July 2016 finding Arbaclofen Placarbil to be safe and well tolerated in controlled abstinence setting, but with high inter-individual PK variability observed. New Phase I bioavailability clinical study protocol (INDV-AP-102) of a new formulation of Arbaclofen Placarbil was approved by the Research Ethics Committee in November 2016 and the CTA was successfully approved by MHRA in January 2017.

Treatment of Schizophrenia

- **RBP-7000, Monthly Depot Risperidone** for the treatment of schizophrenia. Preliminary data from pivotal Phase III Efficacy study were published on May 5th, 2015; more detailed information regarding these data is available at www.indivior.com and in the separate press release issued on May 5th, 2015.

Phase III long-term safety study (RB-US-13-0005) was completed in September 2016 with database lock achieved October 2016.

Pre-NDA meeting held August 2016. Target NDA submission to FDA Q4-2017.

Key Pipeline Dates 2017

Q1	RBP-6000 Long-term safety extension Top Line results
Q1	RBP-7000 long-term safety extension Top Line results
Q2	RBP-6000 NDA filing
June	CPDD Conference - RBP-6000 Phase III efficacy, safety & HEOR data
Oct	ACoP Conference RBP-6000 Phase III Exposure/Response Data
Q4	RBP-7000 NDA filing
Q4	PDUFA date for RBP-6000 assuming Priority Review is granted.

Litigation Update

The Company has recorded a charge of \$220m in the third quarter of 2016 for the investigative and antitrust litigation matters noted below. The Company continues in discussions with the Department of Justice about a possible resolution to its investigation. The Company cannot predict with any certainty whether we will be able to reach ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this reserve.

Department of Justice Investigation

- A federal criminal grand jury investigation of Indivior initiated in December 2013 is continuing, and includes marketing and promotion practices, pediatric safety claims, and overprescribing of medication by certain physicians. The U.S. Attorney's Office for the Western District of Virginia has served a number of subpoenas relating to SUBOXONE® Film, SUBOXONE® Tablet, SUBUTEX® Tablet, buprenorphine and our competitors, among other issues. We are in discussions with the Department of Justice about a possible resolution of the investigation. It is not possible at this time to predict with any certainty the potential impact of this investigation on us or to quantify the ultimate cost of a resolution. We are cooperating fully with the relevant agencies and prosecutors and will continue to do so.

State Subpoenas

- On October 12th, 2016, the Company 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 Company's marketing and promotion of SUBOXONE® products and its interactions with a non-profit third party organization. On November 16th, 2016, the Company was served with a subpoena for records from the state of California Department of Insurance under its California insurance code authority. The subpoena requests documents related to SUBOXONE® Film, SUBOXONE® Tablet, and SUBUTEX® Tablet. The Company is cooperating in these investigations.

FTC investigation and Antitrust Litigation

- The Judge overseeing the legal privilege dispute in the FTC investigation has appointed a Special Master (an independent external lawyer) to investigate the claims of legal privilege and provide a recommendation to the Court on how the documents at issue should be treated. A report and recommendation relating to the first tranche of privileged documents reviewed by the Special Master was finalized in April 2016 and adopted by the Court on August 1st, 2016. Pursuant to this report and the Court's order, Indivior produced certain additional documents. In response to the Judge's instruction the Special Master also has issued, on February 3rd, 2017, a subsequent report and recommendation providing findings on the adequacy of Indivior's descriptions of these documents in its privilege log. The parties must file any responses to the Special Master's findings by February 24, 2017. At that time the Court will consider whether and to what extent to adopt the Special Master's report and then will issue any rulings relating thereto. Finally, a second tranche of documents remains under review by the Special Master. Following that review, the Court's decision then may be subject to appeal by either party.
- Fact discovery is continuing in the antitrust class action litigation described in the Group' annual report for the 2015 financial year ("Class Action Litigation"). Plaintiffs allege, among other things, that Indivior violated federal and state antitrust laws in attempting to delay generic entry of alternatives to SUBOXONE tablets, and plaintiffs further allege that Indivior unlawfully acted to lower the market share of these products.

- Amneal Pharmaceuticals LLC, a manufacturer of generic buprenorphine / naloxone tablets, filed a complaint against the Company in December 2015. This case has been coordinated with the Class Action litigation. Amneal's complaint contains antitrust allegations similar in nature to those set out in the class action complaints, and Amneal has also alleged violations of the Lanham Act. Amneal served an amended complaint on February 3rd, 2017.
- On September 22nd, 2016, 35 states and the District of Columbia filed a complaint against the Company in the same district where the Class Action and *Amneal* litigation is pending. The States' complaint is similar to the other pending complaints, and alleges violations of state and federal antitrust and consumer protection laws. On October 25th, 2016, the Company was informed that the States plan to amend their complaint to add six additional states as plaintiffs. This lawsuit relates to the investigation conducted by various states, as discussed in previous filings. On November 16th, 2016 the States served an amended complaint, adding six additional states as plaintiffs. This lawsuit relates to the investigation conducted by various states, as discussed in previous filings. Discovery has been coordinated with the Class Action Litigation and Amneal cases, subject to certain stays.

