

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington D.C. 20549

FORM 20-F

- ☒ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
- OR
- ☐ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
- For the fiscal year ended
- OR
- ☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
- For the transition period from to
- OR
- ☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

Commission file number:

Indivior PLC

(Exact name of Registrant as specified in its charter and translation of Registrant’s name into English)

England and Wales

(Jurisdiction of incorporation or organization)

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(Address of principal executive offices)

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Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing 5 ordinary shares, having a nominal value of \$0.10 per share	[.]
Ordinary shares, nominal value \$0.10 per share(1)	

(1)Not for trading, but only in connection with the listing of the American Depositary Shares

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Number of outstanding shares of each of the issuer’s classes of capital or common stock as of June 30, 2016:  
720,597,566 ordinary shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☐ Yes ☒ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

☐ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of “accelerated filer and large accelerated filer” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐

International Financial Reporting Standards as issued by the International Accounting Standards Board ☒

Other ☐

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☐ No

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## INTRODUCTION

We are a global specialty pharmaceutical business and are currently the global leader in the treatment of opioid dependence, with 20 years' experience in that field. Our core products, which are currently sold in 42 countries, comprise SUBOXONE® Film (buprenorphine and naloxone sublingual film), SUBOXONE® Tablet (buprenorphine and naloxone sublingual tablets), and SUBUTEX® Tablet (buprenorphine sublingual tablets), all of which are treatments for opioid dependence.

We were incorporated as a public limited company under the laws of England and Wales on September 26, 2014.

Our business was historically developed and managed as a separate division of Reckitt Benckiser Group PLC ("RB" and, together with its subsidiaries, the "RB Group"), a public limited company incorporated under the laws of England and Wales.

Indivior PLC was incorporated for the purpose of acquiring the specialty pharmaceutical business unit (the "Pharmaceutical Business") from RB as part of the demerger, which became effective on December 23, 2014 (the "Demerger"). Following the Demerger, Indivior PLC has operated as a standalone business. For more information regarding arrangements between Indivior and RB subsequent to the Demerger, see "Item 10.C. Material Contracts — Transitional Services Agreement."

Our ordinary shares are listed on the premium listing segment of the Official List of the UK Financial Conduct Authority (the "Official List") and traded on the Main Market of the London Stock Exchange. We are filing this registration statement on Form 20-F in anticipation of the listing of our American Depositary Shares (the "ADSs") on [·] under the symbol "[·]." JPMorgan Chase Bank, N.A., acting as depositary, will register and deliver our ADSs, each of which will represent 5 of our ordinary shares.

## ABOUT THIS REGISTRATION STATEMENT

As used herein, references to "we," "us," the "Company," "Indivior," "Indivior PLC," "Indivior Group" or the "Group," or similar terms in this Form 20-F mean Indivior PLC and, as the context requires, its subsidiaries.

SUBOXONE® Film, SUBOXONE® Tablet, SUBUTEX® Tablet, TEMGESIC® and BUPRENEX® are our trademarks. Any other trademarks and trade names appearing in this registration statement on Form 20-F are owned by their respective holders.

In this registration statement, all references to "U.S. dollars" or "US\$" or "cents" are to the currency of the United States of America, and all references to "pounds Sterling" or "Sterling" or "GB£" or "£" or "pence" are to the currency of the United Kingdom.

Statements made in this registration statement on Form 20-F concerning the contents of any contract, agreement or other document are summaries of such contracts, agreements or documents and are not complete descriptions of all of their terms. If we filed any of these documents as an exhibit to this registration statement or to any registration statement or annual report that we previously filed, you may read the document itself for a complete description of its terms.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this document, including those in "Item 3.D. Risk Factors," "Item 4.B. Business Overview" and "Item 5. Operating and Financial Review and Prospects" constitute "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "forecasts," "plans," "prepares," "anticipates," "expects," "intends," "may," "will" or "should" or, in each case, their negative or other variations or comparable terminology although these are not exclusive means of identifying such statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance or achievements or industry results to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

The forward-looking statements in this document are made based upon our current expectations and beliefs concerning future events impacting us and therefore involve a number of known and unknown risks and uncertainties. Such forward-looking statements are based on numerous assumptions regarding our present and future business strategy and the environment in which we operate, which may prove to be inaccurate. These forward-looking statements are not guarantees of future performance and actual results could differ materially from those expressed or implied in these forward-looking statements.

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In particular, our expectations could be affected by, among other things:

- our ability to protect our patents and other intellectual property, including in connection with pending litigation;
- factors affecting sales of SUBOXONE® Film, SUBOXONE® Tablet, SUBUTEX® Tablet and our other products outside of the United States;
- the timing for approval and likelihood of success of RBP-6000;
- legal defense costs, insurance expenses, settlement costs, the risk of an adverse decision or settlement and the adequacy of reserves related to government investigations, product liability, patent protection, consumer, commercial, securities, antitrust, environmental and tax issues, and other legal proceedings;
- the outcome of research and development activities including, without limitation, the ability to meet anticipated clinical trial commencement and completion dates, regulatory submission and approval dates, in particular with respect to RBP-6000, many of which are outside our control and are difficult to predict, and launch dates for product candidates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data;
- decisions by regulatory authorities regarding whether and when to approve our drug applications, in particular with respect to RBP-6000, as well as their decisions regarding labelling, ingredients and other matters that could affect the availability or commercial potential of our products;
- the speed with which regulatory authorizations, pricing approvals and product launches may be achieved;
- the outcome of post-approval clinical trials, which could result in the loss of marketing approval for a product or changes in the labelling for, and/or increased or new concerns about the safety or efficacy of, a product that could affect its availability or commercial potential;
- competitive developments, including the impact of new product entrants, in-line branded products, generic products, private label products and product candidates that treat diseases and conditions similar to those treated by our products and product candidates;
- 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 our products and product candidates;
- governmental laws and regulations, including those affecting pharmaceutical product pricing, reimbursement or access, as well as our U.S. and foreign operations, including, without limitation, tax obligations and changes affecting the tax treatment by the United States of income earned outside the United States that may result from pending and possible future proposals;

- any significant issues that may arise related to the outsourcing of certain operational and staff functions to third parties, including with regard to quality, timeliness and compliance with applicable legal requirements and industry standards; and
- uncertainties related to general economic, political, business, industry, regulatory and market conditions including, without limitation, uncertainties related to the impact on us, our customers, suppliers and other counterparties of challenging global economic conditions and recent and possible future changes in the global financial markets.

In light of these risks, uncertainties and assumptions, the forward-looking events described in this registration statement may not occur. Forward-looking statements contained in this registration statement apply only as at the date of this registration statement. We undertake no obligation publicly to update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

We strongly recommended that you read the risk factors set out in “Item 3.D. Risk Factors” of this registration statement for a more complete discussion of the factors that could affect our future performance and the industry in which we operate.

**MARKET, ECONOMIC AND INDUSTRY DATA**

This registration statement contains information regarding our business and the industry in which we operate and compete, which we have obtained from various third-party sources. Where information has been sourced from a third party it has been accurately reproduced and, so far as we are aware and are able to ascertain from information published by that third party, no facts have been omitted which would render the reproduced information inaccurate or misleading.

We have generally obtained the market and competitive position data in this document from industry publications and surveys, and from studies conducted or data collected by third-party sources. Unless otherwise indicated, all sources for industry data and statistics are estimates or forecasts contained in or derived from internal or industry sources that we believe to be reliable. Market data used throughout this registration statement was obtained from independent sources and other publicly available information. Although we believe that these sources are reliable, we have not independently verified and do not guarantee the accuracy and completeness of this information.

Market data and statistics are inherently predictive and speculative and are not necessarily reflective of actual market conditions. Such statistics are based on market research, which itself is based on sampling and subjective judgments by both the researchers and the respondents, including judgments about what types of products and transactions should be included in the relevant market. In addition, the value of comparisons of statistics for different markets is limited by many factors, including that (i) the markets are defined differently; (ii) the underlying information was gathered by different methods; and (iii) different assumptions were applied in compiling the data. Accordingly, the market statistics included in this document should be viewed with caution and no representation or warranty is given by any person as to their accuracy.

**PRESENTATION OF FINANCIAL INFORMATION; NON-IFRS MEASURES**

Our consolidated financial statements appearing in this registration statement on Form 20-F are prepared in U.S. dollars and in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (“IFRS”).

Our consolidated financial statements account for the transfer of the Pharmaceutical Business from RB as a reorganization of entities under common control, retroactively at the book values of RB, including allocated costs from RB for all periods prior to the Demerger. For periods subsequent to the Demerger, we are no longer a subsidiary of RB and therefore do not have allocated costs. Rather, we have entered into service and support agreements with RB, and such expenses have been reflected in the accompanying financial statements for periods subsequent to the Demerger. See Note 26 to the consolidated financial statements that summarizes these expenses.

calculated in accordance with IFRS, such as Adjusted operating profit, Adjusted earnings, Adjusted earnings per share and free cash flow.

A summary of the key performance measures discussed in this registration statement, and of how such measures are used by our Board of Directors (the “Board”), is presented in “Item 5. Operating and Financial Review and Prospects,” including cross-references to the sections of this registration statement in which these non-IFRS measures are reconciled to the most directly comparable measure calculated in accordance with IFRS. The Board does not regard these non-IFRS measures as a substitute for the equivalent measures calculated and presented in accordance with IFRS or those calculated using financial measures that are calculated in accordance with IFRS. The non-IFRS measures used may not be directly comparable to similarly-titled measures used by other companies, including our competitors.

EXCHANGE RATE INFORMATION

Our financial information is presented in U.S. dollars, and our functional currency is U.S. dollars. For convenience only, we have translated certain amounts in pounds Sterling into U.S. dollars. Throughout this document, unless otherwise indicated, the following exchange rate has been used: £1 = \$1.47.

The table below sets forth for the periods identified the noon buying rates in number of U.S. dollars per pounds Sterling as certified by the Federal Reserve Bank of New York for customs purposes. We make no representation that any pounds Sterling or U.S. dollar amounts could have been, or could be, converted into U.S. dollars or pounds Sterling, as the case may be, at any particular rate, the rates stated below, or at all.

Year Ended December 31,	At Period End US\$	Average Rate US\$	High US\$	Low US\$
2011	1.55	1.60	1.67	1.54
2012	1.63	1.59	1.63	1.53
2013	1.66	1.56	1.66	1.48
2014	1.56	1.65	1.72	1.55
2015	1.47	1.53	1.59	1.46

Six Months Ended	At Period End US\$	Average Rate US\$	High US\$	Low US\$
June 30, 2016	1.32	1.43	1.48	1.32

Month	High US\$	Low US\$
January 2016	1.47	1.42
February 2016	1.46	1.39
March 2016	1.45	1.39
April 2016	1.46	1.41
May 2016	1.47	1.44
June 2016	1.48	1.32
July 2016 (through July 8, 2016)	1.33	1.29

On July 8, 2016, the exchange rate published by the Federal Reserve Bank of New York for the conversion of pounds Sterling to U.S. dollars was \$1.00=£1.29.

PART I

ITEM 1: IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and Senior Management.

For information on our directors and senior management, see “Item 6.A. Directors and Senior Management.”

**B. Advisers.**

Our principal United States and United Kingdom legal advisers are Covington & Burling LLP, located in the United States at 620 Eighth Avenue, New York, NY 10018 and in the United Kingdom at 265 Strand, London WC2R 1BH.

**C. Auditors.**

PricewaterhouseCoopers LLP has been our auditor since incorporation. For more information on our auditors, see “Item 10.G. Statements by Experts.”

**ITEM 2: OFFER STATISTICS AND EXPECTED TIMETABLE**

Not applicable.

**ITEM 3: KEY INFORMATION**

**A. Selected Financial Data**

The tables below set out our selected financial information, prepared in accordance with IFRS. The consolidated financial information as at December 31, 2014 and 2015 and for the three years ended December 31, 2015 has been derived from our audited financial statements included elsewhere in this registration statement. The financial information as at December 31, 2013 has been derived from our unaudited accounting records. The consolidated interim financial information as at March 31, 2016 and for the three months ended March 31, 2016 and 2015 has been derived from our unaudited condensed consolidated interim financial statements included elsewhere in this registration statement. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year or any future period.

The Company was incorporated in the United Kingdom on September 26, 2014, to serve as the holding company for the various entities of the Pharmaceutical Business of RB. The consolidated financial statements of the Company for periods prior to the Demerger accounted for the transfers of such entities to the Company as a reorganization of entities under common control, retroactively at the book values of RB, including allocated costs of doing business from RB. The Demerger of the Company from RB was effected by each shareholder of the former owner receiving one ordinary share in the Company for each ordinary share in the former owner that they held at the time of the Demerger. The Company and RB entered into the Transitional Services Agreement, which took effect on the date of the Demerger. See “Item 10.C. Material Contracts — Transitional Services Agreement.” Accordingly, periods prior to the Demerger include allocated costs from the former parent RB, and periods subsequent to the Demerger include costs related to the service agreements. See Note 26 to the financial statements related to these related party expenses. We have not presented Selected Financial Data as of and for the years ended December 31, 2012 and 2011, due to the unreasonable time and expense it would take to prepare such information.

All results are from continuing operations. The following selected financial information should be reviewed together with the whole of this document and you should not rely solely on the selected financial information below.

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Statement of income data: (\$ millions except share data)	For the three months ended March 31,		For the year ended December 31,		
	2016	2015	2015	2014	2013
Net Revenues	258	251	1,014	1,115	1,216
Operating profit	101	115	346	562	695
Net income for the period	50	77	215	403	489
Earnings per share — Basic	7	11	30	56	68
Earnings per share — Diluted	7	11	29	56	68
Weighted average number of shares outstanding — Basic	718,577,618	718,577,618	718,577,618	718,577,618	718,577,618
Weighted average number of shares outstanding — Diluted	731,270,573	723,884,628	733,085,153	723,884,628	723,884,628

Balance sheet data: (\$ millions)	March 31, 2016	December 31,		
		2015	2014	2013
Total assets	1,023	937	747	426
Net liabilities	(243)	(292)	(475)	(66)
Share capital	72	72	1,437	1,437

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## B. Capitalization and Indebtedness

The table below sets forth our capitalization and indebtedness as of March 31, 2016. This table should be read in conjunction with “Item 5. Operating and Financial Review and Prospects,” and the unaudited condensed consolidated interim financial statements and the related notes thereto, which appear elsewhere in this registration statement.

(\$ millions)	As at March 31, 2016
<b>Current borrowings</b>	
Bank loans (1)	52
Total current debt	52
<b>Non-Current borrowings</b>	
Bank loans (1)	542
Total non-current debt	542
<b>Total borrowings (1)(2)</b>	594
<b>Shareholders’ deficit</b>	
Share capital	72
Other reserves (3)	(1,321)
Retained Earnings	1,006
Total shareholders’ deficit	(243)
<b>Total capitalization (4)</b>	351

(1) Represents the principal amount of borrowings of \$594 million drawn down under the Term Facility (including \$32 million of unamortized deferred financing costs). Subsequent to March 31, 2016, Indivior repaid an additional \$36 million of principal on the Term Facility. There were no outstanding amounts drawn under the Revolving Credit Facility. Please see “Item 5.A. — The Term Facility and Revolving Credit Facility” for a description of our Term Facility and our Revolving Credit Facility.

(2) At March 31, 2016, \$594 million of our borrowings are guaranteed and secured by Indivior Group restricted subsidiaries.

(3) Represents Other reserves and Foreign currency translation reserve.

(4) Total capitalization is total borrowings and total shareholders’ deficit.

## C. Reasons for the Offer and Use of Proceeds

Not applicable.

## **D. Risk Factors**

*You should carefully consider the risks described below, together with all of the other information in this registration statement on Form 20-F. The risks and uncertainties below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition and results of operations could be seriously harmed and you could lose all or part of your investment. Further, if we fail to meet the expectations of the public market in any given period, the market price of our ADSs could decline. We operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of our control. If any of these risks actually occurs, our business and financial condition could suffer and the price of our ADSs could decline.*

### **RISKS RELATING TO OUR BUSINESS**

**We are primarily dependent on sales of SUBOXONE® Film (buprenorphine and naloxone sublingual film), SUBOXONE® Tablet (buprenorphine and naloxone sublingual tablets), and SUBUTEX® Tablet (buprenorphine sublingual tablets), any decrease in which would significantly affect our results of operations and prospects**

Substantially all our revenues derive from sales of SUBOXONE® Film (a buprenorphine and naloxone-based sublingual film), currently marketed in the United States, Australia and Malaysia, SUBOXONE® Tablet (a buprenorphine and naloxone-based sublingual tablet), currently marketed in 40 countries, and SUBUTEX® Tablet (a buprenorphine-based sublingual tablet), currently marketed in 21 countries, all of which are treatments for opioid dependence. Any factors that decrease the sales of SUBOXONE® Film (which accounted for 80% of net revenues in 2015) or, to a lesser degree, SUBOXONE® Tablet or SUBUTEX® Tablet, would significantly decrease our net revenues. Our ability to maintain or increase sales of SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet is subject to the following risks and uncertainties:

- development and marketing of competitive pharmaceutical products and alternative treatments for opioid dependence, particularly generic and branded versions of SUBOXONE® Film and an increase in the number of generic SUBOXONE® Tablet competitors beyond the current competitors;
- loss of patent protection or ability of competitors to challenge or circumvent our patents;
- issues impacting the production of SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet, including but not limited to the ability to obtain a sufficient importation assessment for buprenorphine from the U.S. Drug Enforcement Administration (the “DEA”) or an import or export license from the UK Home Office and other similar regulatory authorities in other countries;
- technological advances, including the approval of new competing products for the treatment of opioid dependence;
- increase in the level of market acceptance of existing alternative treatments for opioid dependence, including, for example, Vivitrol and Probuphine;
- changes in reimbursement policies of third-party payors;
- exclusion or suspension from U.S. federal and state healthcare programs as a result of the outcome of on-going government investigations;
- legislation allowing or requiring the dispensation of generic products rather than branded products where a generic version of a drug is available;
- government action/intervention, including the imposition of restrictions on medication and treatment to control diversion and misuse;
- intervention by the WHO or by individual governments to reschedule buprenorphine as a substance with a higher potential for abuse than currently accepted;
- marketing or pricing actions by competitors;

- current payors requiring a reduction in pricing;
- public opinion towards treatments for opioid dependence;
- third-party allegations of intellectual property infringement;
- any enforced change in labelling, or other such regulatory intervention;

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- product liability claims; and
- physicians' willingness to prescribe SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet.

We believe we have sufficient working capital for our present requirements, that is, for at least the next 12 months from the date hereof. If sales of SUBOXONE® Film or, to a lesser degree, SUBOXONE® Tablet or SUBUTEX® Tablet, were to decrease significantly, we might need to increase rebates, discounts and chargebacks (which reduce net revenues) to remain competitive. Additionally, we may need to reduce our operating expenses, including research and development expenses, or seek to raise additional funds. Decreases in net revenues, failure to reduce operating expenses or raise additional funding in response to reduced sales or adverse impact of product mix could have a material adverse effect on our business, prospects, results of operations and financial condition. The risks of product concentration are also affected by geographic concentration (with the United States accounting for 80% of net revenues in 2015).

### **The approval and launch of generic or branded products that compete with SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet could have a material adverse effect on our business, prospects, results of operations and financial condition**

#### *Generic products*

The introduction of generic products typically leads to a loss of sales of the branded product and/or a decrease in the price at which branded products can be sold, particularly when there is more than one generic product available in the market. In addition, legislation enacted in the United States allows for, and in some instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available.

In the United States, the exclusivity afforded to SUBOXONE® Tablet by its orphan drug status under U.S. Food and Drug Administration ("FDA") regulations ended in October 2009, and similar exclusivity in the European Union, Norway and Iceland expires in 2016. Our patents (assuming those at application stage are granted) relating to SUBOXONE® Film will expire on various dates up to 2030 (although certain claims of our latest-to-expire patent, U.S. Patent No. 8,475,832, have been found invalid at the District Court level).

In the United States, between October 2009 and July 2011, four manufacturers launched a generic version of SUBUTEX® Tablet. These generic formulations captured 99% of the monotherapy (buprenorphine only) market (by mg volume) and gained a 13% total market share (mono-buprenorphine and buprenorphine/naloxone) within 12 months of launch. We ceased sale and distribution of the branded SUBUTEX® Tablet in the United States in 2011.

In the United States, between March 2013 and January 2016, five manufacturers launched generic versions of SUBOXONE® Tablet. These generic formulations have gained a 14.8% market share (by mg volume) of the buprenorphine market in the United States. A fourth manufacturer received approval from the FDA for a generic version of SUBOXONE® Tablet in September 2014. We expect this fourth generic product, and additional generic products competing with SUBOXONE® Tablet, to enter the U.S. market, which could in the future further impact our share and pricing in the U.S. buprenorphine market, thereby resulting in a material impact on our net revenues and operating profit. We are aware that a further four manufacturers had, or still have, ANDA filings for generic buprenorphine and/or generic buprenorphine/naloxone products for the treatment of opioid dependence filed with the FDA.

Beginning in August 2013, we were informed of abbreviated new drug application ("ANDA") filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc. ("Actavis")), Par Pharmaceutical, Inc. ("Par"), Alvogen Pine Brook, Inc.

(“Alvogen”), Teva Pharmaceuticals USA, Inc. (“Teva”), Sandoz Inc. (“Sandoz”) and Mylan Technologies Inc. (“Mylan”) for the approval by the FDA of generic versions of SUBOXONE® Film in the United States. We filed patent infringement lawsuits against all six generic companies, which means that the FDA cannot approve their generic entrants until the earlier of 30 months after notice to us of their ANDA filings or the disposition of the patent infringement proceedings. We and Sandoz have each submitted a proposed order to dismiss their patent litigation suit which are pending before the court. Trial against Teva, Actavis and Par in the lawsuits involving process patents is scheduled for November 2016. Trial against Teva in the lawsuit involving the Orange Book-listed patents for SUBOXONE® Film is scheduled for November 2016. Trial against Alvogen in the lawsuit involving those Orange Book-listed patents and process patents is scheduled for April 2017. Trial against Mylan in the lawsuit involving the Orange Book-listed patents for SUBOXONE® Film is scheduled for September 2017.

If any company is able to obtain FDA approval for its generic version of SUBOXONE® Film, it may be able to launch the product prior to the expiration of any or all the applicable patents protecting our SUBOXONE® Film, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

*Branded products*

The introduction of branded products that compete with our products may lead to a loss of sales of our products and/or a decrease in the price at which our products can be sold. Orexo Inc. introduced a branded buprenorphine and naloxone sublingual tablet, ZUBSOLV®, in September 2013 which has gained a 4.4% share (by mg volume) of the buprenorphine market in the United States, and Bidelivery Sciences International, Inc. (“BDSI”) launched its branded buccal film product, BUNAVAIL™, in November 2014 which has gained a 0.7% share (by mg volume) of the buprenorphine market in the United States. In June 2016, Braeburn Pharmaceuticals launched the Probuphine Implant, a six month treatment for opioid dependence. The Indivior

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Group filed a patent infringement lawsuit against BDSI on September 22, 2014 asserting a patent licensed from Monosol RX, LLC (“MSRX”) that is not Orange Book-listed for SUBOXONE® Film. In anticipation of launching its product and being sued by the Indivior Group, BDSI filed a lawsuit against the Indivior Group and MSRX in the US District Court for the Eastern District of North Carolina on September 20, 2014 seeking a declaratory judgment of non-infringement and invalidity of two patents relating to SUBOXONE® Film. For more information, see “Item 8.A. — Legal Proceedings.” Although SUBOXONE® Film has a market share (by mg volume) of 60.9% of the U.S. buprenorphine-based opioid dependence treatment market, the Indivior Group expects that increased branded competition could impact its share and pricing in the market. Any of the foregoing competitive developments could have a material adverse effect on our business, prospects, results of operations and financial condition. Among other things, developments of this nature have in the past, and could in the future, require the Indivior Group to increase further the level of rebates and other offsets to gross sales, particularly in its U.S. operations, as well as impact potential volume growth of any affected products, which, in turn, could reduce net revenues and, therefore, its results in future periods.

**Our products may not be prescribed and dispensed in the manner permitted by the U.S. Drug Addiction Treatment Act of 2000 (“Data 2000”)**

In the United States, the DEA classifies controlled substances into five schedules. DATA 2000 permits physicians who meet certain requirements to treat opioid dependence with Schedule III, IV and V narcotic medications that have been specifically approved by the FDA for that indication. Physicians who qualify for a waiver under DATA 2000 by meeting various conditions (including with regard to training and acceptance of limits on the number of patients that can be treated under the waiver) may prescribe and diagnose such medications in settings (for example, their own offices) other than those traditionally associated with opioid dependence treatment, such as methadone clinics.

If buprenorphine is in the future viewed as having a greater potential for abuse than is reflected by its current classification, it may be reclassified as a Schedule II substance, in which case our current and future products which contain buprenorphine would no longer qualify under DATA 2000 and would have to be prescribed and dispensed in the same way as other Schedule II substances approved for the treatment of opioid dependence, such as methadone, which would significantly limit the settings and circumstances in which these products can be prescribed, and therefore have a material adverse effect on sales of our products containing buprenorphine. In addition, increased incidence of misapplication by prescribing physicians, including overriding government-imposed restrictions on patient limits per physician, could result in more stringent requirements. Such developments could have a material adverse effect on our business, results of operations and financial condition.

**Clinical trials for the development of products, including our key pipeline products, may be unsuccessful and our product candidates may not receive authorization for manufacture and sale**

The number and duration of pre-clinical studies and clinical trials that are required varies depending on the product candidate, the indication being evaluated, the trial results and the regulations applicable to the particular product candidate. In addition, we are required to obtain regulatory approvals to conduct clinical trials and manufacture drugs before they can be marketed. This development process takes many years and can be very expensive.

Before obtaining regulatory approvals for the commercial sale of each product under development, we must demonstrate, through clinical and other studies, that the product is safe and effective for the claimed use or uses, and also demonstrate that the product is of appropriate quality. Such clinical and other studies can be delayed or halted for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board to conduct a clinical trial at a prospective study site;
- delays in recruiting patients to participate in a clinical trial;
- failure of clinical trials and clinical investigators to comply with FDA and other regulatory agencies’ good clinical practice (“GCP”) requirements;
- unforeseen safety issues, including negative results from on-going pre-clinical studies and adverse events associated with product candidates;
- inability to monitor patients adequately during or after treatment;

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- difficulty monitoring multiple study sites;
- failure of our third-party clinical trial managers to satisfactorily perform their contractual duties, comply with regulations or meet expected deadlines;
- disagreements with collaborative partners on the planning and execution of product development; or
- insufficient funds to complete the trials.

Both RBP-6000 and RBP-7000 are currently undergoing various Phase III studies. However, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and therefore RBP-6000 and RBP-7000 may fail to show the desired safety and efficacy in later clinical trials despite having progressed successfully through initial clinical testing. In that case, the FDA or the equivalent regulatory authority in jurisdictions outside the United States may determine our data are not sufficiently compelling to warrant marketing approval and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming and substantially delay the receipt of such regulatory approval (which may delay the launch of RBP-6000 beyond 2018 as currently targeted). For example, the FDA issued a non-approval of the Company’s Nasal Naloxone in a Complete Response Letter to the Company in November 2015 which resulted in us discontinuing further development of the formulation incidental to the new drug application (“NDA”), and impairing the related intangible assets as at December 31, 2015. Furthermore, on April 28, 2016 we announced that RBP-6300, the oral swallowable capsule of buprenorphine hemiadipate for the treatment of opioid dependence, completed its Phase I clinical pharmacokinetic study (RB-EU-14-0001) but that it did not achieve the anticipated

pharmacokinetic profile in humans to justify proceeding further with this technology and, as a result, we are evaluating alternative options for the development of an orally bioavailable buprenorphine-based product with abuse deterrent properties. In addition, the development of RBP-7000, currently concluding its Phase III long-term safety extension trial, has been delayed due to an external manufacturing issue identified with one out of six stability batches required for NDA submission. We believe this issue is now rectified and additional batches will be manufactured to provide the required data but this has resulted in a delay to the likely approval date and we currently expect to file an NDA for RBP-7000 in September 2017 and are targeting U.S. approval in mid-2018. Many companies in the pharmaceutical industry have suffered significant setbacks in drug development and there can be no guarantee that FDA approval will ultimately be obtained.