ANDA Litigation and Inter Partes Review

- The ruling after trial against **Actavis** and **Par** in the lawsuit involving the Orange Book-listed patents for SUBOXONE[®] Film issued on June 3rd, 2016. The ruling found the asserted claims of the '514 patent valid and infringed; the asserted claims of the '150 patent valid but not infringed; and the asserted claims of the '832 patent invalid, but found that certain claims would be infringed if they were valid.
- Based on the ruling as to the '514 patent, **Actavis** and **Par** are currently enjoined from launching a generic product. Par has appealed and **Actavis** is expected to appeal this ruling. The generics have also moved to reopen the judgment based on a more stringent claim construction in the **Dr. Reddy's** case. In light of the motions to reopen, **Par's** appeal has been deactivated until the District Court rules on the motions, and the deadline for **Actavis** to file a notice of appeal has been postponed.
- Trial against **Dr. Reddy's, Actavis and Par** in the lawsuits involving the process patent (US Patent No. 8,900,497) took place on November 16th and 21st-23rd, 2016.
- Trial against **Dr. Reddy's** in the lawsuit involving the Orange Book-listed patents for SUBOXONE[®] Film took place on November 7th, 16th, and 21st-23rd, 2016, with **Dr. Reddy's** 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17th, 2017. Indivior believes **Dr. Reddy's** 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17th, 2017, however, **Dr Reddy's** disputes the applicability of the stay to this ANDA.
- Trial against **Alvogen** in the lawsuit involving the Orange Book-listed patents and the '497 process patent for SUBOXONE[®] Film has been postponed and will be rescheduled, with Alvogen's 30-month stay of FDA approval expiring October 29th, 2017.
- By a Court order dated August 22nd, 2016, Indivior's SUBOXONE[®] Film patent litigation against **Sandoz** has been dismissed without prejudice because Sandoz is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE[®] film.
- Trial against **Mylan** in the lawsuit involving the Orange Book-listed patents and the '497 process patent for SUBOXONE[®] Film is scheduled for September 25th, 2017, with Mylan's stay expiring March 24th, 2018. On January 12th, 2017, the District Court issued a claim construction decision in the **Mylan** action that clarified its earlier construction of certain terms in the '514 patent in the **Dr. Reddy's** case.
- Indivior received a Paragraph IV notification from **Teva**, dated February 8th, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of Buprenorphine/naloxone sublingual film. The parties have agreed that infringement by Teva's 16

mg/4 mg dosage strength will be governed by the infringement ruling on the accused 8 mg/2 mg dosage strength in the ANDA now owned by Dr. Reddy's that was the subject of the trial in November 2016.

- The USPTO declined to institute **Teva's** petitions for inter partes review of the three Orange Book-listed patents on procedural grounds.

Dr. Reddy's filed an inter partes review petition on each of the three Orange Book Patents. These petitions are substantively similar to those filed by Teva. The USPTO denied the petitions, finding Dr. Reddy's had failed to establish a reasonable likelihood of showing the challenged claims are unpatentable as obvious. Dr. Reddy's has requested rehearing of the denials.

Mylan has filed a petition seeking an inter partes review of the '514 patent. A decision by the USPTO on whether to institute IPR proceedings is expected in May 2017.

Certain claims of the '832 patent were found invalid in an IPR proceeding brought by **BioDelivery Sciences International (BDSI)**, a decision that has been affirmed by the Court of Appeals for the Federal Circuit.

- In the event of a ruling in these matters that none of the claims of the asserted patents are valid and infringed by the ANDA-filers, and should there be FDA approval of one or more of the ANDAs and subsequent commercial launch of generic SUBOXONE® film, and pipeline products fail to obtain regulatory approval, there is the likelihood that revenues and operating profits of the Company will significantly decline. In these circumstances the Directors believe they would be able to take the required steps to reduce the cost base, however this would result in a significant change to the structure of the business.

French Competition Authority Investigation

- On January 11th, 2017, the French Supreme Court issued a decision dismissing the Company's appeal of a €0.3M fine levied against the Company in connection with a statement of objections that was issued by the French Competition Authority against the Company in November 2012. As discussed in previous filings, this statement of objections was issued in relation to conduct relating to the sale and distribution of SUBUTEX® tablet in France, which was part of a wider investigation involving alleged anti-competitive conduct of a competitor. A private civil claim has been brought against this competitor as a result of the findings against it, and it is therefore possible that a similar private civil claim could be brought against the Indivior Group.

Estate of John Bradley Allen

- On December 27th, 2016, the Estate of John Bradley Allen filed a civil complaint against Indivior Inc. and Indivior PLC, among other parties, in the Northern District of New York seeking relief under Connecticut's products liability and unfair trade practices statutes for damages allegedly caused by Suboxone.

Exchange Rates

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

	FY 2016	FY 2015
US \$: GB £ period end	1.2340	1.4736
US \$: GB £ average rate	1.3579	1.5285
US \$: € Euro period end	1.0519	1.0858
US \$: € Euro average	1.1070	1.1097

Risk Factors

The Directors have reviewed the principal risks and uncertainties for the financial year 2017.

The assumptions in arriving at the Company's financial guidance for the full year 2017 are described on page 3 of this release. To the extent that actual market conditions differ from these assumptions, alternative financial outcomes are possible. However, the Company has issued this guidance based on industry analogues and its own estimates at this time.