Even if the clinical trials of any product under development were to be completed, they may not demonstrate the quality, safety and efficacy required to result in an approvable or a marketable product which would delay or prevent regulatory approval of the product. In addition, regulatory authorities in Europe, the United States and other countries may require additional studies, which could result in increased costs and significant development delays, or termination of a project if it would no longer be economically viable.

**We rely on third parties to conduct our clinical trials, and if they do not properly and successfully perform their legal and regulatory obligations, as well as their contractual obligations to us, we may not be able to obtain regulatory approvals for our product candidates within the timeframes currently envisaged, or at all and may be exposed to regulatory sanctions**

We rely on contract research organizations and other third parties to assist in designing, managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, may not be able to prevent delays. If we, contract research organizations, other third parties assisting us or our study sites fail to comply with applicable GCP requirements, the clinical data generated in the relevant clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications.

In addition, clinical trials must be conducted with products produced under the FDA’s and non-U.S. regulatory agencies’ current good manufacturing practices (“cGMP”) regulations. Our failure, or the failure of third parties conducting clinical trials on our behalf, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process or expose us to regulatory sanctions.

If our clinical trials do not meet regulatory requirements, or if third parties conducting our clinical trials need to be replaced, clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval for our product candidates or succeed in our efforts to create approved line extensions for our existing products or generate additional useful clinical data in support of these products, which would adversely affect our business, prospects, results of operations and financial condition.

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**Our ability to obtain patient participation in clinical trials may impact our ability to successfully conduct such trials**

The identification and qualification of patients for participation in clinical trials of our product candidates is critical to our success. Clinical trials are established under specific protocols which regulate the manner in which they are conducted. Protocols specify the number of patients to be recruited into the study and the characteristics of patients who can and cannot be accepted into the study. We may not be able to identify, recruit and enroll a sufficient number of patients for a number of reasons, such as the specified characteristics being too tightly defined, resulting in a very small population of suitable patients, the emergence of a competing drug, either one that is approved or another drug in the clinical stage of development, limited availability of clinical trial sites for prospective subjects or perceived risks and benefits of the product candidate under study. Clinical trials may be delayed or impacted in the event we are unable to obtain client participation in such trials, which in turn may adversely affect our business, prospects, results of operations and financial condition.

**The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates**

The research, testing, manufacturing, labelling, advertising and promotion, distribution and import and export of pharmaceutical products are subject to extensive regulation, and regulations differ from country to country. Approval in one jurisdiction does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be

unable to obtain approval for our product candidates. For example, we are not permitted to market our product candidates in the United States or in the EU member states until the FDA, the European Commission, or the competent authorities of the EU member states respectively have approved, generally, an NDA, a biologics license application (“BLA”) or a marketing authorization application. The application must contain information demonstrating the quality, safety and efficacy of the medicinal product, including data from the pre-clinical and clinical trials, information pertaining to the preparation and manufacture of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labelling and information concerning the medicinal product and its intended uses. Submission of an application for marketing authorization does not assure approval for marketing in any jurisdiction, and we may encounter significant difficulties or costs in our efforts to obtain approval to market products. If we are unable to obtain regulatory approval for our product candidates, we will not be able to commercialize them and recoup our research and development expenses. If we fail to obtain approval, or approval is delayed or is received for narrower conditions of use than sought, our prospects, financial condition and results of operations could be adversely affected. Even if product candidates are approved there is no guarantee that they will be able to achieve market acceptance.

**A regulator may impose a risk evaluation and mitigation strategy or post-marketing obligations on any new product developed by us**

We may be required to include, as part of an NDA, a proposed risk evaluation and mitigation strategy (a “REMS”) whose goal is to mitigate potential risks which may be associated with the use of a product and to inform patients and prescribers of those risks. We may also be required to include a package insert directed at patients, a plan for communication with healthcare providers, restrictions on a drug’s distribution or a medication guide to provide information to consumers about the drug’s risks and benefits. For example, the FDA requires a REMS for SUBOXONE® Film, and other products that we sell in the future, including RBP-6000, may become subject to a REMS specific to the product or shared with other products in the same class of drug. Depending on the nature of the REMS, the cost to implement the REMS may be high and the impact to the business may be significant.

In the EU, we may be required to adopt a risk management plan (“RMP”) and our products could be subject to specific risk minimization measures, such as restrictions on prescription or supply, the conduct of post-marketing safety or efficacy studies, or the distribution of patient and/or prescriber educational materials.

In addition, post-marketing obligations in the form of further clinical trials may be imposed to further expand on the evaluation of the risk/benefit profile of the product relative to any potential safety concerns. These trials typically occur after approval and according to pre-specified timelines set by regulatory authorities. Depending on the nature of the post-marketing commitment, trial completion can be a lengthy process. Failure to comply with any of these requirements may potentially lead to suspension of the marketing authorization for the product and other penalties. The costs and other consequences of non-compliance with any of the post-approval obligations described above could have an adverse impact on its business, prospects, results of operations and financial condition.

**Product candidates that receive regulatory approval may be unable to achieve expected market acceptance**

Our ability to generate significant revenue from our pipeline products, and in particular from RBP-6000, depends on their acceptance by physicians, patients, third-party payors and the medical community. The market acceptance of any product

depends on a number of factors, including the following:

- indication statement and warnings approved by regulatory authorities on the product label;
- continued demonstration of efficacy and safety in commercial use;
- the prevalence of the disease or condition for which the product is approved and the severity of side effects;
- legislation and regulation controlling the conditions of treatment and the distribution of the product;
- physicians’ willingness to prescribe the product and our ability to educate physicians with respect to new products;

- patients' willingness to take the product;
- with respect to opioid dependence treatments, new governmental or regulatory guidelines or policies limiting the prescription of opioids to patients;
- reimbursement from third-party payors such as government healthcare programs and insurance companies;
- the price of the product relative to alternative treatments, including generic products;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the nature of any post-approval risk management plans mandated by regulatory authorities;
- marketing and distribution support; and
- the existence of alternative products marketed by competitors.

Any factors preventing or limiting the market acceptance of our products, in particular RBP-6000, could have a material adverse effect on its sales and hence its business, results of operations and financial condition.

**Failure to obtain and maintain patents and protect other proprietary rights, including in-licenses of such rights from third parties, may adversely affect us**

Our success depends, in large part, on our ability to obtain and maintain patent and other intellectual property protection, particularly for our drug, compound, product, delivery, formulation and methods of treatment technologies and associated manufacturing processes in relation to both our products and our product candidates. The process of obtaining patents can be lengthy and expensive. We own, or license in, a number of patent rights in the United States and other countries covering certain products and have also developed brand names and trademarks for other products. Our business is currently materially dependent upon a group of owned as well as in-licensed patents relating to SUBOXONE® Film. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and future products are covered by valid and enforceable patents or are effectively maintained as trade secrets or confidential information within the Indivior Group. Our existing patents, and any future patents we obtain, may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely impact our business, prospects, results of operations and financial condition. Moreover, our ability to obtain and enforce patents and other proprietary rights is critical to our business strategy and success.

The patent positions of many pharmaceutical and life sciences companies are highly uncertain and involve complex legal and factual questions. In some cases, the legal principles applying to these cases may be changing or unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty. In addition, we cannot guarantee that:

- we were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- patents will be granted in connection with any of our currently pending or future applications;

- other companies will not independently develop similar or alternative technologies or duplicate any of our technologies by inventing around our claims;

- a third party will not challenge our proprietary rights, and if challenged that a court will hold that our patents are valid and enforceable;
- any patents issued to us or our collaboration partners will cover our products as ultimately developed, or provide us with any competitive advantages, or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on our business.

We also rely on trade secrets and other unpatented confidential information to maintain our competitive position but there can be no assurance that others may not independently develop the same or similar products or technologies, and may also obtain patents and other intellectual property protection for them. We have sought to protect trade secrets and confidential information, in some cases through the provisions of confidentiality and non-use agreements with our employees, consultants, advisers and partners. Nevertheless, it may not always be possible to prevent disclosure of our trade secrets and other confidential information and for us to obtain an adequate remedy in the event of unauthorized disclosure or use of such information.

We have entered into a number of collaborative arrangements for the development and commercialization of products (including MSRX in relation to SUBOXONE® Film and XenoPort for arbaclofen placarbil). In connection therewith, we share certain of our proprietary knowledge with such collaborative partners and it may not be possible or practical to prevent our partners from developing similar or functionally equivalent products. In the event of any disputes between us and such partners, such disputes may threaten our ability to continue using such proprietary knowledge and, in turn, could impact our ability to market our products.

We have entered into and rely upon a number of in-licensing arrangements with third parties, including in relation to SUBOXONE® Film, in order to provide the freedom to use certain of their technologies in our products. If we do not continue to comply with the terms of such licenses, we may not be able to maintain them. The termination of such licenses could have a material adverse effect on our business, results of operations and financial condition. In addition, patent laws in the jurisdictions in which we have operations and/or their interpretation may also change over time. We cannot predict the effect that any such changes would have on our operations and our ability to protect our current and future products and technologies.

If we fail to obtain and maintain sufficient intellectual property protection for our current and future products and technologies, our ability to successfully and fully exploit these products and technologies could be adversely affected, which in turn would adversely affect our business, prospects, results of operation and financial condition.

### **We may not be able to assert proprietary rights in intellectual property developed by our employees, consultants or partners, or under sponsored research agreements**

If our employees, consultants or partners develop inventions or processes independently that may be applicable to our products or technologies under development, disputes may arise about ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those persons or their employers or the persons may be entitled to compensation in respect of those inventions. Protracted and costly litigation could be necessary to enforce and determine the scope of our

proprietary rights.

We have also engaged in collaborations, sponsored research agreements and other arrangements with academic researchers and institutions, some of which have received and may receive funding from government agencies. Although we have sought to retain ownership of all intellectual property rights pertaining to inventions which may result from such collaborations, there can be no assurance that governments, institutions, researchers or other third parties will not also attempt to claim certain rights to such inventions. Failure to secure proprietary rights over such intellectual property, for any reason, could adversely affect our business, prospects, results of operations and financial condition.

### **We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property**

Litigation and other similar proceedings, such as *inter partes* reviews in the United States (which are initiated by third parties to challenge the validity of a patent) relating to infringement, validity or misappropriation of patent and other intellectual property rights in the pharmaceutical and life sciences industry are common. We may receive notifications of challenges to the validity of our patents or alleged infringement of patents owned by third parties. We have historically incurred, and expect that we will continue to incur, significant costs in connection with the ANDA proceedings relating to SUBOXONE® Film in the United States. If we choose to go to court to prevent a third party from infringing our patents, our licensed patents or our partners’ patents (where we have the right to do so), that allegedly infringing third party has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. For example, the U.S. District Court for the District of Delaware ruled in June 2016 that certain claims in our Patent No. 8,475,832 are invalid. (We intend to file a notice of appeal in regard to aspects of this decision.) These lawsuits are expensive and time-consuming, even if we are ultimately successful in stopping the infringement of these patents. In addition, there is a risk that a court will decide that these patents are not valid or not infringed and that we do not have the right to prevent the other party from using the patented subject matter. Dr. Reddy’s Laboratories has filed a petition against us and, as to certain patents, our licensor MSRX, before the U.S. Patent and Trademark Office (“USPTO”) seeking inter partes review of three patents relating to SUBOXONE® Film. Recently, the USPTO declined to institute inter partes review of the same three patents based on similar petitions filed by Teva. In addition, we have filed appeal from an adverse finding by the USPTO regarding BDSI’s petition for inter partes review of Claims 15—19 of U.S. Patent No. 8,475,832. There can be no assurance that these, or other litigation that we may file in the future, will be successful in preventing the infringement of our patents, that we will be able to successfully defend the validity of our patents, that any such litigation will be cost-effective, or that the litigation will have a satisfactory result for us. In addition, such litigation diverts the attention of management and development personnel. Failure to stop infringement of our patents or an unsatisfactory result in litigation would adversely affect our business and results of operations.

A third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party’s patent rights, or that we or such partners are infringing, misappropriating or otherwise violating other intellectual property rights, and may go to court to stop us from engaging in our ordinary course operations and activities, including manufacturing or selling our products. There is a risk that a court could decide that we or our partners are infringing, misappropriating or otherwise violating third-party patents or other intellectual property rights, which could have a material adverse effect on our business and results of operations. In addition, such litigation diverts the attention of management and development personnel.

We may initiate or defend legal proceedings relating to our patents alongside a collaborator or third party with an interest or right in the relevant patents. In this scenario, our strategy for asserting or defending our rights might be impacted by that of our co-claimant or co-defendant which, in turn, may have an adverse impact on our existing commercial relationship.

In the pharmaceutical and life sciences industry, like other industries, it is not always clear to industry participants, including the Indivior Group, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, which we may not be able to do, and which could in turn result in our being required to pay substantial sums. These sums potentially include damages, legal fees, and increased damages if we are found to have infringed such rights wilfully. These damages potentially include increased damages and legal fees if we are found to have infringed such rights wilfully. Further, if a patent infringement suit is brought against us, our research, development, manufacturing or sales activities relating to the product or

product candidate that is the subject of the suit may be delayed, materially affected or terminated by the grant of an injunction against us.

We cannot be certain that others have not filed patent applications for inventions covered by our licensors’ or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to those of the Indivior Group. Any such patent application may have priority over our or our licensors’ patents or applications and could further require us to obtain rights to patent rights covering such subject matter. For example, in June 2016, a third party’s patent application resulted in an issued patent that contains claims that could relate to SUBOXONE® Film. In the United States, if another party has filed a patent application on inventions similar to those of the Indivior Group, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss

of our U.S. patent position with respect to such inventions. Patent interferences are limited or unavailable for applications filed after March 16, 2013.

As a result of patent infringement claims, or in order to avoid potential infringement claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party, which would be likely to include a requirement to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which would potentially give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we, or our collaborators, could be prevented from commercializing one or more of our product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could adversely affect our business, prospects, results of operations or financial condition.

The cost to us of any patent litigation or other proceedings, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of complex patent and other intellectual property litigation more effectively than we can because they have substantially greater resources than the Indivior Group. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue its operations.

Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

**We may not be able to protect our intellectual property rights throughout the world which could have an adverse effect on its business, results of operations and financial condition**

Filing, prosecuting and defending patents relating to all of our product candidates and technologies throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and further, may export otherwise infringing products to territories where we have patent protection but where enforcement is more difficult. These products may compete with our future products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert efforts and attention from other aspects of our business, which could adversely affect our operations and financial condition. Moreover, the patent rights can be challenged in post-grant or inter partes review.

**If we are unable to secure new products or compounds for development, our business, prospects, results of operations and financial condition could be materially adversely affected**

We intend to grow our business over the long term by acquiring or in-licensing and developing additional products and product candidates that we believe have significant commercial potential. For example, on May 14, 2014, we entered into an exclusive worldwide licensing agreement with XenoPort, Inc. for the development and commercialization of a clinical-stage oral product candidate called arbaclofen placarbil for the treatment of alcohol use disorder. Future growth through acquisition or in-licensing will depend upon the availability of suitable products and product candidates for acquisition or in-licensing at acceptable prices and on acceptable terms and conditions. Even if appropriate opportunities are available, we may not be able to successfully identify them, or may not have the financial, marketing and sales resources relative to our competitors that are necessary to pursue them.

In addition, any growth through development will depend upon us identifying and obtaining product

candidates, our ability to develop those product candidates and the availability of funding to complete the development of, obtain regulatory approval for and commercialize these product candidates. We may not be able to successfully manage the risks or other anticipated and unanticipated problems in connection with an acquisition or in-licensing, and may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including the possibility that a product candidate proves not to be safe

or effective in later clinical trials, a product fails to reach its forecast commercial potential or the integration of a product or product candidate gives rise to unforeseen difficulties and expenditures. It is common for multiple products and product candidates to be evaluated for the same indication by multiple parties at the same time, and we cannot predict whether our products' forecast commercial potential will come to fruition. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business, prospects, results of operations and financial condition.

**Failure to retain key personnel or attract new personnel, could have an adverse effect on us**

We rely upon a number of key executives and employees (including our sales force with high quality access to physicians) who have an in-depth and long-term understanding of the industry and our technologies, products, programs, collaborative relationships and strategic goals. Competition for such personnel in the biotechnology and pharmaceutical industries is intense, and there can be no assurance that we will be able to retain such personnel.

We do not carry “key person” insurance. The loss of the services of any of our key executives or employees could delay or prevent the successful completion of some of our vital activities. Any employee may terminate his or her employment at any time without notice or with only short notice and without cause or good reason. The resulting loss of institutional knowledge may have a material adverse effect on our operations and future growth.

**We may fail to obtain and maintain coverage, or an adequate level of reimbursement from governmental or third-party payors for our products**

Our revenues are partly dependent on the coverage and level of reimbursement provided to us by private insurance companies and governmental reimbursement schemes for pharmaceutical products, such as Medicare and Medicaid in the United States. The cost of treatment established by healthcare providers, private health insurers and other organizations, such as health maintenance organizations and managed care organizations, are under downward pressure and this, in turn, could result in lower prices for our products and/or in reduced demand for our products. When generic versions of a product are available, payors may impose access restrictions on the branded product, such as requiring prior authorization, imposing high patient co-pays, or precluding coverage altogether. These restrictions may be placed on our products. In particular, this may result in competitor generic versions of SUBOXONE® Film being preferred to SUBOXONE® Film, thereby further eroding the loss of market share for SUBOXONE® Film in the United States.

In addition, changes to governmental policy or practices could adversely affect the level of reimbursement through governmental schemes. In the United States, there continue to be proposals by legislators at both federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. Similarly, in the EU member states, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices that we will be able to charge for our products and any approved product candidates. Further, an increasing number of EU member states and other foreign countries use prices for products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of products in some countries could contribute to similar downward trends elsewhere.

In addition, the on-going budgetary difficulties faced by a number of EU member states have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of products in some countries, including some EU member states, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies.

The prices for certain of our products, when commercialized, may be high compared to other pharmaceutical products. We may encounter particular difficulty in obtaining satisfactory pricing and reimbursement for any new and highly priced products for which it is considered that the economic and therapeutic rationales are not established. The failure to obtain and maintain pricing and reimbursement at satisfactory levels for such products may adversely affect our results of

operations and prospects.

There can be no assurance that our products will obtain favorable reimbursement status in any country. The failure to obtain and maintain reimbursement, or an adequate level of reimbursement, for our products may have a material adverse effect on our business, prospects, results of operations and financial condition. Manufacturing or supply problems encountered by us or our suppliers could have a material adverse effect on our business, prospects, results of operations and financial condition

**We or our suppliers are subject to strict regulatory and manufacturing requirements**

The manufacture of our products is highly exacting and complex, due in part to strict regulatory and manufacturing requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, lapses in oversight, defective raw materials and environmental factors.

The active pharmaceutical ingredients used in our products are manufactured at the Fine Chemical Plant (“FCP”) located in Hull, United Kingdom. Ownership of the FCP was transferred from Reckitt Benckiser Healthcare (UK) Ltd. (“RB Health”), a member of the RB Group, to Indivior in April 2015. The FCP manufactures the buprenorphine hydrochloride active pharmaceutical ingredient used in the formulation of SUBUTEX<sup>®</sup> Tablet, SUBOXONE<sup>®</sup> Tablet, SUBOXONE<sup>®</sup> Film, TEMGESIC<sup>®</sup> and BUPRENEX<sup>®</sup>. Any issues experienced at the FCP could result in delays in the production of these products.

All facilities and manufacturing techniques used for the manufacture of our products must be operated in conformity with the mandatory manufacturing standards (often referred to as cGMP) of the FDA, the UK Medicines and Healthcare products Regulatory Agency (“MHRA”) and other regulatory authorities. Manufacturing facilities are subject to periodic unannounced inspection by the FDA, MHRA and other regulatory authorities. Failure to comply with applicable legal and regulatory requirements subjects our manufacturing facilities or our third-party suppliers to possible legal or regulatory action, including shutdown, which may adversely affect our ability to manufacture, or our third-party suppliers’ ability to supply, finished products. We rely on a single source in the United States for the production of SUBOXONE<sup>®</sup> Film and on a single source in the United Kingdom for the production of SUBOXONE<sup>®</sup> Tablet and SUBUTEX<sup>®</sup> Tablet.

**We rely on third parties for the supply, manufacture, packaging and distribution of our products**

We rely on a limited number of key third parties for the supply, manufacture, packaging and distribution of our products. In particular, SUBOXONE<sup>®</sup> Film is manufactured under an exclusive license and supply agreement with MSRX signed in August 2008 in reliance on MSRX’s proprietary PHARMFILM<sup>®</sup> technology. In addition, the naloxone hydrochloride active pharmaceutical ingredient is procured mainly from two suppliers for both SUBOXONE<sup>®</sup> Tablet and SUBOXONE<sup>®</sup> Film. Supply of naloxone hydrochloride for SUBOXONE<sup>®</sup> Tablet is single-source while supply for SUBOXONE<sup>®</sup> Film is dual-source. In addition, as part of the Demerger, we entered into a seven-year supply agreement with RB Health, whereby RB Health assumed responsibility for the formulation, compressing, and finished good packaging of SUBUTEX<sup>®</sup> Tablet and SUBOXONE<sup>®</sup> Tablet, as well as the formulation, filling, and terminal sterilization of TEMGESIC<sup>®</sup> and BUPRENEX<sup>®</sup>.

Any delay in supplying, or any failure or refusal to supply, products to, or delays in manufacturing by, our suppliers, or any catastrophe or natural disaster affecting such third party manufacturing facilities or suppliers, could result in our inability to meet the commercial demand for our products, which in turn could materially adversely affect our business, prospects, results of operations and financial condition. In particular, such third party suppliers or manufacturers may not have contingency plans which may allow them to continue to supply or manufacture, within the contractual deadlines or at all, our products.

In addition, the loss of one of any supplier could require us to obtain regulatory clearance for a new supplier in the form of a “prior approval supplement” and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient (“API”) or manufacturing process. It would prove to be particularly difficult to find an alternative supplier to MSRX, given the reliance on MSRX’s proprietary PHARMFILM<sup>®</sup> technology. We believe it could take up to two years or longer in certain cases to qualify a new supplier or manufacturer, and if we are not able to obtain the ingredients or finished products from suppliers or manufacturers on acceptable terms and at reasonable prices, or at all, our business, prospects, results of operations and financial condition could be adversely affected.

**Product liability and product recalls could have a material adverse effect on us**

The testing, manufacturing, marketing and sales of pharmaceutical products entail a risk of product liability claims, product recalls, litigation and associated adverse publicity. Unanticipated side effects of, or manufacturing defects in, our products could exacerbate a patient’s condition or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. In many countries, including in EU member states, national laws provide for strict (no-fault) liability, which applies where harm is caused both by a defective product and by the act or omission of a third party.

Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class of injured patients. Further, third-party payors, either individually or as a putative class, may bring actions seeking to recover monies spent on products. The risk of product liability claims may also increase if we are subject to regulatory action by the FDA, the European Medicines Agency (the “EMA”) or other competent authorities, or following a product recall. The cost of defending such claims is expensive even when the claims are not merited. A successful product liability claim against us could require us to pay a substantial monetary award. Moreover, an adverse judgment in a product liability suit, even if insured or eventually overturned on appeal, could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other products.

**Although we carry product liability insurance, current coverage may not be adequate. Further, product liability insurance is difficult to obtain and may not be available in the future on acceptable terms or at all.**

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority over pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. In addition, product liability claims, product complaints or product quality issues reported by us to authorities as required by local regulations could result in an investigation (conducted by the FDA, the EMA, or the competent authorities of EU member states or other national authorities) into the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs. An investigation could potentially lead to a recall of our products or more serious enforcement actions including seizure, injunction or criminal charges, proposed changes to the indications for which they may be used or suspension or withdrawal of approval. The Company has no insurance coverage for product recalls.

Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

**Insufficient importation assessments for necessary APIs or the failure to obtain or maintain necessary import and export licenses may adversely impact our ability to meet commercial demand or complete clinical trials**

APIs in many of our products and product candidates are controlled substances that are subject to regulation in all of the countries in which we market our products. In the United States, pharmaceutical products containing controlled substances are subject to extensive regulation under the U.S. Controlled Substances Act of 1970, as amended (the “CSA”), which establishes, among other things, certain registration,

security, recordkeeping, reporting, manufacturing and procurement quotas, import, export and other requirements administered by the DEA. All countries in which we market our products are subject to similar controls supervised by the relevant regulatory authorities, for example the Home Office in the United Kingdom.

An annual importation assessment value for buprenorphine is set by each importing country through the International Narcotics Control Board (the “INCB”). In the United States, the DEA limits the availability of buprenorphine, and may limit the availability of active ingredients in other product candidates. As a result, our importation assessment for buprenorphine in the countries in which we market our products may not be sufficient to meet commercial demand or to complete clinical trials for buprenorphine-based and other product candidates. In the United States, for a new drug the DEA may not establish an importation assessment following FDA approval of an NDA for a controlled substance until after the DEA reviews and provides for public comment on the labelling, promotion, risk management plan and other documents associated with such product. A DEA review of such materials may result in potentially significant delays in obtaining an importation assessment for controlled substances, a reduction in the assessment issued to us or the elimination of an assessment entirely.

Any delay or refusal by the DEA or a similar non-U.S authority in establishing our importation assessment for controlled substances, any importation assessment that is established but which is insufficient for our purposes, or any failure to obtain or maintain the necessary import and export licenses from the relevant authorities, could delay, stop or affect clinical trials, product launches or sales of products, which could have a material adverse effect on our business, financial condition and results of operations.

**We may experience delays in the shipment of products and APIs**

The shipment of pharmaceutical products that contain controlled substances, including certain of our products and product candidates, require import and export licenses from the relevant authorities. We may not be granted or, if granted, may not maintain, such licenses. Even if we maintain such licenses, shipments may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in a partial or total loss of revenue from one or more shipments of our products and product candidates and necessary APIs. A partial or total loss of revenue from one or more such shipments could have a material adverse effect on our business, results of operations and financial condition.

**We are dependent on a relatively small number of significant customers for a substantial proportion of our net revenues**

A limited number of significant customers have historically accounted for a substantial portion of our net revenues. Our three largest customers are wholesalers that accounted for 76% of global gross sales in 2015, which equated to 71% of our net revenues (2014: 75% of global gross sales, which equated to 69% of our net revenues).

There can be no assurance that these customers will continue their relationship with us, particularly if generic versions of our products are available at a lesser cost. In particular, there is a risk that any of such customers may be lost as a result of the introduction to an alternative generic to SUBOXONE® Film in the United States. Demand for our products is largely derived from acceptance of the products by physicians, patients, pharmacists and third-party payors. Accordingly, if physicians were no longer willing to prescribe, patients no longer accepted, pharmacists able or mandated to switch the prescription due to the existence of an A/B rated generic (i.e., a generic product which is considered to be a therapeutic equivalent and can be substituted by a pharmacist without the consent of the patient or physician) or third-party payors were no longer willing to reimburse for our products, these significant customers could reduce their purchasing levels or cease buying products from us at any time.

If we cease to do business with a significant customer or if sales of our products to a significant customer materially decrease, due to physician and/or patient demand, pharmacy switching or payors’ lack of willingness to reimburse, our business, prospects, results of operations and financial condition may be materially adversely affected.

In addition, we may have a large amount of outstanding receivables with a significant customer at any one time. If there is an adverse change in the creditworthiness of such a significant customer, or if it were, for example, to file for bankruptcy protection, we could be prevented from collecting our receivables, which would adversely affect our results of operations and financial condition.

**Business interruptions or breaches of data security could disrupt our product sales and delay the development of our product candidates**

Loss of manufacturing facilities, stored inventory or laboratory facilities, including those of third parties, through any natural disaster or man-made catastrophe, or loss of necessary raw materials, could have an adverse effect on our ability to meet demand for our products, to continue product development activities and to conduct our business. We currently

have insurance coverage against such business interruptions; however, such coverage may prove insufficient to compensate us fully for damage to our business resulting from any significant property or casualty loss to inventory or facilities, which could have an adverse impact on our business, prospects, results of operations and financial condition.

In addition, we are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information.

We have also outsourced elements of our information technology and as a result manage a number of third-party vendors who have or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber attacks, all of which would be costly to remedy. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other proprietary information. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent the adverse effect of such events.

Failures of or disruptions to our systems or the systems of third parties on whom we rely, particularly if prolonged, could result in breaches of data security and/or a loss of key data which would adversely affect our reputation, business and results of operations.

**Failure to comply, or the costs of complying, with environmental and health and safety regulations could adversely affect our operations**

We are subject to regulation relating to the protection of the environment and health and safety, including regulations governing air emission, effluent discharge, and the use, generation, manufacture, storage, handling and disposal of certain materials. The cost and complexity of complying with such environmental and health and safety laws and regulations are substantial and failure by us to comply with such regulations or the costs incurred in doing so could have an adverse impact on our business, prospects, results of operations and financial condition.

**Our insurance cover may not be adequate**

Our business exposes us to potential product liability and professional indemnity claims and other risks which are inherent in the research, pre-clinical and clinical evaluation, manufacturing, sales and marketing and use of pharmaceutical products. We have taken out public and products liability insurance covering customary insurable risks in respect of such matters. Additional insurances taken out by us include property damage and business interruption, third party named suppliers, marine and cargo, directors’ and officers’ liability, clinical trials, employers’ liability and personal accident and travel.

While we believe that the cover in place is appropriate for a business of our current size and nature, there is no certainty that coverage limits and indemnity provisions will be adequate to cover all potential claims that could arise against us in the conduct of our business nor that claims will arise from insurable risks. In addition, there are areas where insurance cover, while potentially available, would carry premiums which are not commercially reasonable and/or may be difficult to obtain or maintain on commercially reasonable terms. A successful claim or claims against us in excess of or outside the ambit of our insurance coverage may have a material adverse effect on our business, prospects, results of operations and financial condition.

**We are subject to on-going investigations and information requests which could have a significant effect on our business**

We are currently subject to investigations, for example the on-going federal criminal grand jury investigation of Indivior initiated in December 2013 relating to marketing and promotion practices, pediatric safety claims and overprescribing of medication by certain physicians, including through subpoenas and other information requests, by various governmental authorities, the U.S. Federal Trade Commission (the “FTC”) investigation of Indivior initiated in late 2012 focusing on business practices relating to our core products, and the antitrust investigation into the same conduct being investigated by the FTC commenced in July 2013 by the Attorney General of the State of New York, which preceded a contingent of additional states also initiating a coordinated investigation.

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It is not possible at this time to predict with any certainty or to quantify the potential impact on us. We are however cooperating fully with the relevant agencies and prosecutors and will continue to do so.

If, as a result of these or any future investigations, we are found or suspected to have violated any applicable laws and regulations, we may be subject to a variety of fines, penalties, related administrative sanctions, potential exclusion from government healthcare program reimbursement or civil and/or criminal prosecution, any of which could have a material adverse effect on our reputation, business, financial condition and results of operations.

**We are subject to on-going investigations with the U.S. Internal Revenue Service (the “IRS”)**

We are under IRS audit for tax years 2010/2012 and also 2013/2014. During these tax periods, we have claimed certain manufacturing deductions that the IRS had proposed to disallow in connection with the 2010/2012 audit cycle. We believe the IRS will propose to disallow the deductions for the 2013/2014 cycle as well. We believe that we have sufficient documentation to claim the deductions in all periods. However, there is no guarantee that the IRS will agree with our submissions in this respect, which could result in us being required to repay part or all of the tax benefits relating to these deductions, along with related interest. Such repayments and/or interest may exceed the amount of any provisions made by us with respect to these matters.

We may be subject to other audits or investigations from the IRS from time to time which may expose us to the risk of additional payments needing to be made or of previous tax benefits being disallowed, in each case along with accompanying penalties, if any and which could have a material adverse effect on our reputation, business, financial condition and results of operations.

**We are exposed to risks related to currency exchange rates**

We are incorporated in England and Wales but present our financial statements in U.S. dollars. While we conduct the majority of our operations in the United States, we also carry on business in Europe and Australia, among other places. As a result, our agreements with customers not based in the United States often involve payments denominated in currencies other than U.S. dollars, which creates foreign currency exchange risk. Our operating results are therefore subject to currency fluctuations on translating revenues and costs from those foreign currencies to U.S. dollars. Additionally, if in the future we expand our sales and operations into new markets (as we currently plan to do), with different currencies, this could expose us to additional currency translation risks.

To the extent that we do not hedge our exposure to foreign currency exchange rate fluctuations, or to the extent that such hedging is inaccurate or otherwise ineffective, such exposure could have an adverse effect on our business, financial condition and results of operations.

Exchange rate fluctuations between local currencies and the U.S. dollar also create risk in other ways, including but not limited to: (i) increasing the U.S. dollar cost of non-U.S. research and development expenses and the cost of sourced product components outside the United States (in the case of a weakening of the U.S. dollar); (ii) decreasing the value of our revenues denominated in other currencies (in the case of a strengthening of the U.S. dollar); (iii) distorting the value of non-U.S. dollar transactions and cash deposits; and (iv) affecting commercial pricing and profit margins of our products. These effects can have an adverse impact on our results of operations and financial condition and may also make it more difficult for investors to understand the relative strengths or weaknesses of our underlying business on a period-over-period comparative basis.

**If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of the ADSs.**

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of the ADSs.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial

reporting. We will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until our second annual report following listing. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous

reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

**If we lose our foreign private issuer status in the future, we may incur significant additional expenses**

On June 14, 2016, not more than 50% of our ordinary shares were held by shareholders resident in the United States. We qualify as a “foreign private issuer” (within the meaning of Rule 405 of the Securities Act of 1933, as amended (the “Securities Act”) and Rule 3b-4 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

The determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second financial quarter. Accordingly, we will next make a determination with respect to our foreign private issuer status on June 30, 2017. There is a risk that we could lose our foreign private issuer status if, for example, more than 50% of our issued ordinary share capital is held by U.S. residents. If we lose our foreign private issuer status, we would be required to file reports with the U.S. Securities and Exchange Commission (the “SEC”) as a “domestic issuer” and comply with SEC rules applicable to such issuers beginning January 1, 2018. As a result, we would become subject to the extensive periodic and on-going disclosure and reporting requirements under the U.S. securities laws that apply to domestic issuers, including preparing consolidated financial statements in accordance with U.S. generally accepted accounting principles (in addition to those prepared in accordance with IFRS as required by the listing rules made by the UK Listing Authority under the UK Financial Services and Markets Act 2000 (as set out in the UK Financial Conduct Authority’s Handbook of Rules and Guidance), as amended (the “Listing Rules”)), and preparing quarterly financial statements. We would also be subject to the proxy statement requirements under Section 14 of the Exchange Act, and our officers, directors and principal shareholders would be subject to the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act.

If we are required to report as a domestic issuer, we may incur additional expenses which could have an adverse effect on our results of operations.

**The result of the referendum in the United Kingdom on whether to remain in the European Union could have an impact on our business, financial condition and results of operations.**

The United Kingdom has voted in an advisory referendum to leave the European Union (commonly referred to as “Brexit”). The follow up to the referendum is not yet clear, but it may significantly affect the fiscal, monetary and regulatory landscape in the United Kingdom, and could have a material impact on its economy and the future growth of its various industries, including the pharmaceutical and biotechnology industries. Depending on the terms negotiated between EU member states and the United Kingdom following Brexit, the United Kingdom could lose access to the single European Union market and to the global trade deals negotiated by the European Union on behalf of its members. Such a decline in trade could affect the attractiveness of the United Kingdom as an investment center and, as a result, could have a detrimental impact on corporate growth. This may impact our ability to access funding in the future. Although it is not possible at this point in time to predict fully the effects of an exit of the United Kingdom from the European Union, it could have a material adverse effect on our business, financial condition and results of operations. In addition, it may impact our ability to comply with the extensive government regulation to which we are subject, and impact the regulatory approval processes for our product candidates.

**RISKS RELATING TO THE INDUSTRY**

**We operate in a highly competitive industry, which includes companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than us**

The manufacture and sale of pharmaceuticals is highly competitive. Many of our competitors are large, prominent pharmaceutical, biotechnology, chemical and healthcare companies that have substantially greater financial, operational and human resources than we do. Companies with more extensive resources and larger research and development expenditures have a greater ability to fund clinical trials and other development work necessary for regulatory applications and there is a risk that our competitors may launch competing products before we are able to complete all of the regulatory milestones required to launch our own product. Competitors may also have a greater ability to offer higher rebates, discounts, chargebacks or other incentives to gain commercial advantage, and may be more successful than us in acquiring or licensing new products for development and commercialization. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. If any product that competes with one of our products or product candidates is approved, our sales of that product could decrease, the effect of which would be heightened by our product and geographic concentration, which could have an adverse impact on our business, prospects, results of operations and financial condition.

In addition, many pharmaceutical companies are able to deploy more personnel to market and sell their products than us. We currently have a relatively small number of sales representatives compared with the

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number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization internationally and we may need to commit significant additional funds, management and other resources to the growth of our sales organization. We may not be able to achieve any such necessary growth in a timely or cost-effective manner or realize a positive return on our investment and we may not have the financial resources to achieve the necessary growth in a timely manner or at all. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel and turnover in our sales force and marketing personnel could negatively affect sales of our products. If our sales force and sales organization are not appropriately sized to promote any current or potential future products adequately, the commercial potential of our current products and any future products may be diminished, which could materially adversely affect our business, prospects, results of operations and financial condition.

The pharmaceutical and biotechnology industries are also characterized by continuous product development and technological change. Our products could, therefore, be rendered obsolete or uneconomic through the development of new products or by technological advances in manufacturing or production by our competitors. We must therefore compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain research and development personnel. Significant turnover in our research and development personnel compared to our competitors could negatively affect our ability to formulate and commercialize new products, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

Among other things, competition could continue to require us to increase further the level of rebates and other offsets to gross sales, particularly in our U.S. operations, and could impact potential volume growth of any particular product, which could reduce our net revenues and therefore our results of operations in future periods. Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition. We are dependent on a relatively small number of significant customers for a substantial proportion of our net revenues, and the loss of a significant customer, a significant reduction in purchase volume by, or an adverse change in the creditworthiness of, any such customer could have a material adverse effect on our business, prospects, results of operations and financial condition.

### **The pharmaceutical industry is subject to significant on-going regulatory obligations and oversight, which may result in significant additional expense and potential liability**

The pharmaceutical industry is subject to significant on-going regulatory obligations which are becoming increasingly stringent, such as safety reporting requirements, additional post-marketing obligations and regulatory oversight of the promotion and marketing of its products. In addition, the manufacture, quality control, labelling, packaging, safety surveillance, adverse event reporting, storage, advertising, promotion and record-keeping for its products are subject to extensive and on-going regulatory requirements.

If we become aware of previously unknown problems or potential safety risks associated with any of our products, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us. If we, our products and product candidates, or the manufacturing facilities for its products and product candidates, fail to comply with applicable regulatory requirements, regulatory agencies have wide-ranging powers of enforcement, including the power to impose monetary penalties. In such instances, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and it could become the target of lawsuits, each of which could have a material adverse effect on our business, prospects, results of operations and financial condition.

We are also subject to various U.S. federal and state healthcare laws and regulations, including anti-kickback, false claims, anti-bribery, privacy and other laws intended to reduce fraud and abuse in federal and state healthcare programs. Moreover, there are some laws and regulations that apply even in the absence of a government payor, and there are laws and regulations that require manufacturers to implement compliance programs or marketing codes of conduct that require tracking and reporting of expenses relating to the marketing and promotion of products, and certain state laws that prohibit certain marketing-related activities. Violations of various federal and state laws may be punishable by significant criminal, civil and/or administrative sanctions and penalties, including fines, damages and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability, under certain circumstances, to bring actions on behalf of the government under the federal civil False Claims Act as well as under the false claims laws of many states.

In addition, we are subject to foreign equivalents of the healthcare laws described above, among others, including in the EU laws prohibiting giving healthcare professionals any gift or benefit in kind as an inducement to prescribe our products, and national transparency laws requiring the public disclosure of payments made to healthcare professionals and institutions.

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As a result of the breadth of these laws and regulations and the lack of definitive legal guidance in certain areas, it is possible that some of our business activities could be subject to challenge. Such challenges, irrespective of the underlying merit or the ultimate outcome of the matter, could have a material adverse effect on our business, prospects, reputation, results of operations and financial condition.

**Changes in healthcare law in the United States and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict**

The U.S. Patient Protection and Affordable Care Act, as amended by the U.S. Health Care and Education Reconciliation Act of 2010 (the “Affordable Care Act”), enacted in 2010, contains a number of provisions that are expected to continue to impact our business and operations; in some cases the longer term effects of some of its provisions on us may still be unknown. Changes that may affect our business include those governing enrollment in federal healthcare programs, the imposition of an annual fee on branded prescription pharmaceutical manufacturers and increased rebates payable to state Medicaid programs, rules regarding prescription drug benefits under the health insurance exchanges, changes in the Medicare Part D coverage gap (whereby we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this coverage gap), expansion of the drug pricing program under Section 340B of the Public Health Services Act of 1944, as amended, (the “340B Program”), and new provisions regarding fraud and abuse and enforcement. There are a number of other provisions in the legislation that have still not been addressed by the implementing agency and their potential effect is unknown, including an alternative unit rebate calculation for new formulations. These changes will impact existing government healthcare programs and will result in the development of new programs.

The U.S. Supreme Court has struck down a provision of the Affordable Care Act that penalized states that chose not to expand their Medicaid programs. As a result, some states have elected not to expand their Medicaid programs. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where patients receive insurance coverage under an expanded Medicaid program authorized by the Affordable Care Act, pharmaceutical companies are required to pay Medicaid rebates on drugs used for these patients, which could impact revenues.

Moreover, legislative changes to the Affordable Care Act remain possible, particularly as a result of the election of a new U.S. administration. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales and/or product prices or successfully commercialize our product candidates, which could adversely affect our business, prospects, results of operations and financial condition.

**Failure to comply with payment and reporting obligations under the Medicaid Drug Rebate program or other governmental pricing programs in the United States could result in additional reimbursement requirements, penalties, sanctions and fines**

In the United States, we participate in the Medicaid Drug Rebate and Medicare Part D programs and, by virtue of such participation, are also required by federal law to participate in the 340B Program and Federal Supply Schedule pricing program. These programs require us to pay certain rebates based on pricing data, such as (among others) average manufacturer price and best price, reported by us to the various federal agencies administering the programs.

Pricing and rebate calculations vary among products and programs. The calculations are complex and the calculation methodology is often subject to interpretation by us, governmental or regulatory agencies and the courts. If we become aware that our reporting for a prior period was incorrect, or has changed as a result of recalculation of the pricing data, we are obliged to resubmit the corrected data. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the various programs. Any corrections to our rebate calculations could result in either additional or reduced rebate liability for past periods, depending on the nature of the correction. Price recalculations may also affect the ceiling price at which we are required to offer our products to certain covered healthcare entities, such as safety-net providers, under the 340B Program as well as the prices under which our products are made available to federal government purchasers such as the U.S. Department of Veterans Affairs and the Department of Defense under the Veterans Health Care Act of 1992, as amended (“VHCA”).

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B Program and VHCA refunds, if we are found to have knowingly submitted false average manufacturer price or best price information to the government, we may be liable for civil monetary penalties. Any failure to submit data on a timely basis could result in a civil monetary penalty for each day the information is late beyond the due date. In the case of the Medicaid Drug Rebate program, such failure could also be grounds for Centers for Medicare and Medicaid Services (“CMS”) to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid for our covered outpatient drugs.

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CMS and the Office of the Inspector General have previously indicated that they intend more aggressively to pursue companies who fail to report pricing data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. There can be no assurance that our submissions will not be found by CMS or any other government agency to be incomplete or incorrect.

Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

### **We may be subject to adverse public opinion**

The pharmaceutical industry is frequently subject to adverse publicity on many topics, including product recalls and research and discovery methods, as well as to political controversy over the impact of novel techniques and therapies on humans, animals and the environment. We produce synthetic narcotics which can cause death if used improperly and our products are inherently prone to the health and safety risks arising from their misuse and diversion. Negative publicity about us or our products, or any other part of the industry, may adversely affect our public image, which could impact our operations, impair our ability to gain market acceptance for our products or lead to government intervention, which in turn could have an adverse impact on our business, prospects, results of operations and financial condition.

### **Failure to comply with anti-corruption laws and regulations could result in us becoming subject to fines or penalties**

In the United Kingdom, we are subject to anti-money laundering regulations and other anti-corruption laws, including the Bribery Act 2010. In the United States, we are also subject to anti-money laundering laws and regulations, including the Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”). Any variation or addition to these regulations, either in the United Kingdom or the United States, could impose significant compliance costs on us.

We have mechanisms in place to ensure that we comply with applicable anti-corruption and anti-money laundering regulation. Our compliance procedures are overseen by the Nomination & Governance Committee which monitors our policies, procedures and controls for preventing bribery and money laundering. We have also established a global compliance program applicable to all employees, consultants, sub-contractors and agents. In addition, our business partners must, annually, certify compliance with our Code of Business Conduct.

There can also be no assurance that our required policies and procedures will be followed at all times or will effectively detect and/or prevent violations of applicable compliance regimes by our employees, consultants, sub-contractors, agents and partners. As a result, in the event of non-compliance, we could be subject to fines and/or penalties, damage to our reputation and resulting loss of revenue and profits, which could have a material adverse impact on our business, financial conditions and operations.

Additionally, we are also subject to rules and regulations imposed by, amongst others, HM Treasury and the U.S. Department of the Treasury’s Office of Foreign Assets Control and economic sanctions programs, including those administered by the United Nations and the European Union, which could restrict our business dealings, particularly regarding watch lists published by such bodies restricting the transfer of funds to certain specifically designated countries, which will continue to restrict our dealings. There can be no guarantee that our controls are, or will continue to be, effective and any sanctions imposed by any regulatory body on us for executing a transfer to a country on a watch list could have a material adverse effect on our results of operations, financial condition and future prospects.

## **RISKS RELATING TO THE DEMERGER**

**Following the Demerger, we have been and will continue to be reliant on the RB Group for the provision of certain services, continue to have certain obligations in favor of RB and remain subject to a risk of on-going liabilities resulting from the Demerger**

Following the Demerger, we have continued to be reliant on the RB Group for the provision of certain services, have certain obligations in favor of the RB Group and are subject to a risk of on-going liabilities resulting from the Demerger, including:

- We continue to rely on the RB Group for the provision of certain services including various head office, IT, manufacturing and distribution and detailing services. The duration of the provision of these services varies depending on a number of factors relating to us. If the RB Group fails to provide the expected

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services in whole or in part, or at the required service level or in a timely manner and it becomes necessary to find a replacement provider of any or all of such services at short notice, we could experience difficulty, disruption and increased operating costs which may be exacerbated by the restrictions of operating in a highly regulated industry, which in turn could have an adverse impact on our business, prospects, results of operations and financial condition.

We incurred potentially significant indemnity obligations to RB in connection with the Demerger, as described more fully below.

- The Demerger may give rise to unanticipated tax consequences in the future if the tax authorities in each jurisdiction in which we have a taxable presence do not interpret or apply the relevant tax law and practice in the manner in which we anticipate, which may adversely affect our results of operations and financial condition.
- The Demerger could result in significant tax liability to the RB Group if the Demerger were determined not to qualify as a tax-free transaction for U.S. federal income tax purposes, which could happen if, *inter alia*, we or our shareholders were to engage in certain transactions after the Demerger. We could be required to indemnify RB for any resulting taxes and related expenses which could be material.
- At the time of the Demerger, we agreed to certain restrictions to preserve the treatment of the Demerger as tax-free to RB and its shareholders, which reduces the strategic and operating flexibility of the Indivior Group. Specifically, under the U.S. Tax Matters Agreement, we are generally prohibited, except in specified circumstances, for specified periods of up to 24 months following the Demerger, from:
  - issuing, redeeming or being involved in other significant acquisitions of equity securities of the Indivior Group;
  - transferring significant amounts of the assets of the Indivior Group;
  - ceasing to engage in the active conduct of a trade or business; or
  - engaging in certain other actions or transactions that could jeopardize the tax-free status of the Demerger.

**In connection with the separation from RB, we and RB incurred potentially significant indemnity obligations. If we are required to act on these indemnities to RB, we may need to divert cash to meet those obligations, which could have a material adverse effect on our business, results of operations and financial condition. In the case of RB’s indemnity, there can be no assurance that the indemnity will be sufficient to insure us against the full amount of such liabilities or that RB will be able to satisfy its indemnification obligations in the future**

Pursuant to the Demerger Agreement, the Demerger Tax Deed and the U.S. Tax Matters Agreement, we indemnified RB in respect of any claims and expenses of or incurred by any company within the Indivior Group or the RB Group arising out of or associated with our business prior to the Demerger (whether or not in the ordinary course of business) and in respect of certain tax liabilities that may arise as part of the Demerger or in relation to our business including for taxable years prior to the Demerger. The RB Group may also have a claim against us in connection with the current litigation and regulatory proceedings in which we are involved or

on-going tax audits. Some of these indemnities are unlimited in terms of amount and duration and the amounts payable by us pursuant to such indemnity obligations could be significant and may not be covered by provisions made by us and could have a material adverse effect on our business, financial condition and/or operating results.

For example, under the U.S. Tax Matters Agreement that we entered into with RB in connection with the Demerger, we agreed generally to indemnify RB for taxes and related losses it suffers as a result of the Demerger or the internal restructuring failing to qualify as a tax-free transaction (including such taxes of any third party for which any member of the RB Group is or becomes liable), if the taxes and related losses are attributable to:

- direct or indirect acquisitions of shares or assets of the Indivior Group (regardless of whether we consent to such acquisitions);
- negotiations, understandings, agreements or arrangements in respect of such acquisitions; or
- our failure to comply with certain representations and undertakings, including the restrictions described in the preceding risk factor.

The indemnity provided by us under the U.S. Tax Matters Agreement covers corporate level taxes and related losses

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imposed on the RB Group in the event of a 50% or greater change in the share ownership of Indivior among other events that are prohibited during the specified periods of up to 24 months following the Demerger, as described in the preceding risk factor, as well as taxes and related losses imposed on RB if, due to our representations or undertakings being incorrect or violated, the Demerger or the internal restructuring is determined to be taxable for other reasons. In addition, we agreed to indemnify RB for certain potential U.S. tax liabilities relating to taxable years prior to the Demerger.

Indemnities that we may be required to provide to RB may be significant and could have a material adverse effect on our business, results of operations and financial condition, particularly indemnities relating to certain actions that could impact the tax-free nature of the internal restructuring and the Demerger. Further, there can be no assurance that the indemnity from RB to Indivior under the U.S. Tax Matters Agreement will be sufficient to protect us against the full amount of such liabilities, or that RB will be able to fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from RB any amounts for which we are held liable, we may be temporarily required to bear these losses. Each of these risks could have a material adverse effect on our business, results of operations and financial condition.

**ITEM 4: INFORMATION ON THE COMPANY**

**A. History and Development of the Company**

We were incorporated and registered in England and Wales as a public company limited by share capital with registered number 9237894 on September 26, 2014 under the name Indivior PLC. We are the holding company of the Indivior Group. The principal legislation under which we operate, and under which our ordinary share capital has been created, is the UK Companies Act 2006 as amended (the “Companies Act”) and the regulations made thereunder. We were demerged from RB effective on December 23, 2014. Our ordinary shares are listed on the premium listing segment of the Official List and traded on the Main Market of the London Stock Exchange. Our registered office is 103-105 Bath Road, Slough, Berkshire SL1 3UH, telephone number: +44 (0)1753 217800. Our website address is [www.indivior.com](http://www.indivior.com). Neither the contents of our website nor the content of any website accessible from hyperlinks on our website forms part of or is incorporated into this registration statement.

The treatment of opioid dependence as a therapeutic area emerged within the historical context of efforts to develop a non-addictive analgesic in the early 1920s. The U.S. government’s efforts to tackle the “opium problem” through supply regulation and control, and to address public health concerns through scientific innovation, influenced a gradual shift in research interest towards developing a treatment for opioid dependence.

In 1966 our former owner led the breakthrough discovery of buprenorphine. It was assumed that buprenorphine would have a therapeutic application as an analgesic of low abuse potential. Injectable buprenorphine was approved for severe pain relief in the United Kingdom in 1978, with the sublingual tablet following in 1982. By 1985, injectable buprenorphine had been marketed for analgesic applications in 29 countries and the sublingual tablet in 16 countries.

Our former owner developed, in partnership with the U.S. National Institute on Drug Abuse, a U.S. government agency, buprenorphine for the treatment of opioid dependence. SUBUTEX® Tablet (buprenorphine) sublingual tablet was our first product for the treatment of opioid dependence. SUBUTEX® Tablet was launched on the French market in February 1996 by Schering-Plough, which licensed the global marketing rights to the buprenorphine products from the Indivior Group. Shortly thereafter, SUBUTEX® Tablet was approved in further EU countries. SUBOXONE® Tablet (buprenorphine/naloxone) sublingual tablet was approved across the EU by the EMA in September 2006. In the EU, SUBOXONE® Tablet is protected by regulatory exclusivity until September 2016.

The enactment of DATA 2000 was a significant development in the history of addiction treatment in the United States. Under its provisions, office-based physicians who had completed appropriate training were now able to obtain a federal waiver to treat up to 30 opioid-dependent patients with opioid medications classified by the DEA as controlled substances within Schedules III, IV, and V of the CSA that were specifically approved by the FDA for that indication, and to prescribe and/or dispense these medications in office-based settings. In 2007, the patient cap was extended from 30 to 100 patients for physicians with at least one year's clinical experience with buprenorphine, increasing access for patients seeking treatment in the privacy of a physician's office.

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We launched SUBUTEX® Tablet and SUBOXONE® Tablet in the United States in 2003, following FDA approval in October 2002. In August 2010, the FDA approved SUBOXONE® Film (buprenorphine/naloxone) sublingual film, which succeeded in capturing 69% of the U.S. market for buprenorphine-based opioid dependence treatment by May 2013, based on volume of prescribed milligrams.

In the United States, between October 2009 and July 2011, three manufacturers launched generic versions of SUBUTEX® Tablet, leading to market share erosion of SUBUTEX® Tablet. This, alongside its potential for abuse in comparison with buprenorphine-naloxone formulations, prompted the Indivior Group to discontinue distribution of SUBUTEX® Tablet in the United States in September 2011.

In addition, two generic buprenorphine and naloxone tablets (generic equivalents of SUBOXONE® tablet) entered the market in March 2013, a branded buprenorphine and naloxone tablet entered the market in September 2013, a third and fourth generic buprenorphine and naloxone tablet entered the market in August 2014 and January 2015, respectively and a fifth generic buprenorphine/naloxone tablet came into the market at the end of 2015 marketed by Akorn Inc. (formerly Hi-Tech). Despite the launch of these generic formulations and branded competition, SUBOXONE® Film has been able to maintain a share of approximately 60% of the buprenorphine-based opioid dependence treatment market (by mg volume) over the last three years.

We announced that we were discontinuing distribution of SUBOXONE® Tablet in the U.S. market in September 2012 owing to pediatric safety concerns. In order to ensure continuity in patient treatment, and to provide adequate time for consultation with regulatory bodies and treatment stakeholders, withdrawal did not occur until March 2013.

In April 2013, SUBOXONE® Film received FDA approval for an expanded indication for use in the induction phase of treatment in certain patients. SUBOXONE® Film is one of only two buprenorphine and naloxone-based film products approved for use in this phase of treatment, although SUBOXONE® Film has a market share 10 times greater than that of the alternative. In addition, on September 22, 2015 the FDA approved the buccal route of administration for SUBOXONE® Sublingual Film. Patients may now choose either under-the-tongue (sublingual) or against the cheek (buccal) administration.