Therefore, other than in respect of guidance for the full year 2017, the Directors consider that the principal risks and uncertainties which could have a material impact on the Group's performance in 2017 include:

Business operations and business continuity

- The Group's revenues are primarily derived from sales of Suboxone® Film and any decrease in sales due to competition or supply or quality issues could significantly affect the results of operations and prospects.
- The Group has a single source of supply for buprenorphine, an active ingredient in the Group's products including Suboxone® Film, and any disruption to this source of supply could significantly affect the results of operations and prospects.
- Competition for qualified personnel in the biotechnology and pharmaceutical industries is intense and high-performing talent in key positions is a business-critical requirement.
- Failures or disruptions to the Group's systems or the systems of third parties on whom the Group relies, due to any number of causes, particularly if prolonged, could result in a loss of key data and/or affect operations.
- The Group's computer systems, software and networks may be vulnerable to unauthorized access, computer viruses or other malicious code or cyber threats that could have a security impact. All of these could be costly to remedy and we may be subject to litigation.

Product liability, regulation & litigation

- As an innovative pharmaceutical company, the Group seeks to obtain appropriate intellectual property protection for its products. Its ability to obtain and enforce patents and other proprietary rights particularly for its products, drug formulation and delivery technologies and associated manufacturing processes is critical to business strategy and success. Specifically see disclosures under Litigation Update on pages 8-10 referring to the current status of the Department of Justice and Federal Trade Commission investigations, state subpoenas, the antitrust litigation, and ANDA litigation and Inter Partes reviews, as well as the contingent liabilities disclosures on pages [21-23, note 7].
- The manufacture of the Group's products is highly exacting and complex due in part to strict regulatory and manufacturing requirements. Active Pharmaceutical Ingredients (API) in many of the Group's products and product candidates are controlled substances that are subject to extensive regulation in all the countries in which the Group markets its products.
- The testing, manufacturing, marketing, and sales of pharmaceutical products entail a risk of product liability claims, product recalls, litigation, and associated adverse publicity, each of which could have a material adverse impact on the business, prospects, results of operations and financial condition.

Product development

- The regulatory approval process for new pharmaceutical products and expansion of existing pharmaceutical products is expensive, time-consuming and uncertain. Even if product candidates are approved there is no guarantee that they will be able to achieve expected market acceptance.

Commercial and Governmental payor account, pricing and reimbursement pressure

- The Group's revenues are partly dependent on the availability and level of coverage provided to the Group by private insurance companies and governmental reimbursement schemes for pharmaceutical products, such as Medicare and Medicaid in the US.
- Changes to governmental policy or practices could adversely affect the Group's revenues, financial condition and results of operations. In addition, the reimbursement of treatment established by healthcare providers, private health insurers and other organizations may be reduced.

Compliance with law and ethical behaviour

- Business practices in the pharmaceutical industry are subject to increasing scrutiny by government authorities. Failure to comply with applicable laws and rules and regulations in any jurisdiction may result in fines, civil and/or criminal legal proceedings. Specifically see disclosures under Litigation Update on page 8-10 referring to the current status of the investigative and litigation matters involving the Company, as well as the contingent liabilities disclosures on pages [21-23, note 7]. The Company has taken steps to enhance its compliance capability to handle the expected growth in the business, and will continue to monitor changing compliance requirements due to growth, changes in the business, and changing regulatory requirements.

Acquisitions and business development

- The Group may seek to acquire businesses or products as part of our strategy to enhance our current portfolio.

Product Safety

- The Group's Pharmacovigilance processes should adequately monitor the safety of the Group's products in a comprehensive and thorough manner by appropriately collecting, reviewing, following up or reporting adverse events from all potential sources, and acting on any relevant findings in a timely manner.

The Group's annual report for the 2015 financial year contains, and its annual report for the 2016 financial year will contain, additional detail on these principal business risks together with a report on risk appetite.

Forward-Looking Statements

This announcement contains certain statements that are forward-looking and which should be considered, amongst other statutory provisions, in light of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty as they relate to events or circumstances that will or may 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 2017 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation. Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Suboxone® Tablet, Suboxone® Film, Subutex Tablet and any future products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of the Suboxone® Film patent litigation relating to 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.

For Further Information

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Presentation details

There will be a presentation for analysts and investors at 1200hrs UK time (0700hrs Eastern) today in The Ayres Room, Deutsche Bank, 1 Great Winchester Street, London EC2N 2DB, hosted by Shaun Thaxter, CEO. The presentation will be live webcast and broadcast on the Company’s website, details for which are below. The webcast will be archived on the company’s website at www.indivior.com later today for replay.

Webcast link: <http://edge.media-server.com/m/p/4dgo4vv5> or via the Company’s website.

Webcast access on mobile devices – QR Code: For access to the live and on demand webcast from any IOS apple or Android mobile devices:

Dial-in: Dial in 5-10 minutes prior to the start time using the number / Conference ID below.

Confirmation Code: **8671557**
 Participants, Local - London, United Kingdom: + 44 (0)20 3427 1914
 Participants, Local - New York, United States of America: +1 646 254 3361

About Indivior

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy, health policy and evidence-based best practice models that have revolutionized modern addiction treatment. The name is the fusion of the words individual and endeavour, and the tagline “Focus on you” makes the Company’s commitment clear. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of opioid dependence treatments featuring SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII), SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet, and SUBUTEX® (buprenorphine) Sublingual Tablet, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic conditions and co-morbidities of addiction including alcohol use disorder, cocaine intoxication and schizophrenia. Headquartered in the United States in Richmond, VA., Indivior employs more than 900 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.Indivior.com to learn more.

www.indivior.com

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 (ie, 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 (eg, 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 labor.

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](#) 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 (CII), or SUBUTEX® (buprenorphine) Sublingual Tablets (CIII), please see the respective [full Prescribing Information](#) and [Medication Guide](#) at www.suboxoneREMS.com.

Consolidated income statement

	Notes	Unaudited Q4 2016 \$m	Unaudited Q4 2015 \$m	Unaudited 2016 \$m	Audited 2015 \$m
Net Revenues	2	259	248	1,058	1,014
Cost of Sales		(29)	(25)	(107)	(97)
Gross Profit		230	223	951	917
Selling, distribution and administrative expenses	3	(127)	(127)	(683)	(423)
Research and development expenses	3	(32)	(58)	(119)	(148)
Operating Profit		71	38	149	346
Operating profit before exceptional items		72	62	387	377
Exceptional items	3	(1)	(24)	(238)	(31)
Operating profit		71	38	149	346
Finance expense		(12)	(14)	(51)	(61)
Net finance expense		(12)	(14)	(51)	(61)
Profit before taxation		59	24	98	285
Taxation	4	(11)	2	(82)	(70)
Exceptional items within taxation	4	30	11	19	13
Net income		78	37	35	228

Earnings per ordinary share (cents)

Basic earnings per share	5	11	5	5	32
Diluted earnings per share	5	10	5	5	31

Consolidated statement of comprehensive income

	Unaudited Q4 2016 \$m	Unaudited Q4 2015 \$m	Unaudited 2016 \$m	Audited 2015 \$m
Net (loss)/income	78	37	35	228
Other comprehensive income				
<i>Items that may be reclassified to profit or loss in subsequent years:</i>				
Net exchange adjustments on foreign currency translation	(2)	(5)	1	(14)
Other comprehensive income	(2)	(5)	1	(14)
Total comprehensive income	76	32	36	214

The notes on pages 19 to 25 are an integral part of these condensed consolidated interim financial statements.

Consolidated balance sheet

	Notes	Unaudited 2016 \$m	Audited 2015 \$m
ASSETS			
Non-current assets			
Intangible assets		83	62
Property, plant and equipment		27	32
Deferred tax assets		109	122
		219	216
Current assets			
Inventories		41	48
Trade and other receivables		227	206
Current tax receivable		30	-
Cash and cash equivalents	6	692	467
		990	721
Total assets		1,209	937
LIABILITIES			
Current liabilities			
Borrowings	6	(101)	(34)
Provisions for liabilities and charges		(219)	-
Trade and other payables	8	(658)	(528)
Current tax liabilities		(52)	(41)
		(1,030)	(603)
Non-current liabilities			
Borrowings	6	(434)	(571)
Provisions for liabilities and charges		(40)	(42)
		(474)	(613)
Total liabilities		(1,504)	(1,216)
Net liabilities		(295)	(279)
EQUITY			
Capital and reserves			
Share capital	9	72	72
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(22)	(23)
Retained Earnings		950	967
Total equity		(295)	(279)

The notes on pages 19 to 25 are an integral part of these condensed consolidated interim financial statements.

Consolidated statement of changes in equity

	Share capital	Share Premium	Other Reserve	Foreign Currency Translation reserve	Retained earnings	Total equity
Audited	\$m	\$m	\$m	\$m	\$m	\$m
At January 1, 2015	1,437	-	(1,295)	(16)	(601)	(475)
Comprehensive income						
Net income	-	-	-	-	228	228
Other comprehensive income	-	-	-	(7)	(7)	(14)
Total comprehensive income	-	-	-	(7)	221	214
Transactions recognised directly in equity						
Share-based plans	-	-	-	-	8	8
Deferred taxation on share-based plans	-	-	-	-	(3)	(3)
Dividends paid	-	-	-	-	(23)	(23)
Capital reduction	(1,365)	-	-	-	1,365	-
Total transactions recognised directly in equity	(1,365)	-	-	-	1,347	(18)
Balance at December 31, 2015	72	-	(1,295)	(23)	967	(279)
At January 1, 2016	72	-	(1,295)	(23)	967	(279)
Comprehensive income						
Net (loss)/income	-	-	-	-	35	35
Other comprehensive income	-	-	-	1	-	1
Total comprehensive income	-	-	-	1	35	36
Transactions recognised directly in equity						
Share-based plans	-	-	-	-	10	10
Deferred taxation on share-based plans	-	-	-	-	7	7
Dividends paid	-	-	-	-	(69)	(69)
Total transactions recognised directly in equity	-	-	-	-	(52)	(52)
Balance at December 31, 2016	72	-	(1,295)	(22)	950	(295)

The notes on pages 19 to 25 are an integral part of these condensed consolidated interim financial statements.

Consolidated cash flow statement

	Unaudited	Audited
	2016	2015
For the year ended December 31	\$m	\$m
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating Profit	149	346
Depreciation and amortization	14	40
Share-based payments	10	5
Impact from foreign exchange movements	1	-
(Increase)/decrease in trade and other receivables	(27)	(9)
Decrease/(increase) in inventories	4	(9)
Increase in trade and other payables	142	145
Increase in provisions	219	-
Cash generated from operations	512	518
Net financing costs	(42)	(44)
Transaction costs related to loan	-	(23)
Taxes paid	(63)	(131)
Net cash inflow from operating activities	407	320
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(20)	(27)
Purchase of intangible assets	(15)	(4)
Net cash (outflow) from investing activities	(35)	(31)
CASH FLOWS FROM FINANCING ACTIVITIES		
Cash movements on overdraft	-	(9)
Cash movements in borrowings	(78)	(112)
Dividends paid	(69)	(23)
Net cash (outflow) from financing activities	(147)	(144)
Net increase in cash and cash equivalents	225	145
Cash and cash equivalents at beginning of the period	467	331
Exchange differences	-	(9)
Cash and cash equivalents at end of the period	692	467

The notes on pages 19 to 25 are an integral part of these condensed consolidated interim financial statements.