In the EU, generic versions of SUBUTEX® Tablet have been available for more than six years; but our branded SUBUTEX® Tablet currently maintains a market share of approximately 60% (by mg volume) of the mono-buprenorphine market, giving the Indivior Group a total market share (mono-buprenorphine and buprenorphine/naloxone) of approximately 69%.

Our capital expenditures for 2015, 2014 and 2013 amounted to \$27 million, nil and \$3 million, respectively. These expenditures were primarily for the development of our ERP system, new equipment in research and development laboratories and building refits. Our current capital expenditures are primarily for continued development of our ERP system and design and implementation of our research and development facility in Hull and we expect to finance these expenditures primarily from cash on hand. Purchase of intangible assets for 2015, 2014 and 2013 amounted to \$4 million, \$26 million and nil, respectively. In 2014, the intangible assets purchase of \$26 million related to Nasal Naloxone rights and the in-licensing of arbaclofen placarbil for the treatment of alcohol use disorders. In 2015, \$4 million related to the outright purchase of the Nasal Naloxone technology during the year.

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## B. Business Overview

### Background

We are a global specialty pharmaceutical business and are currently the global leader in the treatment of opioid dependence, with 20 years' experience in that field. Our business was historically developed and managed as a separate division of the RB Group, before being demerged in December 2014, following which we have operated as a standalone business. Our core marketed products are described below:

Product	Active ingredients	Delivery method	Main markets
<b>SUBOXONE® Film</b>	Buprenorphine and Naloxone	Sublingual film that adheres under the tongue for direct absorption into the bloodstream	United States, Australia and Malaysia
<b>SUBUTEX® Tablet</b>	Buprenorphine	Sublingual tablet that is placed under the tongue to dissolve	Primarily Europe, including France, United Kingdom, Germany and Italy
<b>SUBOXONE® Tablet</b>	Buprenorphine and Naloxone	Sublingual tablet that is placed under the tongue to dissolve	40 countries worldwide

Our core products, which are currently sold in 42 countries, comprise SUBOXONE® Film (buprenorphine and naloxone) sublingual film, SUBOXONE® Tablet (buprenorphine and naloxone) sublingual tablet, and SUBUTEX® Tablet (buprenorphine) sublingual tablet, all of which are treatments for opioid dependence. The opioid dependence treatment market in the United States is our key market and sales of SUBOXONE® Film in the United States represented 80% of our net revenues in 2015. SUBOXONE® Film had a market share of approximately 59% in the United States market for buprenorphine-based opioid dependence treatment (based on volumes of prescribed milligrams) in 2015.

Our key pipeline asset within our opioid addiction treatment franchise is Buprenorphine Monthly Depot (RBP-6000), which we are actively developing over the medium-term with a view to launching in the United States in 2018, subject to having received FDA approval. We are committed to delivering innovative, high quality treatments designed to address the chronic relapsing conditions and co-morbidities of addiction and, to the extent that cash flows permit, plans in the longer term to expand the range of products beyond our core opioid dependence treatment business. In addition to extension candidates for opioid dependence treatments, we have a pipeline of new drug candidates for the treatment of alcohol dependence, cocaine intoxication, schizophrenia and opioid overdose.

We also sell small amounts of two 'legacy products': TEMGESIC® sublingual tablets and injections outside the United States for the treatment of moderate to severe pain, and BUPRENEX® injection in the United States for the relief of moderate to severe pain. There is no current or planned marketing activity to support TEMGESIC® or BUPRENEX®, and these products comprised 2.3% of our net revenues in 2015.

In addition, we supply buprenorphine to Otsuka Pharmaceutical Co. Ltd. for use in the manufacture of buprenorphine injection and suppository products, which Otsuka promotes in Japan under the brand name LEPETAN®.

Our core geographic market (based on the country where the sale originates) is the United States, which accounted for 80% of net revenues in the year ended December 31, 2015 (2014: 77%; 2013: 78%) and 82% in Q1 2016.

### Industry overview

#### *Opioid dependence*

Addiction is a growing public health problem globally which still carries the "disease stigma" in many countries, being perceived as a moral failing and sign of personal weakness rather than a chronic and relapsing disease affecting the brain, which can be manageable and responsive to treatment. As a consequence, we believe coherent action to deal with sufferers and addiction is generally lacking.

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The number of opioid-dependent individuals in the United States has grown over the last few years, reaching an estimated 2.5 million people in 2014.

The enactment of DATA 2000 was a significant development in the history of addiction treatment in the United States. Previously, treatment options for opioid dependence were limited: abstinence-based programs had a high rate of relapse and methadone clinics (the only medication-assisted treatment option) were unpopular with opioid-dependent individuals owing to the significant associated societal stigma. As a result, many opioid-dependent individuals remained untreated.

Under DATA 2000, office-based physicians who had completed appropriate training were able to obtain a federal waiver to treat up to 30 opioid-dependent patients with opioid medications classified by the DEA as controlled substances within Schedules III, IV, and V of the CSA that were specifically approved by the FDA for that indication, and to prescribe and/or dispense these medications in their office-based settings. By permitting treatment for opioid dependence in the privacy of physicians' offices, DATA 2000 was significant in creating access to treatment and medicalizing the condition in the same way as other chronic diseases.

In 2007, the patient cap under DATA 2000 was increased from 30 to 100 patients for physicians with at least one year's clinical experience with buprenorphine, further increasing access for patients seeking treatment in the privacy of a physician's office. Even so, fewer than an estimated one in five opioid-dependent individuals currently receive buprenorphine-based treatment for opioid dependence for reasons including a lack of financial coverage, fear of being stigmatized owing to societal attitudes towards the disease, low awareness of treatment options and limited access to treatment in several areas of the United States.

The European market is smaller than the U.S. market with an estimated 1.3 million opioid-dependent individuals, the majority of whom are heroin users. The European market is relatively mature with numbers of patients in treatment being largely stable over the last five years. There are currently approximately 700,000 patients in treatment, but there is also an emerging patient population of opioid analgesic-dependent patients who are currently under-diagnosed. Initial estimates, which we believe are conservative, suggest that in 2013 there were potentially over 300,000 individuals dependent on prescription opioid analgesics in the United Kingdom, France, Germany, Spain, Italy and the Nordic countries.

Treatment methods in the EU differ from the United States. While U.S. patients can obtain a 30-day prescription and self-administer treatment prescribed by a treating physician, supervised dosing in the EU means a daily visit to the clinic for many patients. Methadone and generics are also generally more broadly available as social funding puts pressure on prices, and treatment is more highly regulated with limited direct-to-patient promotion. However, the harm reduction mindset is now changing towards recovery and the EU has begun to recognize the need to implement treatment systems that allow patients to return to a more normal lifestyle.

In the rest of the world it is estimated that there are approximately 27 million people aged 15 to 64 who suffer from drug use disorders or drug dependence. Treatment services are generally very underdeveloped (with the exception of Australia and New Zealand), the key challenge being to convince governments to treat addiction as a chronic medical disease rather than a social disorder.

According to the Australian National Council on Drugs, as at 2015 approximately 48,500 patients are treated annually for opioid dependence in Australia. There is increasing awareness among healthcare providers in Australia of the misuse of opioid analgesics and the need for treatment. Recent policy changes to address this concern in Australia include re-classifying products containing codeine so that they must be dispensed by a pharmacist rather than over the counter.

We believe that there is an opportunity for us to extend the SUBOXONE® franchise to China, where it is believed that there are a large number of opioid-dependent individuals who are not receiving treatment. As at 2014, there were an estimated 7.3 million total opioid dependent people in China, including 1.4 million registered patients.

## ***Schizophrenia***

Schizophrenia is a chronic disorder characterized by a life-long pattern of acute psychotic episodes superimposed upon chronically poor psychosocial adjustment. The symptoms can be grouped into four domains: positive symptoms (for example, delusions, hallucinations, disorganized speech and behavior); negative symptoms (for example, social withdrawal, avolition, blunted affect); cognitive symptoms (for example, impaired sustained attention, executive function and working memory) and affective symptoms (for example, anxiety and depression, hostility and aggression, increased risk of suicide). These occur in different combinations and to a

different degree in each patient. Given the extensive heterogeneity of symptoms among individual patients, schizophrenia can be considered a clinical syndrome rather than a single disease entity.

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Schizophrenia affects 1.1% of the U.S. adult population. Adherence is a major problem leading to relapse and often hospitalization. Between 20-40% of schizophrenia patients attempt suicide and between 5-13% actually die of suicide. Schizophrenia is responsible for an annual \$37.7 billion in direct healthcare costs in the United States. The primary treatments for schizophrenia are antipsychotic medicines, which are a large and established market with over \$12 billion in U.S. sales in 2014. Long-acting injectable (LAI) antipsychotics make up annual sales of \$2.4 billion in the United States and are growing robustly at a compound annual growth rate of approximately 24% over the past five years. Treatment of schizophrenia drives a majority of LAI prescriptions, and Risperidone is the most commonly used antipsychotic used to treat schizophrenia.

Epidemiological and clinical studies have shown that psychiatric disorders, including borderline and antisocial personality disorders, bipolar, psychotic, depression and anxiety disorders are highly co-morbid with substance use disorders, a condition referred to as “dual” or “co-occurring” disorders. The presence of co-occurring conditions increases severity and complicates recovery from addiction, and a natural outgrowth of increased severity is to recognize a multidisciplinary and holistic approach to the treatment of patients suffering from substance use disorders.

Our key pipeline product designed for the treatment of schizophrenia is RBP-7000 for which we published positive clinical data for the Phase III efficacy trial in May 2015. This product is a monthly depot formulation of risperidone, the most widely prescribed compound for the treatment of schizophrenia.

***Other industry areas***

The other industries and areas of addiction in relation to which we have products in development are as follows:

*Alcohol dependence*

Harmful use of alcohol contributed to approximately 3.3 million deaths globally in 2012. An estimated 5% of the global burden of disease is attributable to alcohol consumption. Alcohol is also associated with significant societal costs, including those related to violence, child neglect and abuse, and absenteeism in the workplace. Therapeutic approaches, including pharmacotherapy, play a pivotal role in treating patients with alcohol use disorders but are commonly underutilized.

*Cocaine intoxication*

Cocaine abuse and its complications represent significant public health issues in the United States. Cocaine is the second most commonly used illicit drug in the United States with a rate of 88 per 100,000 population for Disability Adjusted Life Years due to cocaine dependence. Cocaine is also the most common illicit drug involved in emergency room (ER) visits. It is estimated that between 66,000 and 116,000 of cocaine-related ER visits may represent severe cocaine intoxication. Nearly a quarter of all patients with cocaine-related visits are admitted to hospital, including 3% who are admitted to a critical care unit. Cost estimates from U.S. private payors and New Jersey Medicaid suggest emergency room costs of approximately \$800-\$1000 per visit and an additional \$4,200-\$8,600 per admission.

**Key strengths**

We believe that our key strengths include the following:

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**SUBOXONE® is the leading opioid dependence treatment franchise**

WHO indicates that buprenorphine is an essential medication for the treatment of opioid dependence. In the United States, approximately 60% of patients receiving medication-assisted treatment for opioid dependence are treated with buprenorphine. Under DATA 2000, only buprenorphine-based products have been approved for office-based treatment of opioid dependence by certified physicians in the United States. Following the successful introduction of SUBOXONE® Tablet, the Indivior Group developed a film formulation which we believe provides a significant benefit for patients, physicians, payors and regulators. SUBOXONE® Film dissolves faster than SUBOXONE® Tablet and each individual SUBOXONE® Film is packaged in a unit-dose child-resistant pouch. Surveys we conducted showed that over 90% of patients surveyed were satisfied with SUBOXONE® Film, and in a 2013 survey of 269 physicians who treat opioid dependence, 97% were satisfied or very satisfied and 85% rated SUBOXONE® Film as a leading medication for the treatment of opioid dependence. In 2015, 818,811 unique patients received SUBOXONE® Film, an increase from 802,732 patients in 2014.

We have also created a tailored managed care strategy to drive payor acceptance of SUBOXONE® Film, with emphasis on the physician-patient relationship, the high societal cost of opioid dependence, the pharmacoeconomic benefit of treatment and abuse deterrence combined with competitive economic incentives through rebates. We believe the strength of the SUBOXONE® franchise is demonstrated by its favorable formulary position, as well as by SUBOXONE® Film's market share of approximately 60% of the U.S. buprenorphine-based opioid dependence treatment market, despite the entry of both generic and branded tablet competition.

We believe that our intellectual property protection is robust. With respect to SUBOXONE® Film, we have a patent portfolio consisting of formulation patents, process patents and pending patent applications relating to the product. In the United States, we have three listed patents included in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (which lists drug products approved on the basis of safety and effectiveness by the FDA) covering SUBOXONE® Film, with the latest expiring patent providing protection until March 2030.

### **Our key pipeline product, Buprenorphine Monthly Depot (RBP-6000), will operate in attractive high growth markets for the treatment of opioid dependence**

The opioid dependence treatment market in the United States is our key market representing 80% of our net revenues in 2015 (77% in 2014) and 82% in Q1 2016 (80% in Q1 2015) and has experienced consistent growth over the past two years. We believe that the market continues to remain under-penetrated: there are approximately 2.5 million opioid-dependent individuals in the United States, but fewer than one million receive medication-assisted treatment. It is estimated that in 2014 there were 10.3 million individuals misusing prescription opioids in the United States.

We believe there are no signs that the incidence of opioid dependence is slowing. While strict regulations have been implemented aimed at limiting the availability of opioid prescription analgesics to reduce abuse and diversion, those struggling with addiction continue to find alternative opioid options. Progress continues to be made towards medicalizing opioid dependence as a chronic, relapsing condition that should be treated similarly to other chronic diseases, such as diabetes. As a result, there is improved definition of opioid dependence, increased education and certification of physicians and availability of new treatment options, all of which we believe will likely serve to drive market growth. Importantly, an increasing number of payors have begun to recognize the pharmacoeconomic benefit of treatment, considering that for every \$1 spent on treatment, up to \$12 is saved in societal costs (according to a 2004 WHO report), while the societal costs of opioid misuse are estimated to be approximately \$55 billion. For the reasons outlined above, the U.S. opioid dependence market is expected to grow. Considering the high number of opioid-dependent individuals in several other jurisdictions around the world, we further believe that there is also a significant opportunity to grow our business outside the United States.

In addition, considering the high number of opioid-dependent individuals in several other jurisdictions around the world, as described in "Item 4.B. —Industry Overview," we further believe that there is also a significant opportunity to grow our business outside the United States.

### **Innovative product development driven by a strong scientific platform with demonstrable success in the opioid dependence market**

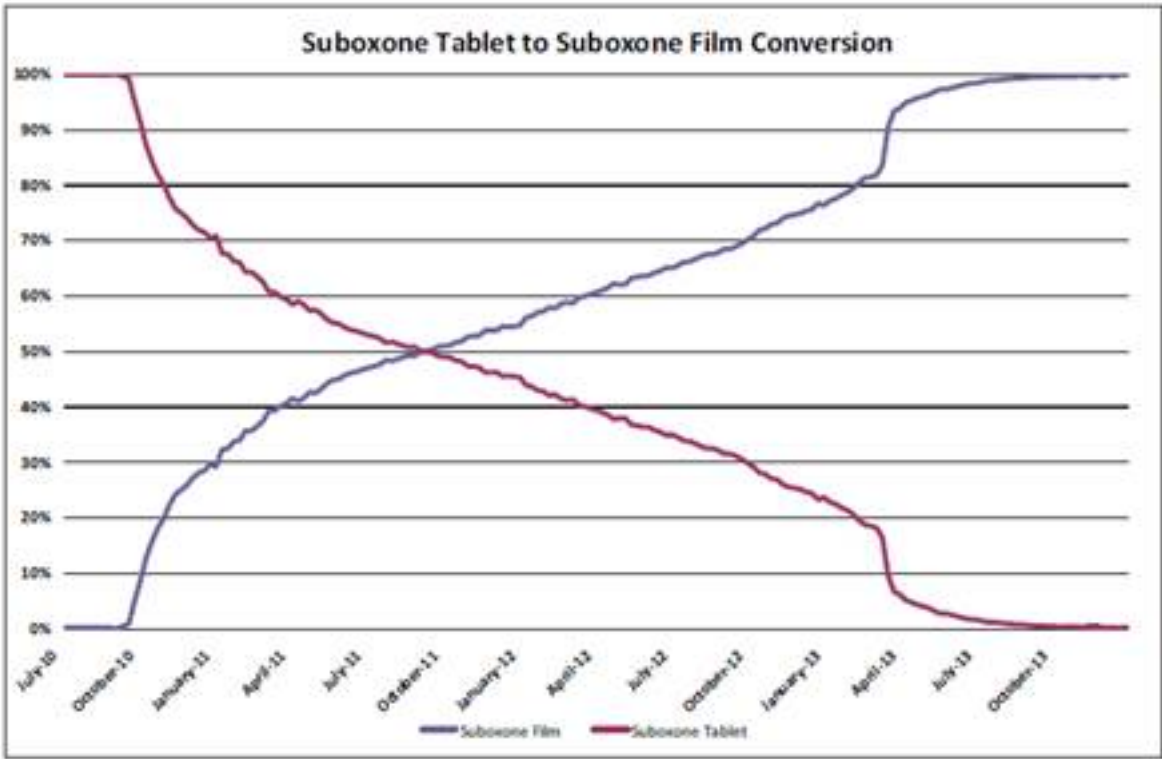
Our business launched the first buprenorphine-based product for the opioid dependence treatment market in 1996 and continues to lead that market after 20 years. We believe that our strong position in the opioid dependence market derives from our strong global research and development team which capitalizes on significant and specialized scientific expertise and knowledge of the brain disease model of behavioral disorders to deliver treatments for the chronic relapsing conditions and co-morbidities of addiction. Our research and development team is led by the Chief Scientific Officer, Dr. Christian Heidbreder, a leading authority on the development of addiction treatments. As at the date of this document, it consisted of 180 personnel.

Our development of the SUBOXONE® Tablet and SUBOXONE® Film formulations are examples of our team’s ability to identify a market need and to successfully bring innovative addiction treatments to market. The research and development team has significant regulatory experience and, as a precursor to the regulatory approval of SUBOXONE® Film in the United States in 2010, successfully completed 21 clinical studies in 18 months.

**Proven ability to successfully extend product franchises through active life-cycle management**

We believe that our leading position in the treatment of opioid dependence and our effective engagement with stakeholders improves our ability to anticipate and identify market and public health trends that can reveal unmet treatment needs. We believe that our global research and development function, clinical development capability and regulatory expertise well positions us to innovate and to develop products designed to address unmet needs, to extend our franchises, strengthen our intellectual property estate and to drive evolution in treatment.

The introduction of SUBOXONE® Film in the United States is an example of our ability to extend a franchise through innovation. Since it was launched, SUBOXONE® Film has attracted a high level of patient and physician satisfaction, along with differentiated value that is recognized by payors. As shown in the chart below, the innovative and differentiated aspects of SUBOXONE® Film resulted in a high level of patient conversion from SUBOXONE® Tablet.



Source: Source Healthcare Analytics Retail Pharmaceutical Audit Suite Weekly Data, 2010-2013

We have successfully reformulated our core buprenorphine product through successive product generations, from mono-buprenorphine tablets, to SUBOXONE® Tablets (being buprenorphine plus naloxone), to SUBOXONE® Film. With each reformulation, we have sought to enhance patients’ experience in taking their opioid treatment medication and to improve their adherence to treatment. Our Buprenorphine Monthly Depot formulation (RBP-6000) represents the next step in the development of the use of buprenorphine in the treatment of opioid dependence, reducing the risk of non-adherence as well as reducing the risk of misuse. We believe that RBP-6000 represents a strong pipeline product for us to focus our development efforts on in the short to medium term.

Within our opioid addiction treatment franchise, and in addition to our lead pipeline product, RBP-6000, we have a pipeline of life-cycle products which are supported by line-extension strategies and development programs designed to optimize the opioid dependence treatment franchise. For example, a higher dose (16 mg) SUBOXONE® Tablet for distribution in the EU was approved by the EMA in December 2015. See “Item 4.B. — Research and Development.”

**Responsible management**

Our management team provides substantial expertise and stability to our business. As at December 2015, 58% of our team of clinical liaisons have worked with physicians for five years or more to help expand patient access to treatment.

Buprenorphine carries recognized risks of accidental overdose, misuse and abuse. In light of these risks, we conduct active risk management programs to ensure patient safety. In the United States, under an FDA-approved REMS, we have been engaged in the dissemination of information for patients, pharmacists and prescribers about the safe use of SUBOXONE® Film designed to (i) mitigate against the recognized risks of accidental overdose, misuse and abuse, and (ii) inform prescribers, pharmacists, and patients of the serious risks associated with SUBOXONE® Film.

In addition, our Medical Science Treatment Advisors (“MSTAs”) provide education on opioid dependence and addiction in response to requests from health professionals in the field. MSTAs also intervene directly with certain physicians who are identified by prescribing information or from information provided by our clinical liaisons as engaging in high-risk prescribing to educate them regarding safe prescribing habits. MSTAs may also engage in one-on-one discussions with certified prescribers and their staff to address general topics regarding addiction treatment. In the EU, we monitor for specific events agreed with the EMA as part of its risk management plan for SUBOXONE® Tablet.

We believe that drug safety is a function that can add value and support rather than being only a function of necessity and we continually look at system improvements. We also seek to provide flexibility in the face of legislative change and business growth in terms of new products and geographies.

**Strong company culture which helps to inspire outstanding performance**

We believe that our culture is a powerful driver of success which fosters entrepreneurship, team spirit and commitment, each executed with a high level of energy within a business mindset of strong financial discipline.

Our purpose is to pioneer life-transforming treatments for patients suffering from addiction and its co-morbidities. To enable this, we have a set of “Guiding Principles” which we believe has successfully guided decision making and set the blueprint for our operations since the launch of the U.S. business in 2003. These Guiding Principles are:

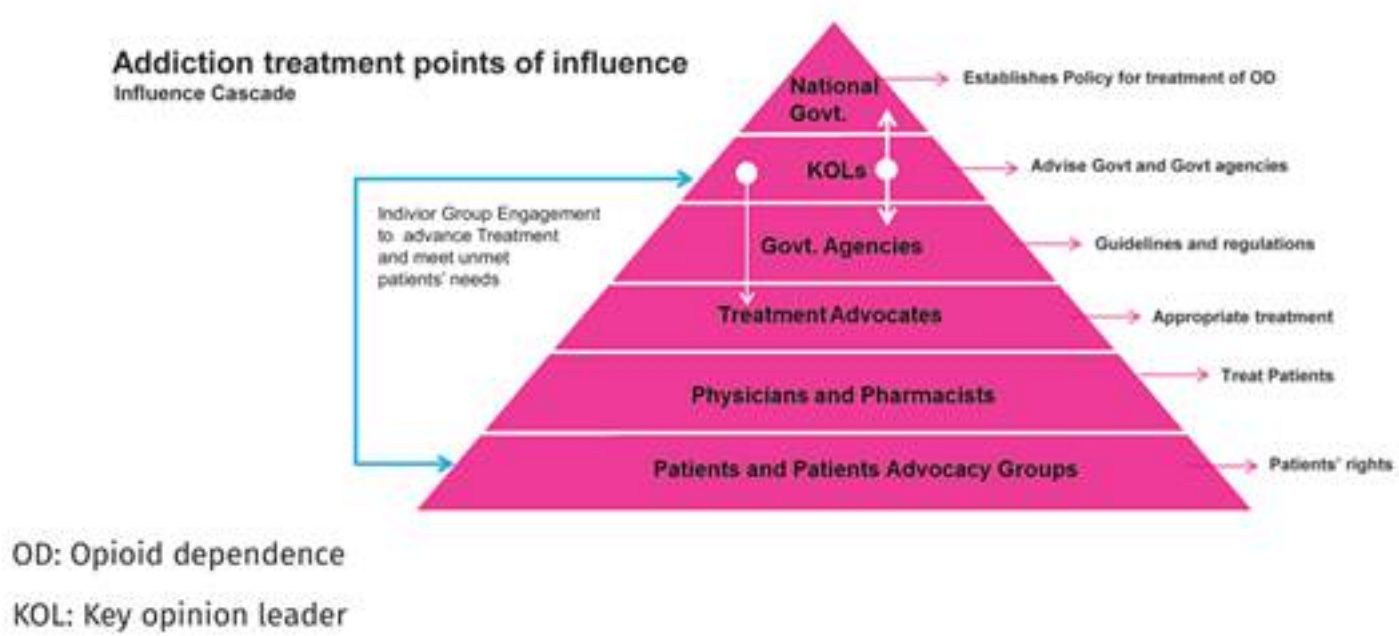
- Focus on patient needs to drive decisions;
- Believe that people’s actions are well-intended;
- Seek the wisdom of the team;
- See it, own it, make it happen;
- Care enough to coach; and
- Demonstrate honesty and integrity at all times.

**Cultivating of strong relationships with key stakeholders**

We have a strong commitment to our patient-focused business. We seek to ensure access to high quality treatment services for patients suffering from the chronic relapsing diseases of addiction by establishing partnerships with relevant stakeholders in the opioid dependence community.

We engage at all levels across the addiction treatment spectrum, interacting with governments, key opinion leaders, physicians, payors, patients and patient advocacy groups in order to expand access to treatment and improve patient outcomes. We believe that our leadership in this market segment is demonstrated by our active participation in policy and legislative dialogue and shifting public

perceptions of underserved patient populations, thereby enhancing access to treatment for patients. The following chart sets out details of the stakeholders who have historically been involved in addiction treatment and our points of influence in the dependence treatment space.



We work closely with physicians and professional medical societies to educate them about DATA 2000 certification and to expand access to treatment. In the United States over 30,000 physicians have been granted a DEA waiver under DATA 2000, permitting them to treat opioid dependence with a Schedule III, IV or V narcotic in their offices with more than 800,000 U.S. patients receiving SUBOXONE® Film in 2015.

In the EU and other countries outside the United States, we have a commercial presence in 23 countries and we sell our products in 43 countries.

**Products of the Indivior Group**

We currently market and promote SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet, each buprenorphine-based treatments for opioid dependence recognized by several health authorities around the world as treatment options to address the growing public health concern relating to the population of opioid-dependent patients. We also sell small amounts of two legacy products: TEMGESIC® sublingual tablets and injections outside the United States for the treatment of moderate to severe pain, as well as BUPRENEX® injection in the United States for the relief of moderate to severe pain; although these products comprised 2.3% of our net revenues in 2015.

Buprenorphine is an opioid with partial agonistic properties at the mu-opioid receptor and antagonistic properties at the kappa-opioid receptor; it dissociates slowly from mu-opioid receptors. Buprenorphine has been shown to be an effective treatment for opioid dependence, including maintenance and detoxification, when used within a framework of medical, social and psychological treatment. Buprenorphine was first marketed as an analgesic for the treatment of moderate to severe pain in 1978 as TEMGESIC® Injection in the United Kingdom and subsequently around the world both as an injection and as a sublingual tablet, although it was marketed in the United States only as an injection.

***SUBUTEX® Tablet (buprenorphine) sublingual tablet***

SUBUTEX® Tablet containing 0.4mg, 2mg, and 8mg buprenorphine was first approved for the treatment of opioid dependence in France in July 1995 and was launched in the French market in February 1996. 2mg and 8mg tablets were subsequently approved in the United States and launched in April 2003, but were discontinued from sale in the United States market in September 2011 due to market share erosion and their potential for abuse in comparison with buprenorphine-naloxone formulations. We currently market SUBUTEX® Tablet in 21 countries.

***SUBOXONE® Tablet (buprenorphine and naloxone) sublingual tablet***

SUBOXONE® Tablet is a fixed-dose combination of buprenorphine and naloxone in the ratio of four parts buprenorphine to one part naloxone. Naloxone is a potent antagonist at opioid receptors and produces opioid withdrawal effects of short duration in opioid-dependent subjects when not administered orally. When administered sublingually, naloxone is poorly absorbed and has no clinically significant effect.