Notes to the consolidated 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 financial statements ('Interim Financial Statements'), reference to the 'Group' means the Company and all its subsidiaries.

The financial information herein has been prepared on the basis of the accounting policies set out in the annual accounts of the Group for the year ended December 31, 2015 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 (IFRS IC) interpretations as adopted by the European Union and the Companies Act 2006 (the Act) applicable to companies reporting under IFRS. In preparing these condensed consolidated 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, 2015, with the exception of changes in estimates that are required in determining the provision for income taxes.

The consolidated 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, 2015. These condensed consolidated financial statements have been reviewed and not audited. These consolidated financial statements have been authorized for issue as at February 21, 2017.

As disclosed in Note 7 relating to the Department of Justice and Federal Trade Commission investigations and antitrust litigation an amount of \$220m has been established as a reserve for all of these matters. The final amount may be materially higher than this reserve. This could impact the Group's ability to operate, which would be further adversely impacted should revenues decline and pipeline products fail to obtain regulatory approval, all of which could mean the Group cannot continue in business without taking necessary measures to reduce its cost base and improve its cash flow. As such, this indicates a material uncertainty that may cast significant doubt on the Group's ability to continue as a going concern. However, the Directors believe they have the ability to carry out the necessary measures and that the Group can continue as a going concern for the foreseeable future. Accordingly, the Directors continue to adopt the going concern basis for accounting in preparing these financial statements, which do not include any adjustments that might result from the outcome of this uncertainty.

The financial information contained in this document does not constitute statutory accounts as defined in section 434 and 435 of the Companies Act 2006. The auditors issued an unqualified opinion and did not contain a statement under section 498 of the Companies Act 2006 on the Group's statutory financial statements for the year ended December 31, 2015. The Group's statutory financial statements for the year ended December 31, 2015 were approved by the Board of Directors on March 8, 2016 and has been delivered to the Registrar of Companies. For the Group's financial statements for the year ended 31 December 2016, the auditors expect to issue a modified auditors report with Emphasis of Matter paragraphs dealing with the Department of Justice and Federal Trade Commission investigations and antitrust litigation and ANDA litigation details of which are included above and in note 7 respectively.

2. SEGMENT INFORMATION

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

As the Indivior Group is engaged in a single business activity, which is the development, manufacture and sale of prescription drugs that are based on Buprenorphine for treatment of opioid dependence, the CEO reviews financial information presented on a combined basis for evaluating financial performance and allocating resources. Accordingly, the company reports as a single reporting segment.

Revenues

Revenues are attributed to countries based on the country where the sale originates. The following table represents revenue from continuing operations attributed to countries based on the country where the sale originates and non-current assets, net of accumulated depreciation and amortisation, by country. Non-current assets for this purpose consist of property, plant and equipment and intangible assets. Revenues for the three and twelve months to December 31, 2016 and 2015 were as follows:

Revenues from sale of goods:

	Q4 2016 \$m	Q4 2015 \$m	2016 \$m	2015 \$m
United States	206	194	857	807
ROW	53	54	201	207
Total	259	248	1,058	1,014

Non-current assets:

	2016 \$m	2015 \$m
United States	64	80
ROW	46	14
Total	110	94

3. OPERATING COSTS AND EXPENSES

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

	Q4 2016 \$m	Q4 2015 \$m	2016 \$m	2015 \$m
Research and development expenses	(32)	(58)	(119)	(148)
Marketing, selling and distribution expenses	(42)	(44)	(144)	(166)
Administrative expenses	(81)	(75)	(520)	(227)
Depreciation and amortization	(2)	(6)	(14)	(24)
Operating lease rentals	(2)	(2)	(5)	(6)
Total	(127)	(127)	(683)	(423)

Exceptional Items

	Q4 2016 \$m	Q4 2015 \$m	2016 \$m	2015 \$m
Cost of Sales	-	-	(11)	-
Reconfiguration and separation costs	-	(8)	-	(15)
Impairment and write-offs	-	(16)	-	(16)
Consulting costs	(1)	-	(7)	-
Legal provision	-	-	(220)	-
Total Exceptional items	(1)	(24)	(238)	(31)

\$238m (2015: \$31m) of exceptional items include legal provisions, write-offs of manufacturing costs and legal and advisory costs related to the exploration of strategic initiatives for the event of a potential negative ANDA ruling. The Company has recorded a charge of \$220m in the third quarter of 2016 for the investigative and antitrust litigation matters set out in note 7 below. Because these matters are in various stages, the Company cannot predict with any certainty the ultimate resolution or cost of all of the matters, and may in the future take additional charges. These exceptional items have been included within operating expenses and Costs of Sales.

4. TAXATION

In the year to December 2016, tax on total profits amounted to \$63m and represented a full year effective tax rate of 64% (2015: 20%); \$19m of these relate to the tax effect on the movement of assets within the Group and additional provisions for unresolved tax matters and prior year adjustments, and are considered to be exceptional. \$6m relate to the tax effect of exceptional items within SD&A and Cost of Sales. The company is filing a claim for "Patent Box" regime benefits in the UK that provide a total benefit of \$37m, of which \$32m is considered exceptional as it relates to prior periods. The company also benefited by \$5m for Research credits in both the US and the UK. No deferred tax has been recognized on the litigation charge in the period as it is uncertain whether the charge will be available for tax relief. Adjustments will be made once a final determination of the litigation charges has been made. Excluding the impact of exceptional items the effective tax rate for the year ended December 31, 2016 is 25% (2015: 22%).

The Group's balance sheet at December 31, 2016 included a tax payable liability of \$52m, corporate tax receivable of \$30m, and deferred tax assets of \$109m.

5. EARNINGS PER SHARE

	Q4 2016 cents	Q4 2015 cents	2016 cents	2015 cents
Basic earnings per share	11	5	5	32
Diluted earnings per share	10	5	5	31
Adjusted basic earnings per share	7	7	35	34
Adjusted diluted earnings per share	7	7	34	34

Basic

Basic earnings per share ("EPS") is calculated by dividing profit/(loss) for the period attributable to owners of the Company by the weighted average number of ordinary shares in issue during the period. 720,597,566 shares were in issue at the reporting date.

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 awards. The weighted average number of shares is adjusted for the number of shares granted assuming the vesting of the awards.

	2016 Average number of shares	2015 Average number of shares
On a basic basis	719,874,634	718,577,618
Dilution for Long Term Incentive Plan (LTIP)	22,499,534	14,507,535
Employee Sharesave Scheme	846,147	-
Adjusted diluted shares	743,220,315	733,085,153

Adjusted Earnings

The Directors believe that diluted earnings per share, adjusted for the impact of exceptional items after the appropriate tax amount, provides additional useful information on underlying trends to shareholders in respect of earnings per ordinary share.

A reconciliation of net income to adjusted net income is as follows:

	Q4 2016 \$m	Q4 2015 \$m	2016 \$m	2015 \$m
Net income	78	37	35	228
Exceptional items	1	24	238	31
Tax effect of exceptional items	(1)	-	(6)	-
Exceptional items within taxation	(29)	(11)	(13)	(13)
Adjusted net income	49	50	254	246

6. FINANCIAL LIABILITIES – BORROWINGS

Current	2016 \$m	2015 \$m
Bank loans	(101)	(34)
	(101)	(34)

Non-current	2016 \$m	2015 \$m
Bank loans	(434)	(571)
	(434)	(571)

Analysis of net debt	2016 \$m	2015 \$m
Cash and cash equivalents	692	467
Borrowings*	(561)	(641)
	131	(174)

*Borrowings reflects the outstanding principal amount drawn, before debt issuance costs

Reconciliation of net debt	2016 \$m	2015 \$m
The movements in the period were as follows:		
Net debt at beginning of period	(174)	(428)
Increase in cash and cash equivalents	225	136
Net repayment of borrowings and overdraft	78	121
Exchange adjustment	2	(3)
Net debt at end of period	131	(174)

The carrying value less impairment provision of current borrowings and cash at bank, as well as trade receivables and trade payables, are assumed to approximate their fair values.

On March 16, 2015, the Company completed syndication of its \$750 million debt facility. As a result of the syndication the new terms of the loan on March 16, 2015 were as follows:

	Currency	Nominal interest margin	Maturity	Scheduled repayments*	Issuance cost \$m	Face value \$m	Carrying amount \$m
Unsecured bank loan	USD	Libor (1%) + 6%	5 years	5%	40	644	644
Unsecured bank loan	EUR	Libor (1%) + 6%	5 years	5%	6	106	106

*For years 1 and 2 only; 10% thereafter

Also included within the terms of the loan were:

- A financial covenant to maintain a leverage covenant (Net debt to Adjusted EBITDA ratio) of 3.25x with step down to 3.00x on June 30, 2016.
- An additional covenant requiring minimum liquidity of \$150 million (defined as cash on hand plus the undrawn amount available under the Company's \$50 million revolving credit facility).

7. CONTINGENT LIABILITIES

The Indivior Group is currently subject to other legal proceedings and investigations, including through subpoenas and other information requests, by various governmental authorities. It is not possible at this time to predict with any certainty the potential impact of these matters on the Company, or to quantify the ultimate cost of a resolution of these matters. The Company has recorded a charge of \$220m in the third quarter of 2016 for the investigative and antitrust litigation matters noted below. The Company continues in discussions with the Department of Justice about a possible resolution to its investigation. The Company cannot predict with any certainty whether we will be able to reach ultimate resolution with the Department of Justice or any or all of the other parties, or the ultimate cost of resolving all of the matters. The final cost may be materially higher than this reserve.

The Indivior business (previously Reckitt Benckiser Pharmaceuticals (RBP)) was demerged from Reckitt Benckiser Group plc (RB) on December 23rd 2014 and Indivior PLC became the new ultimate holding company of the group.

Department of Justice Investigation

- A federal criminal grand jury investigation of Indivior initiated in December 2013 is continuing, and includes marketing and promotion practices, pediatric safety claims, and overprescribing of medication by certain physicians. The U.S. Attorney's Office for the Western District of Virginia has served a number of subpoenas relating to SUBOXONE[®] Film, SUBOXONE[®] Tablet, SUBUTEX[®] Tablet, buprenorphine and our competitors, among other issues. We are in discussions with the Department of Justice about a possible resolution of the investigation. It is not possible at this time to predict with any certainty the potential impact of this investigation on us or to quantify the ultimate cost of a resolution. We are cooperating fully with the relevant agencies and prosecutors and will continue to do so.