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SUBOXONE® Tablet has been designed to discourage intravenous abuse of the tablet formulation in patients dependent on full opioid agonists (e.g., heroin and morphine). Initially, SUBOXONE® Tablet containing 2mg buprenorphine and 0.5mg naloxone, and 8mg buprenorphine and 2mg naloxone, was developed under NDA 20 733 and approved in the United States by the FDA in October 2002 as an orphan drug for maintenance treatment of opioid dependence. In the United States, SUBOXONE® Tablet lost orphan drug exclusivity in October 2009.

We announced that we were discontinuing distribution of SUBOXONE® Tablet in the U.S. market in September 2012 owing to pediatric safety concerns. In order to ensure continuity in patient treatment, and to provide adequate time for consultation with regulatory bodies and treatment stakeholders, withdrawal did not occur until March 2013.

SUBOXONE® Tablet is approved in 47 countries worldwide and marketed in 40 countries, with marketing approval pending in additional countries. In China, a pivotal Phase 3 efficacy trial and a Multiple Dose study of SUBOXONE® Tablets (buprenorphine and naloxone tablet) were completed in December 2015, paving the way for preparation of an NDA to be submitted to China FDA.

### ***SUBOXONE® Film (buprenorphine and naloxone) sublingual film***

SUBOXONE® Film was initially launched in the United States in 2010 and is currently marketed in the United States, Australia and Malaysia. It is one of only two products currently approved by the FDA for the treatment of opioid dependence pursuant to DATA 2000 in both the induction and maintenance phases of treatment, although SUBOXONE® Film has a market share 10 times greater than that of the alternative. SUBOXONE® Film was developed as an alternative to the sublingual tablet with the intention of producing similar safety and efficacy to SUBOXONE® Tablet, but with additional safety and compliance features. SUBOXONE® Film was developed through an exclusive agreement with MSRX, utilizing its proprietary PHARMFILM® technology, to deliver SUBOXONE® Film in a fast-dissolving sublingual film.

SUBOXONE® Film containing 2mg buprenorphine and 0.5mg naloxone, and 8mg buprenorphine and 2mg naloxone, was first approved for the maintenance treatment of opioid dependence in the United States in August 2010, in Australia in December 2010 and in Malaysia in July 2013. Additional dosage strengths of SUBOXONE® Film containing 4mg buprenorphine and 1mg naloxone, and 12mg buprenorphine and 3mg naloxone, were subsequently approved in the United States in August 2012 and in Australia in May 2014. SUBOXONE® Film was also approved in the United States in April 2014 for use in the induction phase of buprenorphine-based treatment of opioid dependence. In addition, on September 22, 2015 the FDA approved the buccal route of administration for SUBOXONE® Sublingual Film. Patients may now choose either under-the-tongue (sublingual) or against the cheek (buccal) administration.

In addition, the CTA to initiate clinical efficacy and safety trials for SUBOXONE® Film was approved by the Chinese Center for Drug Evaluation in November 2015.

### ***TEMGESIC®***

TEMGESIC® is buprenorphine hydrochloride available in 0.2mg and 0.4mg sublingual tablet form and 1ml injection and indicated for the treatment of moderate to severe pain. We distribute TEMGESIC® in Algeria, Australia, Austria, Belgium, Denmark, Finland, France, Germany, Hong Kong, Ireland, Italy, Luxembourg, Morocco, the Netherlands, New Zealand, Norway, South Africa, Spain, Sweden, Switzerland, Taiwan and the United Kingdom. We have appointed MSD Latin America Services S. de R.L. as its exclusive distributor of TEMGESIC® in Ecuador and Mexico.

### ***BUPRENEX® (buprenorphine)***

BUPRENEX® is the brand name for buprenorphine hydrochloride 1ml injections containing 0.324mg of buprenorphine hydrochloride in a 5% dextrose solution and indicated for the treatment of moderate to severe pain. BUPRENEX® injection is distributed only in the United States.

## **Research and Development**

Chronic addictive behaviors are characterized by compulsive drug use, loss of control over drug-seeking and drug-taking and an intense drive to take the drug at the expense of other behaviors, with little regard for subsequent consequences. From a psychiatric

perspective, drug dependence has aspects of both impulse control disorders and compulsive disorders. In addictive and compulsive disorders, which have prominent motivational drivers, dysfunction in the brain’s cortical regions significantly affects cognitive regulatory processes such that the individual fails to inhibit self-defeating urges or desires appropriately. This failure to resist repetitive, maladaptive behaviors is a key clinical feature of addictive disorders, and aspects of decision-making are compromised either directly (signifying a dysfunctional inhibitory system) or indirectly (signifying a dysfunctional reward system).

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We invest in research and development to create innovative products and services that address the needs of patients with the complex chronic condition of addiction. These efforts include the development of new products and formulations that are designed to minimize diversion and misuse, increase compliance with treatment, support public health, improve patient outcomes and expand access to treatment for areas of addiction where no pharmacotherapy is currently available.

Our research and development activities have historically been focused on four clusters of projects (covering opioid use disorder, alcohol use disorder, rescue medications and psychiatric comorbidities) aimed at expanding the range of treatment options for opioid dependence, opening access to rescue medications, focusing on the psychiatric co-morbidities of addiction and addressing unmet medical needs in the treatment of alcohol use disorders.

*Expanding the range of treatment options for opioid dependence*

*RBP-6000 Buprenorphine Monthly Depot*

RBP-6000 (buprenorphine monthly depot) is a sustained release formulation of buprenorphine using the ATRIGEL® delivery system which, upon subcutaneous injection, forms a solid implant in situ and releases buprenorphine over a 28-day period by diffusion. RBP-6000 is filled into a syringe and terminally sterilized. Clinical studies with other active ingredients have demonstrated that the ATRIGEL® delivery system (a proprietary, polymer-based, sustained release, subcutaneous drug delivery technology) is well tolerated and provides consistent, sustained release of the incorporated drug over the designated dosing interval. The ATRIGEL® delivery system is currently used in seven approved products worldwide and is also used in our RBP-7000 (risperidone monthly depot), which demonstrated clinical efficacy and safety during its pivotal Phase III study.

We believe that RBP-6000 has the potential to transform the treatment of opioid use disorder through the very high level of receptor occupancy it achieves (as shown by its Phase II clinical results and, in particular, by the successful opioid blockade study). The expected benefits of high levels of receptor occupancy/opioid blockade are that:

- Patients would likely experience substantially reduced levels of cravings associated with addiction;
- Patients should receive no gratification from abuse of opioids;
- Levels of compliance with treatment should be significantly improved;
- For physicians, there should be significantly improved clinical and patient outcomes using this technology;
- For physicians and wider society, there should be significantly reduced levels of potential diversion and abuse — once injected, the buprenorphine cannot be extracted and diverted; and
- For payors, the benefit will come in reduced costs from higher compliance, better clinical outcomes and reduced abuse and diversion.

The logic that underpins this technology is its potential to significantly improve the levels of compliance with treatment amongst opioid dependent patients which, in turn, would result in better patient outcomes, physician engagement and would reduce the costs of non-compliance to society as a whole. It has recently been estimated that opioid dependence costs society \$55 billion per annum in the United States. RBP-6000 has been a major part of our product pipeline for several years and, in the event of a successful launch, we believe that it has the potential to provide the basis of a rewarding future for Indivior and our shareholders.

Two Phase II clinical trials with RBP-6000 have been completed and an End-of-Phase II meeting with the FDA took place in

September 2014. The Indivior Group received confirmation from the FDA in November 2014 that RBP-6000 could proceed to Phase III of clinical trials and the Phase III clinical development studies are now well advanced:

- The Phase III efficacy study (RB-US-13-0001) achieved its last patient enrollment into the study in November 2015, with the last patient visit achieved on April 29, 2016; and
- The Phase III safety extension study (RB-US-13-0003) is on track, with screening closed in December 2015 and achieved its last patient into the study in February 2016.

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It is expected that the top line results (namely, the statistics that show whether the primary endpoints were met or not in respect of a clinical study) from the Phase III efficacy study will be available at the end of Q3 2016 and the last patient is expected to complete the Phase III safety extension study in Q1 2017. Subject to the outcomes of these two clinical trials, and given that the FDA granted Fast Track designation to RBP-6000 in May 2016, we currently anticipate filing our NDA for RBP-6000 with the FDA in Q2 2017 and, assuming we are granted a priority six-month review period, it is expected that this would lead to potential approval of RBP-6000 before the end of 2017, with launch in early 2018. Priority review by the FDA is available for drugs that for a serious or life-threatening disease or condition (1) eliminate or significantly reduce a drug reaction that limits treatment; (2) show evidence of increased effectiveness in prevention, treatment, or diagnosis of a disease; (3) demonstrate enhancement of patients’ compliance with taking the drug as required and scheduled that is expected to lead to an improvement in serious outcomes, and/or (4) show evidence of effectiveness and safety for a new subgroup of patients. In the event that the FDA does not award priority review status, the revised launch date for RBP-6000 is expected to take place during H1 2018.

There is currently no approved parenterally-administered, sustained-release buprenorphine formulation for the treatment of opioid dependence. Such a formulation could offer significant advantages over existing buprenorphine pharmacotherapy by improving patient compliance and reducing the potential for diversion, abuse, and unintentional pediatric exposure as well as regulating the frequency of patient/physician contact.

***Focusing on the psychiatric co-morbidities of addiction***

***RBP-7000 (risperidone monthly depot)***

RBP-7000 (risperidone monthly depot) is a novel sustained-release formulation of risperidone using the ATRIGEL® delivery system for the subcutaneous administration of risperidone once every 28 days for the treatment of schizophrenia. RBP-7000 consists of a two-syringe system, whose contents are mixed immediately prior to administration. One syringe contains the ATRIGEL® delivery system, and the other contains the sterile drug substance risperidone.

RBP-7000 is currently in a Phase III long-term safety extension study to assess its safety and tolerability as a treatment for subjects with acute schizophrenia. We completed a Phase III efficacy trial in May 2015 that demonstrated that both the 90mg and 120mg doses tested met the primary endpoint with statistically and clinically significant reductions in the symptoms of acute schizophrenia over an 8-week treatment period. The development of RBP-7000 has been delayed due to external manufacturing issues identified with one out of six stability batches required for NDA submission. We believe these issues are now rectified and additional batches will be manufactured to provide the required data, but this has resulted in a delay to the likely approval date and we currently expect to file an NDA for RBP-7000 in September 2017 and are targeting U.S. approval in mid-2018.

***Long term pipeline products***

***SUBOXONE® Film for the EU***

We have been developing SUBOXONE® Film for the EU. The U.S. formulation of SUBOXONE® Film was developed with a product quality reference target that met FDA shelf-life specifications. However, the shelf-life specifications in the EU are more restrictive with respect to buprenorphine assay, naloxone assay and naloxone-related impurities. We have initiated further development work on SUBOXONE® Film to establish shelf-life specifications that are aligned with the current SUBOXONE® Tablet specifications in the EU. This additional development work is being pursued with the aim of improving the physical and chemical stability profile of SUBOXONE® Film. However, our application for SUBOXONE® Film formulation in the EU has been delayed, as the prototype formulation has not met its specified bio-equivalency to EU SUBOXONE® Tablet formulation.

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### ***Addressing unmet needs in the treatment of Alcohol Use Disorder***

The pharmacological properties of baclofen have led to the investigation of its benefit for the treatment of alcohol dependence. Baclofen was originally approved by the FDA in 1977 for use in spasticity associated with neurologic conditions, such as multiple sclerosis and spinal cord lesions. Numerous case reports, case series, and open-label trials have demonstrated that baclofen prolongs the time to first drink, reduces overall drinking days, and facilitates maintenance of abstinence. The French regulatory agency Agence Nationale de Sécurité du Médicament et des Produits de Santé granted a Temporary Authorization for Use (an “ATU”) to baclofen for the treatment of alcohol dependence on March 14, 2014. Under the ATU baclofen is now the subject of a monitoring protocol to collect efficacy and safety data. However, racemic baclofen has a number of significant pharmacokinetic limitations, including a narrow window of absorption in the upper small intestine and rapid clearance from the blood.

On May 14, 2014, we entered into a license agreement with XenoPort, Inc. pursuant to which we have been granted exclusive worldwide rights (including patent rights relating to compositions, dosage and process for manufacturing) for the development and commercialization of XenoPort’s clinical-stage oral product candidate arbaclofen placarbil for all indications. Arbaclofen placarbil is a novel transported pro-drug of R-baclofen designed to overcome the clinical pharmacokinetic deficiencies of racemic baclofen. Unlike racemic baclofen, arbaclofen placarbil is well absorbed from the large intestine, allowing the drug to be successfully formulated in a sustained release formulation that may allow for less frequent dosing and reduced fluctuations in plasma exposure. This in turn may lead to potentially improved clinical efficacy and tolerability, increased subject convenience and compliance from less frequent dosing (BID versus TID/QID), and an improved safety profile compared to immediate release baclofen.

Arbaclofen placarbil recently began its Phase IIA safety trial in humans. The first patient was successfully screened on September 15, 2015 with all randomized subjects dosed successfully on November 28, 2015. It is expected that top line results (i.e., the statistics that show whether the primary endpoints were met or not in respect of a clinical study) from the Phase IIA will be available in the third quarter of 2016. We believe this compound, if approved, could transform the treatment of alcohol use disorder similar to the way buprenorphine changed opioid dependency. We are targeting U.S. and EU approval in 2020 pending the final outcome (data analysis and interpretation) of Phase IIA study (RB-US-14-0001).

### ***RBP-8000 - Cocaine esterase treating cocaine intoxication***

RBP-8000 (cocaine esterase) is being developed for the treatment of cocaine intoxication and is intended as a single dose, intravenous therapy. RBP-8000 is a cocaine esterase that catalyses the hydrolysis of cocaine to the inactive metabolites ecgonine methyl ester and benzoic acid. This action mimics endogenous, natural butyrylcholinesterase, but with approximately 1,000 times greater activity. Cocaine esterase (RBP-8000) is a biological product derived from characterized cells through the use of a variety of expression systems and differs from most biopharmaceuticals in that its activity is not directed towards a pharmacological target per se, but rather a xenobiotic agent (cocaine) that is not normally present in the circulation.

A Type B meeting with the FDA on RBP-8000 for the treatment of cocaine intoxication was successfully held in May 2015 under Breakthrough Therapy Designation. A second Type B meeting was held on March 16, 2016.

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### **Research and development function**

Our research and development team is led by the Chief Scientific Officer, Dr. Christian Heidbreder, a leading authority on the development of addiction treatments. At the date of this document, it consisted of 180 personnel.

The research and development team comprises the following sub-functions:

- (A) Chemistry, Manufacturing and Controls, including personnel based in Hull, United Kingdom and individuals at the

facility in Fort Collins, Colorado ensures that the chemical and physical properties of active pharmaceutical ingredients of all pipeline drug substances and products are analyzed and monitored at all critical phases of the development pathway;

- (B) Clinical, accountable for creating, maintaining and executing all clinical development plans, in order to deliver differentiated target product profiles. The Clinical Organization also includes the Health Economics and Outcomes Research Unit, which demonstrates the cost-effectiveness and positioning of a new product and seeks to facilitate seamless launches shortly after approval; and
- (C) Regulatory, leads the development and implementation of a consolidated global regulatory strategy to guide all assigned products through all development phases and post-approval lifecycle management.

Our research and development function endeavours to conduct all clinical trials (Phase I through Phase IV) in partnership with Clinical Research Organizations. During Phase II and Phase III of clinical trials, because the formulation of the product must be finalized and the scalability of production proven, we engage contractors with the relevant capabilities. During these Phases, therefore, the number of participants in, and consequently the expenses related to, the project increases significantly. Please refer to “Item 5. Operating and Financial Review and Prospects” for further details of research and development expenses during the financial periods included in this document.

### **Relationship with RB following the Demerger**

Since the Demerger, RB and Indivior have operated as separate companies and neither company has a shareholding in the other. We have carried on an independent business as our main activity, have held strategic control over the commercialization of our products and have the freedom to implement our business strategy.

Pursuant to the terms of the Transitional Services Agreement entered into at the time of the Demerger, RB (on behalf of the RB Group) agreed to provide RBP Global Holdings Limited (on behalf of the Indivior Group) with certain services on commercial terms and on an arms’ length basis. These services included (i) the continued provision by RB to RBP Global Holdings Limited of various back office services and support across finance, HR, regulatory, IS, office space and facilities, (ii) the continuation of manufacturing, distribution and sales and marketing services set out in certain existing intergroup agreements between certain members of the RB Group and certain members of the Indivior Group and (iii) the provision of services, (for example software support) pursuant to existing agreements entered into by a member of the RB Group and a third party from which a member of the Indivior Group derives a benefit. A number of the existing intergroup agreements have terminated or may terminate on September 1, 2016. Please refer to “Item 10.C. — Material Contracts” for further information.

The work on separation from RB is materially finished as of July 1, 2016. The project to implement a new, company-wide ERP system has finished. Eleven markets and manufacturing & supply are on ERP. Thirteen other countries’ Finance and HR operations are outsourced to BDO International. All work to transition to Indivior IT systems and applications has been done and we now operate independently from RB with the exception of certain RB R&D systems which are still shared with RB until the move out of the RB facility in Hull targeted for end of 2017.

Existing distribution, detailing and agency agreements between certain RB Group entities and Indivior Group entities relating to the distribution, sales and marketing by the RB Group of our products in jurisdictions where we do not yet have a commercial presence have continued post-Demerger and will continue until such time as they are terminated in accordance with the terms of the Transitional Services Agreement.

### **Regulatory Overview**

Our activities are subject to a rigorous regulatory framework on a local and international level that conditions and affects our activities. The process of obtaining regulatory approvals and the subsequent compliance with applicable laws, regulations and other requirements require the expenditure of substantial time and financial resources. The following is a summary of the regulatory landscape applicable to our business and the reimbursement schemes applicable to its products in

Overview

Pharmaceutical companies operate in a highly regulated environment. In the United States, we must comply with laws, regulations and other requirements promulgated by numerous federal and state authorities, including the FDA and other agencies and divisions of the Department of Health and Human Services, the DEA and other agencies of the Department of Justice, the Consumer Product Safety Commission, the Environmental Protection Agency, the U.S. Bureau of Customs and Border Protection (the “CBP”) and state agencies such as boards of pharmacy. Applicable legal requirements govern to varying degrees the research, development, manufacturing, commercialization and sale of our prescription pharmaceutical products, including pre-clinical and clinical testing, approval, production, labelling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. Failure to comply with applicable legal requirements can result in product recalls, seizures, injunctions, refusal to approve or withdrawal of approval of product applications, monetary fines or criminal prosecution.

Food and Drug Administration

The FDA’s authority to regulate pharmaceuticals comes primarily from the Federal Food, Drug, and Cosmetic Act (“FFDCA”). In addition to reviewing NDAs for branded drugs and ANDA filings for generic drugs, the FDA has the authority to ensure that pharmaceuticals introduced into interstate commerce are neither “adulterated” nor “misbranded.” Adulterated means that the product or its manufacture does not comply with FDA quality and related standards. A drug is adulterated if, among other things: (i) it is prepared under unsanitary conditions such that it may have been contaminated or may cause injury to patients, (ii) its manufacture does not comply with cGMP, (iii) it does not comply with an official compendium, (iv) its strength, purity or quality differs from that which it purports to possess, or (v) if it is manufactured, processed or held in a facility which refuses FDA inspection. Misbranded means, among other things, that the labelings of, or advertising or promotional materials for, the product contain false or misleading information, fail to conform to the FDA approval for the drug, or fail to include required information.

In order to market and sell a new drug product in the United States, a drug manufacturer must file with the FDA an NDA that shows the safety and effectiveness of the new drug. In order to market and sell a generic version of an already-approved drug product, a drug manufacturer must file an ANDA that shows that the generic version is, with narrow exceptions, the same active ingredient, dosage form, strength and route of administration as a previously approved reference product, and “bioequivalent” to that reference product, meaning that it is absorbed at the same rate and to the same extent as the reference product. The FDA classifies certain generic drugs as “therapeutically equivalent,” meaning that they are expected to have the same clinical effect and safety as the branded drug product. Alternatively, a manufacturer may submit an NDA under FFDCA section 505(b)(2) for a drug product that has some differences from an already-approved drug product, but that relies in whole or in part on the findings of safety and/or effectiveness of a previously approved reference product, or on medical literature. A section 505(b)(2) NDA must demonstrate that the proposed product is safe and effective notwithstanding the differences from the approved drug product.

Research, Development and NDA process

The path leading to FDA approval of an NDA for a new drug begins when the drug product is merely a chemical formulation in the laboratory. In general, the process involves the following steps:

- (i) completion of formulation, laboratory and animal testing in accordance with good laboratory practices, which characterizes the drug product from a pre-clinical perspective and provides preliminary evidence that the drug product is safe to test in human beings;
- (ii) filing with the FDA an Investigational NDA, which once effective will permit the conduct of clinical trials (testing in human beings under adequate and well-controlled conditions);
- (iii) designing and conducting clinical trials to show the safety and efficacy of the drug product in accordance with GCP and other requirements;
- (iv) submitting the NDA for FDA review, which must include data on safety and effectiveness, as well as characterization of the drug product and a description of the manufacturing process, controls and facilities;

- (v) satisfactory completion of FDA pre-approval inspections regarding the conduct of the clinical trials and manufacturing at the designated facility or facilities in accordance with cGMP;
- (vi) if applicable, completion of a FDA Advisory Committee meeting in which the FDA requests views and recommendations from outside experts in evaluating the NDA;
- (vii) final FDA approval of the full prescribing information, labelling and packaging of the drug product; and
- (viii) commitments to meet post-approval requirements, including on-going monitoring and reporting of adverse events related to the drug product, implementation of a REMS, if applicable, and conduct of any required Phase IV studies.

Clinical trials are typically conducted in four sequential phases, although they may overlap. The four phases are as follows:

- (i) Phase I trials are typically small (fewer than 100 study subjects, and often involving healthy volunteers) and are designed to determine the pharmacokinetics and toxicity of the drug product.
- (ii) Phase II trials usually involve 100 to 300 participants and are designed to determine whether the drug product produces any clinically significant effects in patients with the intended disease or condition and to provide further information about safety and dosing. If the results of these trials show promise, then a larger Phase III trial may be conducted.
- (iii) Phase III trials are often multi-institution studies that involve a large number of participants and are designed to show efficacy and safety. Phase III (and some Phase II) trials are designed to be pivotal trials. The goal of a pivotal trial is to establish the safety and efficacy of a drug product with sufficient robustness for purposes of regulatory approval.
- (iv) In some cases, the FDA requires Phase IV trials, which are usually performed after the NDA has been approved. Such post-marketing clinical studies or surveillance programs are intended to obtain more information about the risks of harm, benefits and optimal use of the drug product by evaluating the results of the drug product in a larger number of patients. The FDA may require post-approval studies either at the time of approval or, if it becomes aware of new safety information, after approval.

A drug manufacturer may conduct clinical trials either in the United States or outside the United States, but in all cases must comply with GCP and must ensure that there is: (i) a legally effective informed consent process when enrolling participants; (ii) an independent review by an Institutional Review Board to minimize and manage the risks of harm to participants; and (iii) on-going monitoring and reporting of adverse events related to the drug product.

In addition, under the Pediatric Research Equity Act 2003, as amended, all NDAs must include assessments on a drug in pediatric patients unless the applicant receives a waiver or deferral. A drug sponsor may also seek to conduct a clinical trial of a drug product on pediatric patients based on a written request from the FDA in order to obtain a form of marketing exclusivity as permitted under the Best Pharmaceuticals for Children Act 2002, as amended.

The path leading to FDA approval of a section 505(b)(2) NDA for a drug product that has differences from an already-approved product is somewhat shorter. In a section 505(b)(2) NDA, the drug sponsor relies, in whole or in part, on investigations to which the sponsor does not have a right of reference to establish that its proposed product is safe and effective. For example, a section 505(b)(2) NDA may rely on published literature or on the FDA's prior finding of safety and effectiveness of another company's product. Section 505(b)(2) NDAs are typically used for new products with differences from previously approved products such as in dosage forms, dosage strengths, route of administration or indication and where, therefore, an ANDA may not be used. New clinical trial data may also be needed to establish that the proposed product is safe and effective given its differences.

Under the U.S. Prescription Drug User Fee Act 1992, as amended, the FDA has the authority to collect fees from drug manufacturers who submit NDAs and section 505(b)(2) NDAs for review and approval. These user fees help the FDA fund the drug review process. For U.S. fiscal year 2016, the user fee rate has been set at \$2,374,200 for an NDA and \$1,187,100 for an NDA not requiring clinical data, generally certain section 505(b)(2) NDAs. The FDA has

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months for applications given priority review and approximately ten months for standard review, with two additional months added to each of these time periods for new molecular entities.

#### *ANDA process*

The path leading to FDA approval of an ANDA is very different from that of an NDA. By statute, the drug manufacturer does not complete pre-clinical studies and safety and efficacy clinical trials, and instead focuses on a showing of sameness and bioequivalence to a previously approved RLD, typically a branded drug approved under an NDA. Sameness means, with limited exceptions, the same active ingredient or ingredients, dosage form, strength, route of administration and labelling. Bioequivalence is generally established by studies that involve comparing the absorption rate and concentration levels of a generic drug in the human body to that of the RLD. In the event that the generic drug behaves in the same manner in the human body as the RLD, the two drug products are considered bioequivalent. The FDA considers a generic drug therapeutically equivalent, and therefore the drug is generally substitutable under state pharmacy dispensing law, where it is shown to be the same as and bioequivalent to the RLD. Legislation enacted in most states in the United States allows or, in some instances mandates, that a pharmacist dispense an available generic drug that has been rated therapeutically equivalent when filling a prescription for a branded product, in the absence of specific contrary instructions from the prescribing physician. ANDA filings must include information on manufacturing processes, controls and facilities comparable to an NDA.

In August 2013, it was reported that the average review time for an ANDA is about 35 months. In 2010, Congress passed into law the Generic Drug User Fee Act to address the FDA's backlog, which at the time was over 2,000 ANDA filings. This legislation granted the FDA authority to collect, for the first time, user fees from generic drug manufacturers who submit ANDA filings for review and approval, and the fees collected help the FDA fund the drug approval process. For U.S. fiscal year 2016, the user fee rate is set at \$76,030 for an ANDA and \$38,020 for a prior approval supplement to an ANDA. The FDA will also collect from generic drug manufacturers a separate fee where they reference a so-called Drug Master File for a contract manufacturer, and separate annual manufacturing facility fees for API and finished drug products. The FDA anticipated that the review process timeframe would not begin to improve until U.S. fiscal year 2015. For U.S. fiscal year 2016, the FDA has committed to reviewing 75% of original ANDA submissions within 15 months.

Aside from the backlog described above, the timing of FDA approval of ANDA filings depends on other factors, including whether an ANDA holder has challenged any listed patents to the reference listed drug (the "RLD") and whether the RLD is entitled to one or more periods of non-patent data or marketing exclusivity under the FFDCA, as discussed elsewhere in this section.

#### *Patent and non-patent exclusivity periods*

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files a section 505(b)(2) NDA that relies upon reference to an approved NDA for which the patents are listed, or an ANDA to secure approval of a generic version of the previously approved drug, must make a certification in respect of listed patents. If the ANDA or section 505(b)(2) NDA applicant certifies that there are no listed patents or that the listed patents have expired, the FDA may approve the application immediately. If the applicant certifies that the patents have not expired, the FDA may only approve the application upon expiry of the patents. Alternatively, the applicant may certify that the listed patents are invalid, unenforceable and/or not infringed by the proposed drug (a "Paragraph IV certification"). The applicant must give notice to the holder of the NDA for the RLD and the patent holder (if different) of the bases upon which the patents are challenged. If the NDA holder or patent owner sues the applicant for infringement within 45 days, the FDA may not approve the ANDA or section 505(b)(2) NDA until the earliest of: (i) 30-months after receipt of the notice by the holder of the NDA for the RLD; (ii) entry of a district court of appellate court judgment holding the patent invalid, unenforceable or not infringed; (iii) such other time as the court may order; or (iv) the expiry of the patent. If an infringement suit is not initiated within 45 days of notice to the NDA holder, the FDA may approve the application immediately.