State Subpoenas

- On October 12th, 2016, the Company 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 Company's marketing and promotion of SUBOXONE[®] products and its interactions with a non-profit third party organization. On November 16th, 2016, the Company was served with a subpoena for records from the state of California Department of Insurance under its California insurance code authority. The subpoena requests documents related to SUBOXONE[®] Film, SUBOXONE[®] Tablet, and SUBUTEX[®] Tablet. The Company is cooperating in these investigations.

FTC investigation and Antitrust Litigation

- The Judge overseeing the legal privilege dispute in the FTC investigation has appointed a Special Master (an independent external lawyer) to investigate the claims of legal privilege and provide a recommendation to the Court on how the documents at issue should be treated. An initial report and recommendation relating to the first tranche of privileged documents reviewed by the Special Master was finalized in April 2016 and adopted by the Court on August 1st, 2016. Pursuant to this report and the Court's order, Indivior produced certain additional documents. In response to the Judge's instruction the Special Master also has issued, on February 3rd, 2017, a subsequent report and recommendation providing findings on the adequacy of Indivior's descriptions of these documents in its privilege log. The parties must file any responses to the Special Master's findings by February 24, 2017. At that time the Court will consider whether and to what extent to adopt the Special Master's report and then will issue any rulings relating thereto. Finally, a second tranche of documents remains under review by the Special Master. Following that review, the Court's decision then may be subject to appeal by either party.

- Fact discovery is continuing in the antitrust class action litigation described in the Group' annual report for the 2015 financial year ("Class Action Litigation"). Plaintiffs allege, among other things, that Indivior violated federal and state antitrust laws in attempting to delay generic entry of alternatives to SUBOXONE tablets, and plaintiffs further allege that Indivior unlawfully acted to lower the market share of these products.
- Amneal Pharmaceuticals LLC, a manufacturer of generic buprenorphine / naloxone tablets, filed a complaint against the Company in December 2015. This case has been coordinated with the Class Action litigation. Amneal's complaint contains antitrust allegations similar in nature to those set out in the class action complaints, and Amneal has also alleged violations of the Lanham Act. Amneal served an amended complaint on February 3, 2017.
- On September 22nd, 2016, 35 states and the District of Columbia filed a complaint against the Company in the same district where the Class Action and *Amneal* litigation is pending. The States' complaint is similar to the other pending complaints, and alleges violations of state and federal antitrust and consumer protection laws. On October 25th, 2016, the Company was informed that the States plan to amend their complaint to add six additional states as plaintiffs. This lawsuit relates to the investigation conducted by various states, as discussed in previous filings. On November 16th, 2016 the States served an amended complaint, adding six additional states as plaintiffs. This lawsuit relates to the investigation conducted by various states, as discussed in previous filings. Discovery has been coordinated with the Class Action Litigation and Amneal cases, subject to certain stays.

ANDA Litigation and Inter Partes Review

- The ruling after trial against **Actavis** and **Par** in the lawsuit involving the Orange Book-listed patents for SUBOXONE[®] Film issued on June 3rd, 2016. The ruling found the asserted claims of the '514 patent valid and infringed; the asserted claims of the '150 patent valid but not infringed; and the asserted claims of the '832 patent invalid, but found that certain claims would be infringed if they were valid.
- Based on the ruling as to the '514 patent, **Actavis** and **Par** are currently enjoined from launching a generic product. Par has appealed and **Actavis** is expected to appeal this ruling. The generics have also moved to reopen the judgment based on a more stringent claim construction in the **Dr. Reddy's** case. In light of the motions to reopen, **Par's** appeal has been deactivated until the District Court rules on the motions, and the deadline for **Actavis** to file a notice of appeal has been postponed.
- Trial against **Dr. Reddy's, Actavis and Par** in the lawsuits involving the process patent (US Patent No. 8,900,497) took place on November 16th and 21st-23rd, 2016.
- Trial against **Dr. Reddy's** in the lawsuit involving the Orange Book-listed patents for SUBOXONE[®] Film took place on November 7th, 16th, and 21st-23rd, 2016, with **Dr. Reddy's** 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17th, 2017. Indivior believes **Dr. Reddy's** 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17th, 2017, however, **Dr Reddy's** disputes the applicability of the stay to this ANDA.
- Trial against **Alvogen** in the lawsuit involving the Orange Book-listed patents and the '497 process patent for SUBOXONE[®] Film has been postponed and will be rescheduled, with Alvogen's 30-month stay of FDA approval expiring October 29th, 2017.
- By a Court order dated August 22nd, 2016, Indivior's SUBOXONE[®] Film patent litigation against **Sandoz** has been dismissed without prejudice because Sandoz is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE[®] film.
- Trial against **Mylan** in the lawsuit involving the Orange Book-listed patents and the '497 process patent for SUBOXONE[®] Film is scheduled for September 25th, 2017, with Mylan's stay expiring March 24th, 2018. On January 12th, 2017, the District Court issued a claim construction decision in the **Mylan** action that clarified its earlier construction of certain terms in the '514 patent in the **Dr. Reddy's** case.
- Indivior received a Paragraph IV notification from **Teva**, dated February 8th, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of Buprenorphine/naloxone sublingual film. The parties have agreed that infringement by Teva's 16 mg/4 mg dosage strength will be governed by the infringement ruling on the accused 8 mg/2 mg dosage strength in the ANDA now owned by Dr. Reddy's that was the subject of the trial in November 2016.
- The USPTO declined to institute **Teva's** petitions for inter partes review of the three Orange Book-listed patents on procedural grounds.