A key motivation for ANDA applicants to challenge patents is the 180-day market exclusivity period (“**generic exclusivity**”) granted to the developer of a generic version of a product that is the first to submit an ANDA with a Paragraph IV certification. For a variety of reasons, there are situations in which a

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company may not be able to take advantage of an award of generic exclusivity. The determination of when generic exclusivity begins and ends is complicated, and is subject to a number of forfeiture provisions.

The holder of the NDA for the RLD may also be entitled to certain non-patent exclusivity during which the FDA cannot accept for filing or approve an application for a competing generic product or section 505(b)(2) NDA product. Generally, if the RLD is a new chemical entity, the FDA may not accept for filing any application that references the innovator’s NDA for five years from the approval of the innovator’s NDA. However, this five-year period is shortened to four years where an applicant’s ANDA includes a Paragraph IV certification, and the 30-month stay on FDA approval is lengthened accordingly. In other cases, where the innovator has provided certain clinical study information essential for approval, the FDA may accept for filing, but may not approve, an ANDA or section 505(b)(2) application that references the corresponding aspect of the innovator’s NDA for a period of three years from the approval of the innovator’s NDA. Certain additional periods of exclusivity may be available, such as orphan exclusivity if the RLD is indicated for use in a rare disease or condition, or pediatric exclusivity if the RLD is studied for pediatric patients based on a written request from the FDA.

*Risk Evaluation and Mitigation Strategies*

The FDA has the authority to require the manufacturer to provide a REMS that is intended to ensure that the benefits of a drug product (or class of drug products) outweigh the risks of harm. The FDA may require that a REMS include elements to assure safe use to mitigate a specific serious risk of harm, such as requiring that prescribers have particular training or experience or that the drug product is dispensed in certain healthcare settings. The FDA has the authority to impose civil penalties on or take other enforcement action against any drug manufacturer who fails properly to implement an approved REMS. Separately, there are prohibitions on a drug manufacturer using an approved REMS to delay generic competition. The FDA has been active in instituting class-wide and product-specific REMS for opioid products. For example, in December 2011, the FDA approved a single, class-wide REMS for transmucosal immediate-release fentanyl products (called “the TIRF REMS Access Program”) that requires manufacturers, distributors, prescribers, dispensers and patients to enrol in a real-time database that maintains a closed-distribution system.

In July 2012, the FDA approved a class-wide REMS (called the “Extended-Release and Long-Acting Opioid Analgesics REMS”) that affected more than 30 extended-release and long-acting opioid analgesics (both branded and generic products). This REMS requires drug manufacturers to make available training on appropriate prescribing practices for healthcare professionals who prescribe these opioid analgesics and to distribute educational materials on their safe use to prescribers and patients. The FDA requires a REMS for SUBOXONE® Film, and other products that the Indivior Group sells in the future may become subject to a REMS specific to the product or shared with other products in the same class of drug.

ANDA filings are generally subject to REMS requirements where applicable, and branded and generic companies are required to adopt a shared REMS unless the FDA grants a waiver.

*Quality assurance requirements*

The FDA enforces requirements to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging and holding of drugs conform to cGMP. The cGMP requirements that the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, and are designed to ensure that the finished products meet all the required identity, strength, quality and purity characteristics. Ensuring compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval and post-approval inspections of facilities engaged in the development, manufacture, processing, packaging, testing and holding of the drugs subject to NDAs and ANDA filings. Prior to approval, if the FDA concludes that the facilities to be used do not or did not meet cGMP, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection.

The FDA also conducts periodic post-approval inspections of drug manufacturing facilities to assess their cGMP status. Adverse inspections can lead to FDA inspectional observations, warning letters, seizure, recalls, injunctions, and shutdown of facilities. In addition, where products or components for manufacturing are being imported into the United States, the FDA may issue an import alert to prevent shipments into

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the country. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products, preventing further approvals for applications involving the facility or facilities and issue and classifying that company as an “unacceptable supplier,” thereby disqualifying that company from selling products to governmental agencies.

### *Reporting requirements*

Pharmaceutical manufacturers are subject to adverse event reporting requirements during clinical trials and following approval, with expedited reporting for certain serious adverse events and periodic reporting for other adverse events. To comply with these requirements, manufacturers must have robust procedures for surveillance, receipt, evaluation and reporting of adverse events. Manufacturers must also submit annual reports to FDA for each approved product, and field alert reports where there is a quality or mislabeling issue with a product already distributed to the market.

### *Labelling and marketing*

For all pharmaceuticals sold in the United States, the FDA and other regulatory and law enforcement bodies also regulate sales and marketing to ensure that drug product claims made by manufacturers are not false, misleading or otherwise improper. Manufacturers are required to file copies of all product-specific promotional materials with the FDA’s Office of Prescription Drug Promotion at the time of their first use. Failure to implement a robust internal company review process and to comply with FDA requirements regarding labelling and promotion increases the risk of enforcement action by the FDA, the U.S. Department of Justice or the states.

In addition, the FDA has the authority to require labelling changes after approval of a drug if it becomes aware of new safety information.

### *Import and export requirements*

To import pharmaceuticals into the United States, the importer must file an entry notice and bond with the CBP. All drugs are subject to FDA examination before release by the CBP. Any article that appears to be in violation of the FFDCA may be refused admission and a notice of detention and hearing may be issued. If the FDA ultimately refuses admission, the CBP may issue a notice for redelivery and assess liquidated damages for up to three times the value of the drugs.

Products for export from the United States are subject to foreign countries’ import requirements and the exporting requirements of the FDA. For example, international sales of drugs manufactured in the United States that are not approved by the FDA for use in the United States are subject to FDA export requirements. Foreign countries often require, among other things, an FDA certificate for products for export, also called a Certificate for Foreign Government, in which the FDA certifies that the product has been approved in the United States and that the manufacturing facilities are in compliance with cGMP. To obtain this certificate, the drug manufacturer must apply to the FDA.

### *Drug Enforcement Administration*

The DEA is the federal agency in the United States responsible for enforcement of the CSA. The CSA classifies drugs and other substances based on identified potential for dependence and abuse. Schedule I controlled substances, such as heroin and LSD,

have a high abuse potential and have no currently accepted medical use; thus they cannot be lawfully marketed or sold. Opioids, such as oxycodone, morphine, hydrocodone and buprenorphine are either Schedule II or Schedule III controlled substances. Consequently, the manufacture, storage, distribution and sale of these substances are all highly regulated.

The DEA regulates the availability of API, products under development and marketed drug products that are Schedule II by setting annual quotas. We must apply to the DEA every year for a manufacturing quota to manufacture API and a procurement quota to manufacture finished dosage products. The DEA has discretion to grant or deny manufacturers’ manufacturing and procurement quota requests.

DEA regulations make it extremely difficult for a manufacturer in the United States to import finished dosage forms of controlled substances manufactured outside the United States, particularly for Schedule II controlled substances and narcotics in other Schedules. These rules reflect a broader enforcement approach by the DEA to regulate the manufacture, distribution and dispensing of legally-produced controlled substances. Accordingly, drug manufacturers who market and sell finished dosage

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forms of controlled substances in the United States often manufacture or have them manufactured in the United States.

The DEA also requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring system includes well-defined due diligence, “know your customer” efforts and order monitoring.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. The facilities must have the security, control and accounting mechanisms required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also regulate controlled substances, and manufacturers, distributors and third-party API suppliers and manufacturers, are subject to such regulation by several states with respect to the manufacture and distribution of these products.

***Drug Addiction and Treatment Act 2000***

DATA 2000 permits qualified physicians to obtain a waiver from the separate registration requirements of the Narcotic Addict Treatment Act 1974 to treat opioid dependence with Schedule III, IV and V opioid medications or combinations of such medications that have been specifically approved by the FDA for that indication. Such medications may be prescribed and dispensed. Buprenorphine is currently the only narcotic medication approved by the FDA for the treatment of opioid dependence within the Schedules listed above.

In order to qualify for a waiver under DATA 2000, physicians must hold a current state medical license, a valid DEA registration number and must meet one or more of the following conditions:

- (i) the physician holds a sub-specialty board certification in addiction psychiatry from the American Board of Medical Specialties;
- (ii) the physician holds an addiction certification from the American Society of Addiction Medicine;
- (iii) the physician holds a sub-specialty board certification in addiction medicine from the American Osteopathic Association;
- (iv) the physician has completed not less than eight hours of training with respect to the treatment and management of opioid-addicted patients. This training can be provided through classroom situations, seminars at professional society meetings, electronic communications or otherwise. The training must be sponsored by one of five organizations authorized in DATA 2000 to sponsor such training, or by any other organization that the Secretary of the Department of Health and Human Services determines to be

appropriate;

- (v) the physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in Schedule III, IV or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary of the Department of Health and Human Services by the sponsor of such approved drug;
- (vi) the physician has other training or experience, considered by the state medical licensing board (of the state in which the physician will provide maintenance or detoxification treatment) to demonstrate the ability of the physician to treat and manage opioid-addicted patients; or
- (vii) the physician has other training or experience the Secretary of the Department of Health and Human Services considers demonstrates the ability of the physician to treat and manage opioid-addicted patients.

In addition, physicians must attest that they have the capacity to refer addiction treatment patients for appropriate counselling and other non-pharmacological therapies, and that they will not have more than 30 patients on such addiction treatment at any one time unless, not sooner than one year after the date on which the practitioner submitted the initial

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notification, the practitioner submits a second notification to the Secretary of the Department of Health and Human Services of the need and intent of the practitioner to treat up to 100 patients.

### ***Government benefit programs***

Statutory and regulatory requirements for Medicaid, Medicare, Tricare and other government healthcare programs govern provider reimbursement levels for government beneficiaries, including requiring that all pharmaceutical companies pay rebates to individual states based on Medicaid utilization of the manufacturer's products. The federal and state governments may continue to enact measures in the future aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds.

From time to time, legislative changes are made to government healthcare programs that impact our business. For example, the Medicare Prescription Drug Improvement and Modernisation Act 2003 created a new out-patient prescription drug coverage program for people with Medicare through a new system of private market drug benefit plans. This law provides an out-patient prescription drug benefit to seniors and individuals with disabilities in the Medicare program ("Medicare Part D"). Congress continues to examine various Medicare policy proposals that may result in pressure on the prices of prescription drugs in the Medicare program.

In addition, the Affordable Care Act provides for major changes to the U.S. healthcare system, which may transform the delivery and payment for healthcare services in the United States. While some provisions of the Affordable Care Act have already taken effect, many of the provisions to expand access to healthcare coverage are just being implemented or are yet to be implemented. Thus, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure will require expanded implementation efforts on the part of federal and state agencies embarking on rule-making to develop the specific components of their new authority. We intend to monitor closely the implementation of the Affordable Care Act and related legislative and regulatory developments. The overall impact of the Affordable Care Act reflects a number of uncertainties; however, we believe that the impact to our business will be largely attributable to changes in the Medicare Part D coverage gap, the imposition of an annual fee on branded prescription pharmaceutical manufacturers and increased rebates payable to state Medicaid programs. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator average manufacturers' price for new formulations and the expansion of the ceiling prices under section 340B of the Public Health Services Act 1944, as amended, (the 340B Program) to new entities.

### ***Healthcare fraud and abuse laws***

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services covered by government healthcare programs or reward past purchases or recommendations. In addition, the federal False Claims Act prohibits presenting or causing to be

presented a false claim for payment by a federal healthcare program, and this law has been interpreted to include claims caused by improper drug manufacturer product promotion or the payment of kickbacks. Under the so-called Sunshine Act and related provisions of the Affordable Care Act, we must report to the federal government information on payments and transfers of value made to physicians and certain healthcare institutions, and also on drug samples distributed. In addition, if we receive protected patient health information, it may be subject to federal or state privacy laws. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws apply to hospitals, physicians and other potential purchasers of our products and are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs. In addition, some states in the United States have enacted compliance and reporting requirements that apply to drug manufacturers.

We must comply with the FCPA and similar worldwide anti-bribery laws in non-U.S. jurisdictions, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside the United States are with governmental entities and are therefore subject to such anti-bribery laws.

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**European Union**

*Overview*

In the EU, medicinal products are subject to extensive pre- and post-marketing regulation by regulatory authorities at both the EU and national levels. Additional rules also apply at the national level relating specifically to controlled substances. The June 2016 referendum in the United Kingdom on whether to remain in the European Union could have an impact on the regulation of our product candidates. For more information, see “Item 3.0. Risk Factors.”

*Clinical trials and marketing approval*

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization (“ICH”) guidelines on GCP. Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU member state in which the trial will be conducted. Under the new Regulation on Clinical Trials, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

After completion of the required clinical testing, a drug manufacturer must obtain a marketing authorization before it may place its medicinal product on the market in the EU. There are various application procedures available depending on the type of product involved. The centralized procedure gives rise to marketing authorizations that are valid throughout the EU and, by extension (after national implementing decisions), in Norway, Iceland and Liechtenstein, which, together with the EU member states, comprise the EEA. Applicants file marketing authorization applications with the EMA where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use (“CHMP”). The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. The centralized procedure is compulsory for medicinal products that (i) are derived from biotechnology processes; (ii) contain a new active substance (not yet approved on November 20, 2005) indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions; (iii) are orphan medicinal products; or (iv) are advanced therapy medicinal products, such as gene or cell therapy medicines. For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralized marketing authorization to the EMA, as long as the CHMP agrees that (i) the medicine concerned contains a new active substance (not yet approved on November 20, 2005); (ii) the medicine is a significant therapeutic, scientific, or technical innovation; or (iii) its authorization under the centralized procedure would be in the interest of public health.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing

authorization applications to the national medicines regulators through one of three procedures: (i) a national procedure, which results in a marketing authorization in a single EU member state; (ii) the decentralized procedure, in which applications are submitted simultaneously in two or more EU member states; and (iii) the mutual recognition procedure, which must be used if the product has already been authorized in at least one other EU member state, and in which the EU member states are required to grant an authorization recognizing the existing authorization in the other EU member state, unless they identify a serious risk to public health. A national procedure is only possible for one-member state; as soon as an application is submitted in a second member state the mutual recognition or decentralized procedure will be triggered.

Marketing authorization applications for generic medicinal products do not need to include the results of pre-clinical and clinical trials but can instead refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

In the EU, companies developing a new medicinal product must agree a Paediatric Investigation Plan (“PIP”) with

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the EMA and must conduct pediatric clinical trials in accordance with that PIP unless a waiver applies, for example because the relevant disease or condition occurs only in adults. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval). This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

***Pharmacovigilance and risk management***

The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (“PSURs”).

All new marketing authorization applications must include a RMP describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs or the conduct of additional clinical trials or post-authorization safety studies.

***Promotional restrictions***

All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

***Manufacturing***

Medicinal products may only be manufactured in the EU, or imported into the EU from another country, by the holder of a manufacturing authorization from the competent national authority, such as the MHRA. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with EU cGMP before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with cGMP.

The manufacture, import, export, storage, distribution and sale of controlled substances are subject to additional regulation at

the national level. In many EU member states the regulatory authority responsible for medicinal products is also responsible for controlled substances. Responsibility is, however, split in some member states, including the United Kingdom, where the Home Office is responsible for controlled substances while the MHRA is responsible for medicinal products. Generally, any company manufacturing or distributing a medicinal product containing a controlled substance in the EU will need to hold a controlled substances license from the competent national authority and will be subject to specific record-keeping and security obligations. Separate import or export certificates are required for each shipment into or out of the member state.

***Pricing and reimbursement***

Governments influence the price of medicinal products in the EU through pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Such differences in national pricing regimes may create price differentials between EU member states. The downward pressure on healthcare costs in general, particularly prescription medicines, has become intense. As a result, barriers to entry of new products are becoming increasingly high and patients are unlikely to use a drug product that is not reimbursed by their government.

In addition, in most EU member states physicians are encouraged or even required to prescribe generic rather than

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branded products and many governments of EU member states also advocate generic substitution by requiring or permitting pharmacists to substitute a different company’s generic version of the branded drug product that was originally prescribed.

**Rest of the world**

***Current markets***

After the United States and the EU, our largest markets are Canada and Australia, where we market our products pursuant to standards set by Health Canada and the Therapeutic Goods Administration respectively. We also market our products in certain other developed countries. The laws, guidelines and standards promulgated by the relevant regulatory authorities that regulate the development, testing, manufacturing, marketing and selling of pharmaceuticals in each of these jurisdictions are broadly similar to those in the United States and the EU, although the precise requirements may vary from country to country.

We also market our products in various emerging markets, where regulatory review and oversight processes continue to evolve. At present, such countries typically require prior regulatory approval or marketing authorization from large, developed markets (such as the United States) before they will initiate or complete their review. Some countries also require the applicant to conduct local clinical trials as a condition of marketing authorization. Many emerging markets continue to implement measures to control drug product prices, such as implementing direct price controls or advocating the prescribing and use of generic drugs.

***China***

We are currently seeking regulatory approval to market our products in China, where pharmaceutical companies and the drug development and marketing processes are heavily regulated. We will need to comply with China’s Drug Administration Law and related implementing regulations, which single out narcotic drugs and psychotropic drugs for special controls, such as additional restrictions on import and export and production quotas. Sale may be restricted, depending upon the risk class, to and by certain wholesalers and to certain pre-approved healthcare institutions. There is also a significant body of regulation from various central and local agencies with jurisdiction over different parts of the development and marketing processes including research and development, approval, license maintenance, manufacturing, import and distribution, and post-marketing surveillance. China imposes price and reimbursement controls generally, and in particular on narcotic and psychotropic drugs. We also note that China’s regulatory environment is highly fluid. The government has modified many policies affecting certain aspects of drug approval in the last year and legislative and policy changes are expected to continue regularly for the next two to three years. Our potential activities in China may touch upon the jurisdiction of many agencies but the primary regulators will be the China Food and Drug Administration, the National Health and Family Planning Commission, and the National Development and Reform Commission, as well as various authorities at ports of entry.

**Environmental**

Our operations, like those of other pharmaceutical companies, involve the use of substances regulated under environmental laws, primarily in manufacturing processes and, as such, we are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations. Certain environmental laws assess strict (i.e. can be imposed regardless of fault) and joint and several liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. These agencies may require that we reimburse the government for costs incurred at these sites or otherwise pay for the cost of investigation and clean-up of these sites, including compensation for damage to natural resources. Environmental laws are complex, frequently amended and have generally become more stringent over time.

**Manufacturing**

***Active Pharmaceutical Ingredients***

The active pharmaceutical ingredients used in our products are manufactured at the Fine Chemical Plant (“FCP”) located in Hull, United Kingdom. Ownership of the FCP was transferred from RB Health, a member of the RB Group, to Indivior in April 2015. The employees working at the FCP have also transferred to the Indivior Group.

The FCP manufactures the buprenorphine hydrochloride (“HCl”) active pharmaceutical ingredient used in the formulation of SUBUTEX® Tablet, SUBOXONE® Tablet, SUBOXONE® Film, TEMGESIC® and BUPRENEX®. The FCP has the capacity to produce all our current buprenorphine HCl requirements with approximately 35% available capacity remaining. The FCP utilizes caustic materials as part of the manufacturing process, as well as a thermal reaction; however, these aspects of the process are tightly controlled and, we believe, represent low risk to the surrounding environment. Following the transition of

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FCP control to the Indivior Group, we now produce buprenorphine HCl for use in the manufacture of SUBUTEX® Tablet, SUBOXONE® Tablet, SUBOXONE® Film, TEMGESIC® and BUPRENEX®.

The naloxone HCl active pharmaceutical ingredient is procured mainly from two suppliers for both SUBOXONE® Tablet and SUBOXONE® Film. Supply of naloxone HCl for SUBOXONE® Tablet is single-source while supply for SUBOXONE® Film is dual-source.

Buprenorphine HCl and products containing buprenorphine HCl are classified as controlled narcotics and require permits for import and export. An annual importation assessment value for buprenorphine HCl and products containing buprenorphine HCl is set by each importing country through the INCB. Once the assessment value has been reached for a given country, no additional import permits may be issued unless proper justification for an assessment value increase is provided to the respective country’s governing body, which reports to the INCB. While this process has not impacted product supply to our patients in the past, it presents a manufacturing and product supply risk that must be monitored closely.

***Tablet and injection products***

As part of the Demerger, we entered into a seven year supply agreement with RB Health, whereby RB Health assumed responsibility for the formulation, compressing, and finished good packaging of SUBUTEX® Tablet and SUBOXONE® Tablet, as well as the formulation, filling, and terminal sterilization of TEMGESIC® and BUPRENEX®.

***SUBOXONE® Film***

SUBOXONE® Film is manufactured under an exclusive license and supply agreement with MSRX signed in August 2008. Under the terms of the agreement, MSRX is the global exclusive manufacturer and primary packager of SUBOXONE® Film and is prohibited from developing any other film product containing buprenorphine without our written consent. The agreement expires upon expiry of the last MSRX patent to expire. Both buprenorphine HCl and the naloxone HCl are supplied free of charge by RB Health to MSRX to be used in the manufacture of SUBOXONE® Film.

MSRX has two manufacturing facilities located in Portage, Indiana. Manufacture and primary packaging of all SUBOXONE® Film output for the U.S. market is now approved at both facilities. Manufacture and primary packaging of SUBOXONE® Film output for the Rest of World is currently approved at one facility.

Serialization and secondary packaging of SUBOXONE® Film is performed by a third party in the United States, Australia and the United Kingdom, under a supply agreement that expires in December 2016 and provides that such third party shall be the exclusive supplier for volumes up to 8,800,000 cartons annually. We are in negotiations to extend this contract beyond 2016.

All finished SUBOXONE® Film product is shipped to our U.S. third-party distribution service provider and either distributed for sale within the United States or exported to other markets where it is approved for sale.

### ***RBP-6000***

RBP-6000 is a buprenorphine depot product currently in Phase III development. We have entered into a development agreement for the formulation and filling of RBP-6000. We intend to agree to terms of a commercial supply agreement prior to launch of the product.

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### **Sales, Marketing and Distribution**

The extent of our focus on sales, marketing and distribution during the periods under review in this document is demonstrated by the fact that selling, marketing and distribution expenses constituted the largest category of our expenses, accounting for \$166 million in 2015 (2014: \$147 million; 2013: \$160 million) (Q1 2016: \$32 million; Q1 2015: \$38 million). Please refer to “Item 5. Operating and Financial Review and Prospectus” of this document for further details of selling and distribution expenses.

Our three largest customers (who are wholesale pharmaceutical companies in the United States) accounted for 76% of global gross sales in 2015 which equated to 71% of our net revenues (2014: 75% of global gross sales, which equated to 69% of our net revenues; 2013: 75% of global gross sales, which equated to 70% of our net revenues), 71% of our net revenues in Q1 2016 and 70% of our net revenues in Q1 2015. Our largest customer accounted for 28% of our net revenues in 2015 (2014: 28%; 2013: 28%), 28% of our net revenues in Q1 2016 and 28% of our net revenues in Q1 2015.

### **Competition**

The introduction of generic or branded products that compete with the Indivior Group’s products could impact the market share of the Indivior Group’s products and pricing and, therefore, its results of operations. The introduction of generic products typically leads to a loss of sales of a branded product and/or a decrease in the price at which branded products can be sold. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available.

The Indivior Group currently faces competition from generic and branded products in various markets. In the United States:

- The Company is aware of certain competitors who are developing products or have recently launched (Braeburn’s Probuphine Implant) which may compete with RBP-6000. Such products may impact the market share which could be obtained by RBP-6000 (assuming receipt of FDA approval and a successful commercial launch) as well as the pricing which could be obtained for this product, which, in turn, could affect the Group’s results of operations.

In addition, during the periods under review, the following developments affected the Company’s market share in the US:

- Two manufacturers launched generic alternatives to SUBOXONE® Tablet in March 2013 and have since together gained a mid-teen share of the market
- A branded buprenorphine and naloxone sublingual tablet was introduced in September 2013 and has gained a share of approximately 4.5% (based on volume (mg)) of the buprenorphine market in the United States.
- In June 2014, the FDA approved a third generic alternative to SUBOXONE® Tablet, which was launched in August 2014.

- In September 2014, the FDA approved a fourth generic alternative to SUBOXONE® Tablet, which was launched in December 2014.
- At the end of 2015 a fifth generic buprenorphine/naloxone tablet was approved and entered the market in January 2016.
- BDSI launched its branded buccal film product, BUNAVAIL™, in November 2014. In September 2014, the Indivior Group filed a patent infringement lawsuit against BDSI and, in anticipation of launching its product and being sued by the Indivior Group, BDSI filed a protective declaratory judgment action against the Indivior Group and MSRX in September 2014 seeking a declaratory judgment of non-infringement and invalidity of three patents relating to SUBOXONE® Film. Please refer to “Item 8.A. — Legal Proceedings” for further details of the patent infringement lawsuit and related litigation.

In the EU, the Indivior Group’s market share of buprenorphine (based on volume (mg)) stayed relatively consistent from 70% in 2014 and 2015 to 71% in Q1 2016 and 70% in Q1 2015.

## **Sales and marketing**

Our current commercial activity in the United States is entirely dedicated to SUBOXONE® Film. Our sales organization in the United States comprises over 250 trained and experienced pharmaceutical professionals many of whom also have clinical backgrounds. This includes 198 clinical liaisons whose primary role is to educate physicians and their staff in both the treatment of addiction as a disease as well as the science of SUBOXONE® Film. We believe that the quality of relationships creates ease of access to, and time with, physicians within their offices. The clinical liaisons also act as a vital link between the various stakeholders within the addiction community, including key opinion leaders, counsellors, treatment advocates, pharmacists, nurses and healthcare providers in specialized treatment centers. These activities are supported by dedicated and experienced professionals in our managed care group who create access to treatment for patients by partnering with U.S. commercial payors and federal and local governmental payors.

In the rest of the world, our commercial activities are currently dedicated to SUBUTEX® Tablet, SUBOXONE® Tablet and SUBOXONE® Film. Depending on the size and demands of each of the markets, there are dedicated teams of clinical liaisons, health policy liaisons, or a combination of both, so as to accelerate access to treatment for patients.

Our commercial activities also include marketing and related services and commercial support services, utilizing the expertise of third-party vendors such as advertising and PR agencies, market research organizations, and other sales support-related services. In addition, we have established strong marketing expertise in disease state and treatment awareness, embedded in various platforms including grassroots, digital and traditional media. Our products are predominantly distributed by the major wholesalers in each country who supply both independent pharmacies and national pharmacy chains.

In each of our markets, our commercial activities are further supported by strategic planning, business analytics and measurement, and quarterly territory plans, ensuring that each market and sales territory is effectively resourced to maximize market access, and to deliver our market growth commitments.

## **Distribution**

At present, we distribute our products globally using contracted third-party distribution services. In the EU, we utilize 22 distribution partners across 31 countries. In North America, we utilize two distribution partners, one in the United States and one in Canada. In all the markets outside of North America and Europe in which we sell our products, we use nine distribution partners across 12 countries.

## **Intellectual Property**

We own or license a number of patents and patent rights in the United States and other countries covering or relating to certain of the products and pipeline products mentioned above, and have created brand names and also registered trademarks where appropriate for our products. Generally, and where possible, we rely upon patent protection to ensure market exclusivity for the life of the patent. We consider the overall protection of our patents, trademarks and license rights to be of material value and acts to protect these rights from infringement or misuse

where appropriate.

The majority of an innovative product’s commercial value is usually realized during the period in which the product has market exclusivity. In the branded pharmaceutical industry, an innovator product’s market exclusivity is generally determined by two forms of protection: patent rights held by the innovator company; and any regulatory forms of exclusivity to which the innovator is entitled. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there are often very substantial and rapid declines in the branded product’s sales. The rate of this decline varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have some market viability based either upon the goodwill generated by the product name, which typically benefits from trademark protection, or upon the difficulties associated with replicating the product formulation or bioavailability.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals as they can provide the innovator with the right to exclude others from practising an invention related to the product. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms, and processes for (or intermediates useful in) the manufacture of products. Protection for aspects of individual products extends for varying periods in accordance with the expiry dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Many developed countries provide certain non-patent incentives for the development of pharmaceuticals. For example, the United States, EU and Japan each provides for a minimum period of time after the approval of certain new drugs during which the regulatory agency may not rely upon the innovator’s data to approve a competitor’s generic copy. Regulatory exclusivity is also available in certain markets as incentives for research on new indications, orphan drugs (drugs that demonstrate promise for the diagnosis or treatment of rare diseases or conditions) and medicines that may be useful in treating pediatric patients. Regulatory exclusivity is independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a second innovative competitor from gaining regulatory approval prior to the expiration of regulatory exclusivity when the second innovative competitor has conducted its own safety and efficacy studies on its drug, even when that drug is identical to that marketed by the first innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict with certainty the length of market exclusivity for any of our branded products because of the complex interaction between patent and regulatory forms of exclusivity, the relative success or lack thereof of potential competitors’ experience in product development and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

We also own, or license, patent rights (i.e. granted patents or pending applications) in certain key jurisdictions in respect to our products and pipeline products. The patent rights listed below are those which are critical to our products and the primary product candidates in our pipeline:

Number	Held by	Granted geographic scope	Expiry (1)	Description
<i><b>SUBOXONE® Film</b></i>				
US 8,017,150 (and foreign equivalents)	MSRX and used by the Indivior Group under exclusive license	United States, Australia, Canada, Europe, Japan	2023	A film product having an opiate and a defined polymer component
US 8,603,514 (and foreign equivalents)	MSRX and used by the Indivior Group under exclusive license	United States, Australia, Canada, China, India, Japan	2024	A drug delivery composition having a uniform content of the drug
US 8,475,832	Indivior Group	United States, Australia,	2030	A film product which

(and foreign equivalents)		China, Europe, Japan, Mexico, South Africa		comprises a combination of buprenorphine and naloxone
<i><u>RBP-6000</u></i>				
US 8,921,387 (and foreign equivalents)	Indivior Group	United States, Australia, South Africa, New Zealand, United Kingdom	2032	Commercial Buprenorphine Depot Formulation
<i><u>RBP-7000</u></i>				
US 9,180,197 (and foreign equivalents)	Indivior Group	United States, Australia, New Zealand, Europe, United Kingdom	2028	Commercial Risperidone Depot Formulation
<i><u>Arbaclofen Placarbil</u></i>				
US 7,109,239 (and foreign equivalents)	XenoPort and used by the Indivior Group under exclusive license	United States, Europe, Australia, Canada, China, Hong Kong, India, Israel, Japan, Mexico, Norway, New Zealand, Russia, Singapore, South Africa, South Korea	2025	Arbaclofen Placarbil for Alcohol Use Disorders

(1) Date listed reflects the date of the latest expiring patent (not accounting for any patent term extension).

Historically, our business has been materially dependent upon a group of owned and in-licensed U.S. and non-U.S. patents relating to SUBOXONE® Film. As announced by us on June 3, 2016, in a judgment issued on June 3, 2016 in respect of our first Orange Book patent infringement lawsuits against Actavis and Par, the District Court in Delaware found that Actavis’ and Par’s ANDA products infringe the asserted claims of U.S. Patent No. 8,603,514, one of our Orange Book listed patents for SUBOXONE® Film, and that the asserted claims of U.S. Patent No. 8,603,514 are not invalid. The Court also ruled that the asserted claims of U.S. Patent No. 8,017,150, which is set to expire in 2023, are valid, but that they are not infringed by Actavis’ or Par’s ANDA products. The Court found that the asserted claims of U.S. Patent No. 8,475,832 are invalid, but that certain of the claims of this patent would be infringed by Actavis and Par’s ANDA products if they were valid. On June 28, 2016, Par filed a notice of appeal of the District Court of Delaware’s rulings.

In addition to patents and regulatory forms of exclusivity, we also market products with trademarks. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registrations of such trademarks are for fixed terms and subject to renewal as provided by the laws of the particular country.

Furthermore, and while not a patent right, we also have regulatory exclusivity for SUBOXONE® Tablet in the EU.

The Indivior Group is involved in on-going litigation relating to its intellectual property portfolio, the outcome of which may have a material and adverse effect on our ability to enforce our intellectual property. See “Item 3.D. Risk Factors — We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products.” For more information, please refer to “Item 8.A. —Legal Proceedings.”

The Company is the ultimate holding company of the Indivior Group. The following table sets out details of the Company’s significant subsidiaries:

<u>Name</u>	<u>Country of incorporation or registration</u>	<u>Proportion of ownership interest</u>
RBP Global Holdings Ltd	England and Wales	100%
Indivior Global Holdings Limited	England and Wales	100%
Indivior UK Ltd	England and Wales	100%
Indivior EU Ltd	England and Wales	100%
Indivior Inc.	United States	100%

**D. Property, Plant and Equipment**

The following table contains information regarding existing or planned material tangible fixed assets owned or leased by the Indivior Group.

<u>Location</u>	<u>Tenure</u>	<u>Principal use</u>	<u>Size</u>
Richmond, Virginia	Lease	Office space	71,197 square feet
Fort Collins, Colorado	Lease	Office space and Manufacturing plant	23,200 square feet
Hull, England	Lease	Manufacturing plant	86,810 square feet
Slough, England	Lease	Office space	13,864 square feet

**ITEM 4A: UNRESOLVED STAFF COMMENTS**

Not applicable.

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**ITEM 5: OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

*The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated historical financial statements as at December 31, 2014 and 2015 and for the three years ended December 31, 2015 (the “Consolidated Annual Financial Statements”) and the unaudited condensed consolidated interim historical financial statements as at March 31, 2016 and for the three months ended March 31, 2016 and 2015 (the “Q1 Interim Results”) and related notes (together the “Historical Financial Information”). The Historical Financial Information has been included in “Item 18. Financial Statements.” The following discussion should also be read in conjunction with the other information relating to our business contained in this document, including “Item 3.A. Selected Financial Data” and “Item 3.D. Risk Factors.”*

*The Historical Financial Information has been prepared in accordance with IFRS.*

*The following discussion includes forward-looking statements that reflect our plans, estimates and beliefs and involves risks and uncertainties. Our actual results could differ materially from those discussed in these statements. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this document, particularly in “Item 3.D. Risk Factors.”*

*References below to “2015,” “2014” and “2013” are to the financial years ended December 31, 2015, December 31, 2014 and December 31, 2013, respectively. References to “Q1 2016” and “Q1 2015” are to the three-month interim financial periods ended*

## Overview

### Introduction to the Indivior Group

We are a global specialty pharmaceutical business specializing in the treatment of addiction and its co-morbidities. Our core marketed products, which are currently sold in 42 countries, comprise SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet, all of which are treatments for opioid dependence.

The following table summarizes our key measures of financial condition and results of operations for the period under review:

(\$ in millions except share data)	For the three months ended March 31,		For the years ended December 31,		
	2016	2015	2015	2014	2013
Net Revenues	258	251	1,014	1,115	1,216
Operating profit	101	115	346	562	695
Adjusted operating profit*	101	117	377	586	695
Net Income	50	77	215	403	489
Earnings per share - basic	7	11	30	56	68
Adjusted earnings*	55	79	246	420	489
Adjusted earnings per share*	8	11	34	58	68
Free Cash Flow*	93	165	289	414	788

\*See “Item 5. Operating and Financial Review and Prospects — Key Performance Metrics” for a description of how we define adjusted operating profit, adjusted earnings, adjusted earnings per share and free cash flow, why we believe it is useful to investors and a reconciliation to profit for the period from continuing operations.

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For the periods under review, we had one business segment, being the manufacture and distribution of products for the treatment of opioid dependence. Substantially all our net revenues for such periods were derived from sales of SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet. SUBOXONE® Film accounted for 80% of our net revenues in 2015 (2014: 77%; 2013 78%), 82% in Q1 2016 (Q1 2015: 80%), and had a market share of approximately 59% in the U.S. market for buprenorphine-based treatments for opioid dependence (based on volume (mg) in 2015).

The U.S. market is the largest contributor to our gross sales and net revenues. Sales rebates and other offsets to gross sales (reflected in net revenues) are principally a U.S. market phenomenon. The following table sets out a breakdown of net revenues as between the United States and the rest of the world.

(\$ in millions)	For the three months ended March 31,		For the year ended December 31,		
	2016	2015	2015	2014	2013
United States	211	200	807	855	950
Rest of world (including United Kingdom)	47	51	207	260	266
Total Indivior Group Net Revenues	258	251	1,014	1,115	1,216

### Presentation of historical financial information

The Company’s consolidated financial statements account for the transfer of the Pharmaceutical Business from RB as a reorganization of entities under common control, retroactively at the book values of RB, including allocated costs from RB for all periods prior to the Demerger. For periods subsequent to the Demerger, the Company is no longer a subsidiary of RB and therefore does not have allocated costs. Rather, the Company has entered into service and support agreements with RB, and such expenses have been

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**Trend information**

***Recent developments***

Beginning in August 2013, we were informed of ANDA filings in the United States by Actavis, Par, Alvogen, Teva, Sandoz and Mylan for the approval by the FDA of generic versions of SUBOXONE® Film in the United States. As announced by us on June 3, 2016, in a judgment issued on June 3, 2016 in respect of our first Orange Book patent infringement lawsuits against Actavis and Par, the District Court in Delaware found that Actavis’ and Par’s ANDA products infringe the asserted claims of U.S. Patent No. 8,603,514, one of our Orange Book listed patents for SUBOXONE® Film, and that the asserted claims of U.S. Patent No. 8,603,514 are not invalid. The Court also ruled that the asserted claims of U.S. Patent No. 8,017,150, which is set to expire in 2023, are valid, but that they are not infringed by Actavis or Par’s ANDA product. The Court found that the asserted claims of U.S. Patent No. 8,475,832 are invalid, but that certain of the claims of this patent would be infringed by Actavis and Par’s ANDA products if they were valid.

We and Sandoz have each submitted a proposed order to dismiss our patent litigation suit which are pending before the court. Trial against Teva, Actavis and Par in the lawsuits involving process patents is scheduled for November 2016. Trial against Teva in the lawsuit involving the Orange Book-listed patents for SUBOXONE® Film is scheduled for November 2016. Trial against Alvogen in the lawsuit involving those Orange Book-listed patents and process patents is scheduled for April 2017. Trial against Mylan in the lawsuit involving the Orange Book-listed patents for SUBOXONE® Film is scheduled for September 2017.

The list price of SUBOXONE® Film in the United States was increased modestly in January 2016, the first price increase since 2012. We continue to offer tactical rebates in connection with formulary access for SUBOXONE® Film, in the face of continuing aggressive discounting by competitors. Branded competitors have made limited impact on the market. Generic tablet pricing has begun to show some signs of greater discounting volatility in the generic marketplace. However, this has not had a negative impact on SUBOXONE® Film market share in Q1 2016.

A number of proposals to increase access to medically assisted treatment have recently been advanced. Congress has passed proposals which, amongst other things, propose to increase the 100 patient cap and allow nurse practitioner and physician assistant prescribing. President Obama, through the Department of Health & Human Services and the Substance Abuse and Mental Health Services Administration, has issued a proposed rule change to raise the 100 patient cap and consider other changes through a comment process.

**Significant factors affecting the Indivior Group’s results of operations**

Our results of operations have been affected during the periods under review, and will continue to be affected in the future, by the following factors:

***Market factors***

Our net revenues are impacted by the share of the market we hold, as well as the overall market growth. Market share is primarily impacted by competition and government austerity measures (such as generic first initiatives). Market growth is impacted by increased treatment penetration, which is a function of patient awareness and desire to seek treatment, as well as the number of certified physicians available to deliver treatment. Competitive pressures can drive pricing and can also influence decisions of third-party payors regarding inclusion of products on their list of approved drugs covered by insurance. To increase access to treatment for patients, we are engaged with government agencies, key opinion leaders in addiction and healthcare professionals to bring patient outcomes to the forefront of decision making. Additionally, we are engaged in non-branded marketing to increase awareness for patients and families impacted by addiction on a country by country basis as allowed by local regulations.

The introduction of generic or branded products that compete with the Indivior Group’s products could impact the market share of the Indivior Group’s products and pricing and, therefore, its results of operations. The introduction of generic products typically leads to a loss of sales of a branded product and/or a decrease in the price at which branded products can be sold. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician



**Distribution channels**

In the United States, we have distribution agreements with the three largest wholesalers, which accounted for 78% of our global gross sales in 2015 (2014: 75%; 2013: 75%). These wholesalers, in turn, distribute our products through various channels including the following:

- *Commercial managed care.* This category comprises insurance programs intended to reduce the cost of providing health benefits and improve the quality of care to their members. One of the most common forms of managed care is the use of a panel or network of healthcare providers that provide care to enrollees. Also within commercial managed care is the Medicare Part D Program, a social insurance program administered by the U.S. government.
- *Medicaid.* Medicaid is a jointly funded, Federal-State health insurance program that covers children, the aged, blind, and/or disabled and other people who are eligible to receive federally assisted income maintenance payments, including prescription drugs. We are obligated to offer “Best Price” under Medicaid, being the lowest price at which the manufacturer sells a drug to any purchaser in any pricing structure (inclusive of discounts and rebates).
- *Federal.* This channel encompasses the provision of outpatient drugs to federal government purchasers, including the U.S. Department of Veterans Affairs and the Department of Defense, or under the 340B Program. Pricing discounts are provided separately for drugs provided under these schemes.
- *Cash.* This channel covers end customers paying cash directly at the pharmacy. Often, we provide discount coupons to customers where cash is used for payment.

In the rest of the world, distribution channels differ by country. For example, in France, we engage with different wholesalers, hospitals, pharmacies and individuals, while in Australia, we engage with a single pre-wholesaler that negotiates the import and onward distribution of the products across the country.

**Pricing**

We offer various types of price reductions for its products, particularly in the United States, which is reflected in net revenues. For the rest of the world, the difference between gross sales and net revenues is nominal. In the United States, we offer:

- *Medicaid, federal and commercial managed care rebates.* These are rebates granted to Medicaid, U.S. federal agencies and commercial managed care providers that purchase products from us. The level of these rebates varies by channel and product. Patients covered by insurance will often benefit from coupons to reduce any out-of-pocket payments they would otherwise be required to make.

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- *Fees under core distribution agreements.* These fees represent distribution fees paid to wholesalers for services such as inventory and distribution management, chargeback administration and billing and receivables management.
- *Other.* This includes cash discounts offered to wholesalers for prompt payment, coupons (for promotional purposes, including to support patients that transfer from SUBOXONE® Tablet to SUBOXONE® Film, or for new SUBOXONE® Film patients) and product returns.

During the periods under review, total rebates as a proportion of gross revenue have gradually increased. In addition, the launch of generic SUBOXONE® tablets in 2013 and 2014 and a branded buprenorphine and naloxone tablet in 2013, caused a reduction in our market share and subsequently increased pricing pressure through greater rebates. Consolidation among third-party payors also contributed to increased pricing pressure. As such, during these periods, net pricing has decreased. The 2014 launch of a branded buprenorphine and naloxone film has had a similar effect in the latter part of 2015. At the end of 2015 a fifth generic buprenorphine/naloxone tablet was approved and entered the market in January 2016. The generic price did decrease at the beginning of 2016, which is consistent timing with previous years. The decrease has not had a material impact on film share to date.

**Research and development**

Research and innovation in respect of RBP-6000 and RBP-7000 continues to be a key strategic priority for us. In the longer term, research and development generally is expected to drive our success and will depend to a great extent on our ability and investment in new product development for the treatment of addiction and its co-morbidities. Please refer to “Item 4.B. — Research and Development” for details of our on-going research and development projects.

Our research and development function designs its clinical studies internally and operates an outsourced business model in relation to Phase I, Phase II, Phase III and Phase IV trials where we have agreements in place with a number of clinical research organizations. During the periods under review, we increased our investment in research and development projects from \$76 million in 2013 to \$115 million in 2014 and \$148 million in 2015.

While the aggregate costs to complete the development of RBP-6000 and RBP-7000 are expected to be material, the total costs relating to the development and commercial launch of these products will depend upon a number of factors, including our ability to successfully complete each milestone for these products, the rate at which these projects advance (including the progress and results of clinical studies and of obtaining regulatory approvals), and the ultimate timing for completion. Given the potential for significant delays and the high rate of failure inherent in the research and development of new pharmaceutical products, it is not possible to accurately estimate the total cost to complete all projects currently in development.

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***Legal and regulatory proceedings***

Our ability to anticipate, manage and successfully resolve regulatory investigations, resolve claims that are brought against us, avoid or otherwise resolve product liability claims, as well as the costs of litigation it brings as a plaintiff, have an impact on our results of operations. We have historically incurred, and expect that we will continue to incur, significant costs in connection with such investigations and proceedings. Such costs will be incurred during a period where our cash flows and financial resources are limited as a result of the expected loss in market share and related revenue resulting from the launch of a generic film alternative to SUBOXONE® Film in the United States, and as a result may represent a significant portion of our overall expenses.

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Please refer to “Item 8.A.—Legal Proceedings” for further details of litigation and disputes. We reported total legal provisions of \$40 million, \$40 million, and \$41 million respectively, as at December 31, 2015, December 31, 2014 and December 31, 2013.

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***Foreign currency translations***

Our functional and presentation currency is U.S. dollars. Items included in the financial statements of each of the Indivior Group’s entities, branches and operations are measured using the currency of the primary economic environment of operations (i.e. the functional currency) and, where relevant, transactions are translated into U.S. dollars using exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the translation at period end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the statement of income.

**Key income statement items**

***Net revenues***

Net revenues comprise revenue from sales of pharmaceutical products (i.e. gross sales), net of sales returns, customer incentives and discounts and certain sales-based payments paid or payable to healthcare authorities. We estimate and recognize returns, discounts, incentives and rebates in the period in which we recognize the underlying sales, as a reduction of gross sales.

*Cost of sales*

Cost of sales includes all costs directly related to bringing products to their final selling destination. It includes purchasing and receiving costs, direct and indirect costs to manufacture products, including materials, labour and overhead expenses necessary to acquire and convert purchased materials and supplies into finished goods. Cost of sales also includes royalties on certain licensed products, inspection costs, depreciation, freight charges and costs to operate equipment.

*Selling, distribution and administrative expenses*

Selling, distribution and administrative expenses comprise personnel costs (primarily, the clinical sales force), as well as marketing expenses, amortization of distribution rights, travel and other selling and distribution related expenses, corporate overheads and other administrative expenses. Selling, distribution and administrative expenses also included expenses relating to recognition of legal provisions.

*Research and development expenses*

Research and development expenses comprise internal research costs and external costs of human and animal trials, and corresponding equipment required. Research and development expenditure is expensed as incurred prior to filing for regulatory approval, as the Indivior Group has determined that filing for regulatory approval is the earliest point at which a project’s successful outcome can become probable.

*Net finance expense*

Net finance expenses are the finance costs of borrowings recognized in the income statement over the term of those borrowings.

*Taxation*

Tax charges represent the aggregate amount included in the determination of profit or loss for the year in respect of current tax and deferred tax. Current tax is the amount of income taxes payable (recoverable) in respect of the taxable profit/(loss) for a year. Deferred tax represents the amounts of income taxes payable/(recoverable) in future periods in respect of taxable (deductible) temporary differences and unused tax losses.

**A. Results of Operations**

The results of operations that follow reflect the historic periods under review and should not be taken as indicative of future performance. The following table sets out information relating to the consolidated interim and annual income statements during the periods under review.

In the explanations below, we disclosure fluctuations in certain income statement line items in terms of constant currency, which is the impact on those line items resulting from the difference between application of current exchange rates and application of corresponding prior period exchange rates.

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*Comparison of the three months ended March 31, 2016 and March 31, 2015*

(\$ in millions)	For the three months ended March 31,	
	2016	2015
Net Revenues	258	251
Cost of sales	(21)	(24)

<b>Gross profit</b>	<b>237</b>	<b>227</b>
Selling, distribution and administrative expenses	(105)	(92)
Research and development expenses	(31)	(20)
<b>Operating profit</b>	<b>101</b>	<b>115</b>
Net finance expense	(15)	(13)
<b>Profit before taxation</b>	<b>86</b>	<b>102</b>
Taxation	(36)	(25)
<b>Net Income</b>	<b>50</b>	<b>77</b>

**Net revenues.** Net revenues increased by \$7 million, or 3%, to \$258 million in Q1 2016 from \$251 million at Q1 2015. The increase was mainly due to a price increase on SUBOXONE® Film, market growth and marginally higher market share driving volumes in the United States (\$23 million), offset by higher rebate levels in the United States (\$13 million) and the impact of adverse translation into U.S. dollars from weaker currencies in Rest of World (Euro, Australian Dollar and Sterling). At constant exchange rates, the growth in net revenues was \$9 million, or 4%.

**Cost of sales.** Cost of sales decreased by \$3 million, or 13%, to \$21 million in Q1 2016 from \$24 million in Q1 2015 due to the elimination of royalties paid under our manufacturing agreement with Monosol. Gross profit as a percent of Net revenues was 92% in Q1 2016, an increase of 2% from 90% in Q1 2015, primarily resulting from the price increase described above.

**Selling, distribution and administrative expenses.** Selling, distribution and administrative expenses increased by \$13 million, or 14%, to \$105 million in Q1 2016 from \$92 million in Q1 2015. The increase mainly reflects a \$19 million increase in administration costs (U.S. litigation costs of \$10 million, standalone public company costs of \$5 million) partially offset by a \$2 million decrease in reconfiguration and separation costs incurred in Q1 2015.

**Research and development expenses.** Research and development expenses increased by \$11 million, or 55%, to \$31 million in Q1 2016 from \$20 million in Q1 2015, as a result of the two pivotal Phase III trials running in Q1 2016 and a more even phasing of research and development investment in 2016 as compared to 2015.

**Net finance expense.** Net finance expense increased by \$2 million, or 15%, to \$15 million in Q1 2016 from \$13 million in Q1 2015, resulting from the interest and amortization costs for the \$750 million borrowing facility marginally reduced by the impact of the buyback of \$75 million of that facility in December 2015. The prior quarter had the benefit of a lower interest rate as the finalization of the debt syndication occurred in mid-March 2015, which also increased the debt issuance costs.

**Taxation.** Tax expense increased by \$11 million, or 44%, to \$36 million in Q1 2016 from \$25 million in Q1 2015 on the pre-tax profit for the period but this included \$5 million of one-off tax costs arising from movement of assets within the group and additional provisions for unresolved tax matters. The effective tax rate was 42%, reflecting the mix of profits between countries in the period and the one-off tax costs and additional provision described above.

**Net income.** As a result of the above factors, net income amounted to \$50 million in Q1 2016, down from \$77 million in Q1 2015. At constant exchange rates, net income reduced by \$27 million, or 35%.

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### *Comparison of the years ended December 31, 2015 and December 31, 2014*

(\$ in millions)	For the years ended December 31	
	2015	2014
<b>Net Revenues</b>	<b>1,014</b>	<b>1,115</b>
Cost of sales	(97)	(95)
<b>Gross profit</b>	<b>917</b>	<b>1,020</b>
Selling, distribution and administrative expenses	(423)	(343)
Research and development expenses	(148)	(115)
<b>Operating profit</b>	<b>346</b>	<b>562</b>
Net finance expense	(61)	(1)
<b>Profit before taxation</b>	<b>285</b>	<b>561</b>

Taxation	(70)	(158)
<b>Net Income</b>	<b>215</b>	<b>403</b>

**Net revenues.** Total net revenues decreased by \$101 million, or 9%, to \$1,014 million in 2015 from \$1,115 million in 2014. The decrease was primarily attributable to higher rebates to payors in connection with formulary access and higher coupons for cash-paying patients in the United States as a result of competitive pricing pressure (\$113 million), lower average U.S. market share as a result of increased generic and branded competition (\$45 million), and the impact of adverse translation into U.S. dollars from weaker currencies in the Rest of World (Euro, Australian Dollar and Sterling) (\$33 million), offset by a \$89 million growth in the U.S. market. At constant exchange rates, net revenues decreased by \$67 million, or 6%, from \$1,115 million in 2014 to \$1,048 million in 2015.

**Cost of sales.** Cost of sales increased by \$2 million, or 2%, to \$97 million in 2015 from \$95 million in 2014 due to higher sales volumes in the United States. Gross profit as a percent of sales was 90% in 2015, slightly below the gross profit in 2014 of 91%.

**Selling, distribution and administrative expenses.** Selling, distribution and administrative expenses increased by \$80 million, or 23%, to \$423 million in 2015 from \$343 million in 2014. The increase was mainly attributable to standalone public company costs, at \$54 million and increased legal expenses relating to the ongoing litigation of \$26 million.

**Research and development expenses.** Research and development expenses increased by \$33 million, or 29%, to \$148 million in 2015 from \$115 million in 2014, reflecting the level of activity in our clinical development pipeline, which has advanced compared to prior year, and in particular to the fact that there were four pivotal Phase III trials running in 2015, together with the commencement of two new clinical trials. Research and development expenses in 2015 included a charge of \$16 million relating to Nasal Naloxone following its non-approval by the FDA in November 2015 and where, following a review, we have decided to discontinue further development of the existing formulation other than in support of the French ATU.

**Net finance expense.** Net finance expenses increased by \$60 million to \$61 million in 2015 from \$1 million in 2014, corresponding to the annual cost of interest and amortization on the \$750 million Term Facility.

**Taxation.** The tax charge decreased by \$88 million, or 56%, from \$158 million in 2014 to \$70 million in 2015. The effective tax rate was 25% in 2015 and 28% in 2014. The decrease in the effective tax rate was driven by the mix of profits by tax jurisdiction plus the benefit of a change in U.S. taxation relating to research and development expense. In addition, the tax rate was impacted by additional amounts recognized with respect to unresolved tax matters of \$26 million, offset by an adjustment recognized with respect to prior period tax matters of \$25 million which resulted from revisions to estimates made upon completion of certain statutory tax returns primarily relating to group relief available through interest deductions and application of transfer prices.

**Net income.** Net income was \$215 million in 2015, representing a decrease of \$188 million, or 47%, from \$403 million in 2014, as a result of the factors described above. At constant exchange rates, net income decreased by \$164 million, or 41%. The decline in net income was primarily due to lower net revenues and higher operating costs associated with operating as a standalone company following the Demerger in December 2014, increased legal expense and higher research and development expenses as described above.

#### **Comparison of the years ended December 31, 2014 and December 31, 2013**

(in \$ millions)	For the year ended December 31,	
	2014	2013
<b>Net revenues</b>	<b>1,115</b>	<b>1,216</b>
Cost of sales	(95)	(104)
<b>Gross profit</b>	<b>1,020</b>	<b>1,112</b>
Selling, distribution and administrative expenses	(343)	(341)
Research and development expenses	(115)	(76)
<b>Operating profit</b>	<b>562</b>	<b>695</b>
Net finance expense	(1)	—
<b>Profit before taxation</b>	<b>561</b>	<b>695</b>
Taxation	(158)	(206)
<b>Net income</b>	<b>403</b>	<b>489</b>

**Net revenues.** Net revenues declined by \$101 million, or 8%, to \$1,115 million in 2014 from \$1,216 million in 2013, reflecting increased generic tablet and branded (tablet and buccal patch) competition to SUBOXONE® Film in the United States (\$95 million) and price cuts in Europe due to governmental austerity measures (\$6 million).

**Cost of sales.** Cost of sales decreased by \$9 million, or 9%, to \$95 million in 2014 from \$104 million in 2013, primarily driven by decreased sales. Gross profit as a percent of Net revenues remained consistent at 91% in 2014 and 2013.

**Selling, distribution and administrative expenses.** Selling, distribution and administrative expenses increased by \$2 million to \$343 million in 2014 from \$341 million in 2013.