Dr. Reddy's filed an inter partes review petition on each of the three Orange Book Patents. These petitions are substantively similar to those filed by Teva. The USPTO denied the petitions, finding Dr. Reddy's had failed to establish a reasonable likelihood of showing the challenged claims are unpatentable as obvious. Dr. Reddy's has requested rehearing of the denials.

Mylan has filed a petition seeking an inter partes review of the '514 patent. A decision by the USPTO on whether to institute IPR proceedings is expected in May 2017.

Certain claims of the '832 patent were found invalid in an IPR proceeding brought by **BioDelivery Sciences International (BDSI)**, a decision that has been affirmed by the Court of Appeals for the Federal Circuit.

- In the event of a ruling in these matters that none of the claims of the asserted patents are valid and infringed by the ANDA-filers, and should there be FDA approval of one or more of the ANDAs and subsequent commercial launch of generic SUBOXONE® film, and pipeline products fail to obtain regulatory approval, there is the likelihood that revenues and operating profits of the Company will significantly decline. In these circumstances the Directors believe they would be able to take the required steps to reduce the cost base, however this would result in a significant change to the structure of the business.

IRS Notice on Manufacturing Deductions

- In August 2015 the IRS issued notices of a proposed adjustment for the disallowance of certain manufacturing deductions claimed by the Company following its audit of 2011 and 2012 income tax years. During the 4th quarter of 2015, the Company was notified by the IRS of their intention to audit 2013 and 2014 income tax years and have since been notified that the IRS intend to disallow these claims in 2013 and 2014 audit cycle. The Company will appeal the proposed disallowance. The Company has evaluated its positions with respect to these claims and has provided \$22m tax reserve for amounts claimed on all open periods as its best estimate of its expected settlement position for this issue.

8. TRADE AND OTHER PAYABLES

	2016 \$m	2015 \$m*
Sales returns and rebates	(402)	(287)
Trade payables	(33)	(27)
Accruals	(212)	(202)
Other tax and social security payables	(11)	(12)
Total	(658)	(528)

*The December 31 2015 balances have been adjusted to correct a prior period classification between Trade payables and Accruals.

Customer return and rebate accruals, primarily in the US, are provided for by the Group at the point of sale in respect of the estimated rebates, discounts or allowances payable to customers. Accruals are made at the time of sale but the actual amounts paid are based on claims made some time after the initial recognition of the sale. As the amounts are estimated they may not fully reflect the final outcome and are subject to change dependent upon, amongst other things, the channel (e.g. Medicaid, Medicare, Managed Care, etc) and product mix. The level of accrual is reviewed and adjusted quarterly in the light of historical experience of actual rebates, discounts or allowances given and returns made and any changes in arrangements. Future events could cause the assumptions on which the accruals are based to change, which could affect the future results of the Group.

9. SHARE CAPITAL

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2016	718,577,618	\$0.10	72
Allotments	2,019,948	\$0.10	-
At December 31, 2016	720,597,566	\$0.10	72

	Equity Ordinary Shares	Issue price	Nominal value \$m
Issued and fully paid			
At January 1, 2015	718,577,618	\$2.00	1,437
Nominal value reduction	-	(\$1.90)	(1,365)
At December 31, 2015	718,577,618	\$0.10	72

The holders of ordinary shares (par value \$0.10) are entitled to receive dividends as declared from time to time and are entitled to one vote per share at general meetings of Indivior PLC.

The initial shareholders resolved, by a special resolution, passed on October 30, 2014, to reduce Indivior PLC's share capital by decreasing the nominal value of each Indivior Ordinary Share from \$2.00 to \$0.10. This created distributable reserves on the balance sheet that will provide Indivior with, among other things, capacity for the payment of future dividends.

As required under section 645 of the Companies Act 2006, the High Court of Justice has confirmed the reduction of the Company's share capital. Following the registration of the Order of the Court with the Companies House, the Capital Reduction became effective on January 21, 2015.

Allotment of ordinary shares

During the year, 2,019,948 ordinary shares (2015: nil) were allotted to satisfy vestings/exercises under the Group's Long Term Incentive Plan.

10. RELATED PARTIES

Subsequent to the demerger from former parent, RB, on December 23, 2014, Indivior continues to receive certain services like office space rental and other operational services on commercial terms and on an arm's length basis. Adrian Hennah, the RB CFO, served on the Indivior PLC Board of Directors until the AGM on May 11th, 2016. The amount included within SD&A in respect of these services is \$4m.

11. POST BALANCE SHEET EVENTS

There have been no material post balance sheet events.

Consolidated income statement (Adjusted)

		Unaudited Q4 2016 \$m	Unaudited Q4 2015 \$m	Unaudited 2016 \$m	Unaudited 2015 \$m
ADJUSTED	Notes				
Net Revenues	2	259	248	1,058	1,014
Cost of Sales		(29)	(25)	(96)	(97)
Gross Profit		230	223	962	917
Selling, distribution and administrative expenses	3	(126)	(119)	(456)	(408)
Research and development expenses	3	(32)	(42)	(119)	(132)
Operating Profit		72	62	387	377
Finance expense		(12)	(14)	(51)	(61)
Net finance expense		(12)	(14)	(51)	(61)
Profit before taxation		60	48	336	316
Taxation	4	(11)	2	(82)	(70)
Net income		49	50	254	246