**Research and development expenses.** Research and development expenses increased by \$39 million, or 51%, to \$115 million in 2014 from \$76 million in 2013 to support the development of the Company’s product pipeline, attributable primarily to RBP-6000 and RBP-7000 in Phase III clinical development as well as some earlier stage projects in Phase II.

**Net finance expense.** Net finance expenses of \$1 million were incurred in 2014 in connection with interest payable on the Company’s borrowings of \$750 million under the Term Facility between our entry into the borrowing facility on December 19, 2014 and the close of the financial year on December 31, 2014. No finance expense was incurred in 2013.

**Taxation.** The tax charge decreased by \$48 million, or 23%, from \$206 million in 2013 to \$158 million in 2014. The effective tax rate was 28% in 2014 and 30% in 2013, due primarily to a corporate tax rate decrease in the United Kingdom from 23% in 2013 to 21% in 2014 and the different mix of taxable profits in overseas jurisdictions.

**Net income.** Net income for 2014 was \$403 million, a decline of \$86 million, or 18%, from \$489 million in 2013 as a result of the factors described above. The decline in net income was primarily due to lower net revenues, higher research and development costs associated with the advancement of its clinical development pipeline and one-off costs related to the demerger.

**Key Performance Metrics**

In considering the financial performance of the business, management analyzes the primary financial performance measures of Adjusted Operating Profit, Adjusted Earnings, Adjusted Earnings per Share, and Free Cash Flow. Adjusted Operating Profit, Adjusted Earnings, Adjusted Earnings per Share, and Free Cash Flow are not measures defined by IFRS. The most directly comparable IFRS measure to Adjusted Operating Profit and Adjusted Earnings is our profit for the relevant period and for Free Cash flow it is Cash flows from operating activities.

We believe Adjusted Operating Profit and Adjusted Earnings, as defined below, are useful to investors as they exclude items which do not impact our day-to-day operations and which management in many cases does not directly control or influence. Similar concepts of Adjusted Operating Profit and Adjusted Earnings are frequently used by securities analysts, investors and other interested parties in their evaluation of our company and in comparison to other companies, many of which present an adjusted operating profit or earnings-related performance measure when reporting their results. We believe that our Free cash flow metric measures how well we turn profit into cash through management of working capital and a disciplined approach to capital expenditure. A high level of cash generation is key to supporting our dividend policy.

Adjusted Operating Profit, Adjusted Earnings, Adjusted earnings per share and Free Cash Flow have limitations as analytical tools. They are not recognized terms under IFRS and therefore do not purport to be an alternative to operating profit as a measure of operating performance or to cash flows from operating activities as a measure of liquidity.

Adjusted Operating Profit, Adjusted Earnings, Adjusted earnings per share and Free Cash Flow are not necessarily comparable to similarly titled measures used by other companies. As a result, you should not consider these performance measures in isolation from, or as a substitute analysis for, our results of operations.

(\$ in millions except share data)	For the three months ended March 31,		For the years ended December 31,		
	2016	2015	2015	2014	2013
Adjusted operating profit (1)	101	117	377	586	695
Adjusted earnings (2)	55	79	246	420	489
Adjusted earnings per share (3)	8	11	34	58	68
Free Cash Flow(4)	93	165	289	414	788

(1) Adjusted operating profit is profit for the period with the following adjustments:

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(\$ millions)	For the three months ended March 31,		For the years ended December 31,		
	2016	2015	2015	2014	2013
Income for the period	50	77	215	403	489
Taxation	36	25	70	158	206
Net finance expense	15	13	61	1	—
Reconfiguration and separation costs (i)	—	2	15	24	—
Nasal Naloxone Impairment and write—offs (ii)	—	—	16	—	—
<b>Adjusted operating profit</b>	<b>101</b>	<b>117</b>	<b>377</b>	<b>586</b>	<b>695</b>

- (i) Reconfiguration and separation costs represents primarily of legal and advisory costs related to business reconfiguration activities which have been included within operating expenses.
- (ii) Nasal Naloxone Impairment and write-offs represents relating to Nasal Naloxone following a Complete Response Letter from FDA in November 2015 and a decision by the Company to discontinue further development of the existing formulation.

(2) Adjusted earnings is profit for the period with the following adjustments, and their tax effect:

(\$ millions)	For the three months ended March 31,		For the years ended December 31,		
	2016	2015	2015	2014	2013
Income for the period	50	77	215	403	489
Reconfiguration and separation costs	—	2	15	24	—
Nasal Naloxone Impairment and write—offs	—	—	16	—	—
Taxation relating to the above items	—	—	(10)	(7)	—
Taxation related to movement of assets within the Group	5	—	—	—	—
Additional reserves for uncertain tax positions held (i)	—	—	19	—	—
Revisions to prior period estimates relating to income taxes (ii)	—	—	(9)	—	—
<b>Adjusted earnings</b>	<b>55</b>	<b>79</b>	<b>246</b>	<b>420</b>	<b>489</b>

- (i) This amount is included within “Adjustments to amounts carried in respect of unresolved tax matters” on page F-24, and relate to ongoing positions held during the period.
- (ii) This amount is included within “Adjustments in respect of prior years” on page F-24.

(3) Adjusted earnings per share provides additional useful information on underlying trends to shareholders in respect of earnings per ordinary share.

(4) Free cash flow is net cash flow from operating activities plus net cash flow from investing activities:

(\$ millions)	For the three months ended March 31,		For the years ended December 31,		
	2016	2015	2015	2014	2013
Cash flow from operations	97	165	320	440	791
Cash flow from investing activities	(4)	—	(31)	(26)	(3)
<b>Free cash flow</b>	<b>93</b>	<b>165</b>	<b>289</b>	<b>414</b>	<b>788</b>

## B. Liquidity and Capital Resources

### Overview

At March 31, 2016 we had \$593 million of liquidity which comprised \$543 million of cash and cash equivalents and \$50 million of undrawn facilities. Historically, our principal source of funding has been cash from operations. The principal uses of our funds have been to fund our operating costs, research and development and corporate expenses. Based on our current and anticipated levels of operations, and the condition in our markets and industry, we believe that our cash on hand and cash flows from operations will enable us to meet our working capital, capital expenditures and debt service and other funding requirements for the foreseeable future.

Indivior PLC is a holding company with no direct source of operating income. It is therefore dependent on its capital raising abilities and dividend payments from its subsidiaries. The ability of companies within the Indivior Group to pay dividends and Indivior PLC's ability to receive distributions from its investments in other entities are subject to restrictions, including, but not limited to, the existence of sufficient distributable reserves.

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*Cash flow*

The following table summarizes the principal components of our cash flows for the periods under review:

(\$ in millions)	For the three months ended March 31,		For the year ended December 31,		
	2016	2015	2015	2014	2013
Net cash inflow from operating activities	97	165	320	440	791
Net cash outflow from investing activities	(4)	—	(31)	(26)	(3)
Net cash used in financing activities	(17)	(18)	(144)	(90)	(806)
Net increase / (decrease) in cash and cash equivalents	76	147	145	324	(18)

*Net cash provided by operating activities*

Net cash provided by operating activities was \$97 million in Q1 2016, a decrease of \$68 million, or 41%, compared to \$165 million in Q1 2015. The decrease was mainly attributable to working capital movements, with increases in working capital providing cash of \$8 million in Q1 2016 as compared to \$91 million in Q1 2015.

Net cash provided by operating activities was \$320 million in 2015, a decrease of \$120 million, or 27%, compared to \$440 million in 2014. The decrease mainly reflected lower operating profits of \$216 million in the year, plus higher tax payments in the period of \$131 million compared to \$59 million in 2014 partially offset by a significant improvement in net working capital with a release of cash of \$127 million.

Net cash provided by operating activities in 2014 was \$440 million, a decrease of \$351 million, or 44%, compared to \$791 million in 2013. This decrease was primarily due to \$133 million lower profits, increased trade payable payments ahead of the Demerger, and transaction costs related to our debt facilities.

*Net cash used in investing activities*

Net cash used in investing activities was \$4 million in Q1 2016 relating to the purchase of property, plant and equipment in the UK.

Net cash used in investing activities increased from \$26 million in 2014 to \$31 million in 2015 mainly due to investment in property, plant and equipment primarily related to the development of our ERP system, new equipment in our research and development laboratories, building refits and \$4 million in relation to the purchase of intangible assets. The investment in 2014 was in relation to the purchase of our Nasal Naloxone technology rights and the in licensing of Arbaclofen Placarbil for the treatment of alcohol use disorders.

Net cash used in investing activities was \$3 million in 2013, which reflected cash paid for purchases of property, plant and

equipment.

### *Net cash used in financing activities*

Net cash used in financing activities decreased by \$1 million, or 6%, from \$18 million in Q1 2015 to \$17 million in Q1 2016. We made repayments of \$9 million and \$17 million in relation to the Term Facility in Q1 2015 and Q1 2016 respectively. In Q1 2015, we repaid \$9 million of overdrafts.

Net cash used in financing activities increased by \$54 million, or 60%, from \$90 million in 2014 to \$144 million in

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2015. In 2014, \$750 million was received from drawing down on the Term Facility at the time of the Demerger, which was then utilized to pay a \$500 million dividend to our then parent company. Prior to the completion of the Demerger, excess cash flow generated by us was transferred to our then parent company, in 2014 this amount was \$349 million. In 2015, we made a repayment of \$112 million in relation to the Term Facility including \$75 million repurchased in December 2015, repaid \$9 million of overdrafts and made a payment in relation to the interim dividend to Shareholders of \$23 million.

Net cash used in financing activities was \$806 million in 2013, which was attributable to \$239 million in relation to a dividend payment to our then parent company and a transfer of a further \$567 million to its then parent company.

### ***Borrowings***

See “Item 3.B. Capitalization and Indebtedness” for details relating to our capitalization and indebtedness as at the dates indicated therein.

### *The Term Facility and Revolving Credit Facility*

Pursuant to a Credit Agreement, dated as of December 19, 2014, and amended as of March 16, 2015 (the “Credit Agreement”), by and among Morgan Stanley Senior Funding, Inc., as administrative agent and collateral agent (the “Administrative Agent”), Indivior Finance S.à r.l. (the “Lux Borrower”), Indivior Finance (2014) LLC (the “US Co-Borrower,” and together with the Lux Borrower, the “Indivior Term Borrowers” and each an “Indivior Term Borrower”), RBP Global Holdings Limited (the “Borrower Representative,” and together with the Indivior Term Borrowers, the “Indivior Borrowers” and each an “Indivior Borrower”), the other Loan Parties (as defined therein) party thereto and the lenders and issuing banks from time to time party thereto, the Indivior Borrowers borrowed a \$750 million term “B” loan (the “Term Facility”), comprised of (x) a €100 million euro tranche and (y) the balance in a U.S. dollar tranche, and a \$50 million revolving credit facility (the “Revolving Credit Facility,” together with the Term Facility, the “Facilities”), which includes a \$10 million swingline facility and \$25 million letter of credit facility.

Pursuant to the Credit Agreement, the Indivior Borrowers borrowed the Term Facility, comprised of (x) a €100 million euro tranche and (y) the balance in a U.S. dollar tranche, and the Revolving Credit Facility, which includes a \$10 million swingline facility and \$25 million letter of credit facility. The Indivior Borrowers used the proceeds under the Credit Agreement (i) to pay a dividend to Reckitt Benckiser Investments Limited, (ii) for general corporate purposes and (iii) to pay the fees, premiums, expenses and other transaction costs in connection with the Credit Agreement and the related transactions (including the Demerger). The Indivior Borrowers have been paying down debt to the maximum amount of 20% which is allowed for on-market purchases. The Indivior Borrowers made a repayment of \$75 million in December 2015 and have repaid \$45.7 million to date in 2016, in each case at a discount and without incurring early repayment charges.

The Credit Agreement is governed by New York law. The Term Facility amortizes quarterly at a rate of (i) 5% per annum prior to March 31, 2017 and (ii) 10% per annum commencing on March 31, 2017, with the remainder of the principal amount of the term loans outstanding on December 19, 2019 to be paid on such date. Additional mandatory prepayments are required under certain circumstances, as described below. Indivior Finance S.à r.l., one of the Indivior Group borrowing entities under the Term Facility, is a private limited liability company (*société à responsabilité limitée*) organized and established under the laws of the Grand Duchy of Luxembourg, and is a wholly owned subsidiary of RBP Global Holdings Limited. With respect to the obligations under the Term Facility, Indivior Finance (2014) LLC is jointly and severally liable, as is customary with such facilities. The obligations of the Indivior Borrowers under the debt Facilities are guaranteed by each Indivior Borrower (other than with respect to its own obligations as an Indivior Borrower) and certain wholly owned subsidiaries of RBP Global Holdings Limited (collectively, the “Guarantors”). The

Indivior Borrowers and each Guarantor has also granted security to support their obligations. Such guarantees and security have not been granted by any wholly owned subsidiaries that are designated as Unrestricted Subsidiaries (as defined in the Credit Agreement), are Immaterial Subsidiaries (as defined in the Credit Agreement) or are subject to certain other exceptions, in each case, in accordance with the Credit Agreement. Such guarantees, and the obligations of the Indivior Borrowers, are secured by substantially all the assets of the Indivior Borrowers and the Guarantors, including a fixed charge covering all of our ordinary shares, subject to certain customary exceptions.

Under the Credit Agreement the Indivior Borrowers under the applicable Facilities are entitled to elect to pay interest on any loan (other than a swingline loan) either based on a “LIBO Rate” or (other than in the case of loans denominated in currencies other than U.S. dollars) at the “Alternate Base Rate,” plus in each case, a different, applicable margin (see below). The LIBO Rate is the published LIBO Rate, as adjusted to reflect applicable reserves prescribed by

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governmental authorities but subject to a floor of 1.00% per annum. The Alternate Base Rate is the rate per annum equal to the highest of (i) the Federal Funds Effective Rate in effect on such day *plus* 0.50%, (ii) the published LIBO Rate (calculated based upon an interest period of one month) *plus* 1.00% and (iii) the “Prime Rate,” which is a rate announced publicly by the Administrative Agent as its prime rate. Solely with respect to U.S. dollar denominated term loans, the Alternate Base Rate shall not be less than 2.00%. To the extent denominated in U.S. dollars, swingline loans are required to be based on the Alternate Base Rate.

The Term Facility margin shall be either 6.00% in respect of a LIBO Rate loan or (solely with respect to U.S. dollar denominated term loans) 5.00% in respect of an Alternate Base Rate loan. The Revolving Credit Facility margin is adjusted quarterly on a prospective basis based upon the ratio of net total debt to consolidated adjusted EBITDA (the “Total Leverage Ratio”). With respect to the Revolving Credit Facility margin applicable to revolving loans, if the Total Leverage Ratio is (i) greater than 1.25 to 1.00, then the LIBO Rate spread is 5.50% while the Alternate Base Rate spread is 4.50%; (ii) less than or equal to 1.25 to 1.00 but greater than 1.00 to 1.00, then the LIBO Rate spread is 5.25% while the Alternate Base Rate spread is 4.25%, and (iii) less than or equal to 1.00 to 1.00, then the LIBO Rate spread is 5.00% while the Alternate Base Rate spread is 4.00%. The commitment fee with respect to the unused portion of the Revolving Credit Facility is also adjusted quarterly on a prospective basis based upon the Total Leverage Ratio. Such commitment fee is (x) 0.50% if the Total Leverage Ratio is greater than 1.25 to 1.00 or (y) 0.375% if the Total Leverage Ratio is equal to or less than 1.25 to 1.00.

The Credit Agreement includes an accordion feature such that a minimum of \$150 million of additional incremental loans are permitted plus additional further incremental loans of first lien or second lien debt up to amounts based on various leverage ratios and subject to various conditions, including as to the absence of certain events of default, accuracy of certain representations and warranties, intercreditor relations, maturity, weighted average life to maturity, prepayments, interest rate margins, borrower identity, guarantors and security and other terms and conditions (including, without limitation, an “MFN” provision providing that the interest rate applicable to any incremental facility or loan must be not more than 50 basis points above the corresponding interest rate applicable to the Term Facility and the Revolving Credit Facility, and any loans under each respective facility). In addition, refinancing facilities are permitted to refinance loans or replace commitments under the Credit Agreement subject to various conditions including as to the absence of certain events of default, maturity, borrower identity, security, principal amount, intercreditor relations and priority.

The Term Facility is subject to mandatory prepayment in respect of (i) certain non-ordinary course asset dispositions, exchanges or transfers, (ii) proceeds received under any casualty insurance policy or as a result of the taking of assets of any of the Indivior Borrowers or their restricted subsidiaries pursuant to a condemnation or similar event, in each case above a threshold of \$10,000,000 per fiscal year and subject to certain re-investment rights and (iii) the proceeds of certain debt issuances. The Indivior Borrowers are also required, in certain circumstances, to make certain prepayments of the Excess Cash Flow (as defined in the Credit Agreement) of the Indivior Borrowers and their restricted subsidiaries for the fiscal year then ended. The Borrower Representative has the option to reduce the amount to be paid by the aggregate amounts that have been otherwise prepaid at the option of the Indivior Borrowers or retired and cancelled as a result of certain assignments. The percentage of Excess Cash Flow to be paid is calculated as to 50% of an aggregate principal amount of Excess Cash Flow in the event the Total Leverage Ratio of Net Debt to Consolidated Adjusted EBITDA (each as defined in the Credit Agreement) equals or is in excess of 1.00x; this is reduced to 25% of Excess Cash Flow if the Total Leverage Ratio calculated on a pro forma basis is less than 1.00x, but greater than or equal to 0.50x. Such prepayment is not required if the Total Leverage Ratio calculated on a pro forma basis is less than 0.50x.

Under the Credit Agreement the Indivior Borrowers make representations and warranties as well as affirmative covenants and are subject to negative covenants customary for facilities of this nature, including a limitation on disposal of assets, a limitation on

mergers and acquisitions and other fundamental changes, limitations on share buybacks and redemptions, dividends and other “restricted payments,” a limitation on further negative pledges, a limitation on indebtedness, a limitation on prepayments and redemptions of certain indebtedness, a limitation on subsidiary distributions, a limitation on liens, sale and lease-back transactions and investments, a restriction on changes to any material line of business (including the business of the restricted subsidiaries of the Indivior Borrowers), restrictions on modifying the terms of certain debt and general restrictions on the organizational documents and fiscal year of the Indivior Borrowers. These negative covenants are subject to various carve outs, grace periods and qualifications and, in some instances, are also applicable to the restricted subsidiaries of the Indivior Borrowers.

The Credit Agreement contains a minimum liquidity covenant requiring that the Indivior Borrowers and their restricted subsidiaries not allow liquidity to be less than \$150 million on the last day of each fiscal quarter with respect to the period of four consecutive fiscal quarters then most recently ended for which financial statements have been delivered (or are required to have been delivered) under the terms of the Credit Agreement (a “Test Period”). Additionally, the Indivior Borrowers and their restricted subsidiaries are required to comply with a net first lien leverage ratio (the “Leverage Covenant”) which, in broad terms, is a ratio of the consolidated secured debt of the Indivior Borrowers and

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their restricted subsidiaries to a measure of consolidated adjusted EBITDA (as such items are defined under the Credit Agreement), and is to be tested on the last day of any Test Period. Pursuant to the Leverage Covenant, the Indivior Borrowers must not exceed a maximum net first lien leverage ratio as follows: (i) 3.25 to 1.00 prior to June 30, 2016, (ii) 3.00 to 1.00 on and after June 30, 2016 but prior to December 31, 2016, (iii) 2.75 to 1.00 on and after December 31, 2016 but prior to June 30, 2017, and (iv) 2.50 to 1.00 on and after June 30, 2017.

Under the Credit Agreement, the debt Facilities are subject to customary events of default for facilities of this nature including non-payment of principal, interest, fees or any other amounts when due, breach of certain covenants or representations, cross event of default and cross acceleration, insolvency and insolvency events, material monetary judgments, pension defaults, material invalidity of guarantees or security, ranking and change of control. In the event of an event of default under the Credit Agreement (and at any time thereafter during the continuance of such event of default) the Administrative Agent may, and at the request of the lenders shall, terminate the debt Facilities and/or demand repayment in full of any borrowings outstanding under the debt Facilities, together with accrued interest thereon and all fees and other accrued obligations of the Indivior Borrowers.

**C. Research and Development Expenses, Patents and Licenses, etc.**

See “Item 4.B.—Intellectual Property,” “Item 4.B.—Research and Development,” and “Item 5. Operating and Financial Review and Prospects.”

**D. Trend Information**

See “Item 5. Operating and Financial Review and Prospects—Trend Information.”

**E. Off-Balance Sheet Arrangements**

As at March 31, 2016, the Group had no off-balance sheet arrangements.

**F. Tabular Disclosure of Contractual Obligations**

The following table summarizes our contractual commitments and obligations as of March 31, 2016.

(\$ in millions)	PAYMENTS DUE BY PERIOD				
	TOTAL	LESS THAN 1 YEAR	BETWEEN 1 AND 3 YEARS	BETWEEN 3 AND 5 YEARS	MORE THAN 5 YEARS
Borrowings	594	48	44	502	—
Operating lease obligations	13	4	5	2	2
Total	607	52	49	504	2

In connection with our asset purchases and licensing of potential product candidates, we have agreed to pay certain additional amounts contingent upon the achievement of certain agreed development, regulatory, product or other milestones. Please refer to “Item 4.B. Business Overview” and “Item 10.C. Material Contracts” for further details.

In addition, we have incurred additional capital expenditures of \$4 million to date in 2016 and anticipate further additional capital expenditures of \$41 million over the next financial year, primarily relating to information systems and the design and construction of a new research and development facility. We

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incurred \$61 million in additional expenses in 2015 to service our debt.

**G. Safe harbor**

See “Cautionary Note Regarding Forward-Looking Statements” on page 1.

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**ITEM 6: DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**A. Directors and Senior Management**

The following table sets forth information regarding our directors as of the date of this registration statement.

NAME	POSITION	DIRECTOR SINCE	TERM EXPIRES
Howard Pien	Chairman	2014	2017
Rupert Bondy <sup>(1),(2)</sup>	Senior Independent Director	2014	2017
Cary Claiborne	Chief Financial Officer, Director	2014	N/A
Dr. Yvonne Greenstreet <sup>(3),(4)</sup>	Non-Executive Director	2014	2017
Dr. A. Thomas McLellan <sup>(2),(4)</sup>	Non-Executive Director	2014	2017
Lorna Parker <sup>(1),(2)</sup>	Non-Executive Director	2014	2017
Daniel J. Phelan <sup>(1),(2)</sup>	Non-Executive Director	2014	2017
Christian Schade <sup>(3),(4)</sup>	Non-Executive Director	2014	2017
Daniel Tassé <sup>(1),(3)</sup>	Non-Executive Director	2014	2017
Shaun Thaxter	Chief Executive Officer, Director	2014	N/A

<sup>(1)</sup>Remuneration Committee member  
<sup>(2)</sup>Nomination & Governance Committee member  
<sup>(3)</sup>Audit Committee member  
<sup>(4)</sup>Science & Policy Committee member

The following table sets forth information regarding our senior managers as of the date of this registration statement.

NAME	POSITION
Debby Betz	Chief Corporate Affairs & Communications Officer
Mark Crossley	Chief Strategy Officer
Jon Fogle	Chief Human Resources Officer
Tony Goodman	Chief Business Development Officer
Dr. Christian Heidbreder	Chief Scientific Officer
Javier Rodriguez	Chief Legal Officer
Richard Simkin	Chief Commercial Officer

The address of each Director and Senior Manager is 103-105 Bath Road, Slough, Berkshire SL1 3UH, United Kingdom.

## Biographies

### Howard Pien — *Chairman*

Mr. Pien has worked in the pharmaceutical and biotechnology industries for over 30 years. He is currently a board director of the development-stage biopharmaceuticals companies: ImmunoGen, Inc., Juno Therapeutics Inc. (as Non-Executive Chairman) and Sage Therapeutics, Inc.. Mr. Pien's past non-profit board appointments include the industry associations BIO and PhRMA, as well as Oakland Children's Hospital and Fox Chase Hospital.

From 2007 to June 2016, Mr. Pien was a board member of Vanda Pharmaceuticals, Inc. (Chairman from 2012 to 2016), a commercial stage public company, specializing in CNS. From 2007 to 2009, Mr. Pien was the Chairman and CEO of Medarex, Inc., a public biotechnology company, until it was acquired by Bristol-Myers Squibb Company. From 2003 to 2006, he was the Chairman and CEO of Chiron, Corp., a public biotechnology company, which was acquired by Novartis AG. His previous board directorships include Talon Therapeutics, Inc., Arresto BioSciences, Inc., Ikaria, Inc. and ViroPharma Inc. (where he was lead independent director) — all biopharmaceutical companies that were acquired in strategic transactions. Between 1991 and 2003, he held various executive positions at GlaxoSmithKline plc ("GSK") and its predecessor, SmithKline Beecham Limited, as President of U.S., International, and Pharmaceuticals. Prior to GSK, Mr. Pien

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worked for Abbott Laboratories, Limited for six years and Merck & Co., Inc. for five years.

Mr. Pien graduated from MIT with a BS in engineering, and from Carnegie-Mellon University with an MBA.

### Rupert Bondy — *Senior Independent Director*

Mr. Bondy joined energy company BP in 2008 as Group General Counsel, with worldwide responsibility for legal and compliance matters. He is a member of the English Bar and the California Bar as well as various professional bodies and committees.

Mr. Bondy began his career as a lawyer in private practice. In 1989, he joined the U.S. law firm Morrison & Foerster LLP, working in San Francisco and London, and from 1994 worked for UK law firm Lovells LLP in London. In 1995, he joined SmithKline Beecham Limited as Senior Counsel for mergers and acquisitions and other corporate matters. He subsequently held positions of increasing responsibility and, in 2001, following the merger of SmithKline Beecham Limited and Glaxo Wellcome PLC to form GlaxoSmithKline plc he was appointed Senior Vice President and General Counsel.

Mr. Bondy obtained his undergraduate degree from King's College, Cambridge and was then a Harkness Fellow for a year at Harvard University. He also spent a year as a teaching fellow at Stanford Law School, where he obtained a Master's Degree in Law.

### Cary J. Claiborne — *Chief Financial Officer*

Mr. Claiborne was appointed Chief Financial Officer of Indivior in November 2014. Prior to joining Indivior, Mr. Claiborne was the CFO of Sucampo Pharmaceuticals, Inc., a public global biopharmaceutical company focused on discovery, development and commercialization, from 2011 to 2014. From 2009 to 2010, Mr. Claiborne was President, CEO and a member of the board of directors of New Generation Biofuels, Inc., a public biofuel technology company, as well as its CFO from 2007 to 2009. From 2004 to 2007, Mr. Claiborne was CFO of Osiris Therapeutics, Inc., a public stem cell therapeutics company, leading the company's initial public offering in 2006. From 2001 to 2004, he was Vice President — FP&A of Constellation Energy Group, Inc., a diversified energy company. From 2000 to 2001, he was Vice President — FP&A of The Home Depot, Inc. Prior to Home Depot, Mr. Claiborne worked for MCI Corporation for three years.

Mr. Claiborne spent the first 15 years of his career in a series of positions of increasing responsibility in financial management and senior management, including President and CEO of New Enterprise Wholesale Services at GE Capital Global Holdings, LLC and

General Electric Company since 1982. Mr. Claiborne is also a member of the board of directors of MedicAlert Foundation, where he also serves as the Chairman of the Audit Committee.

Mr. Claiborne graduated from Rutgers University with a BA in Business Administration, and from Villanova University with an MBA.

**Dr. Yvonne Greenstreet — *Non-Executive Director***

Dr. Greenstreet has over 20 years’ global experience in the pharmaceutical industry, spanning research and development, strategy and commercial development. Dr. Greenstreet serves on the board of directors of Pacira Pharmaceuticals, Inc., Advanced Accelerator Applications S.A. and Moelis & Company LLC. She is also on the Advisory Board of the Bill and Melinda Gates Foundation.

Between 2011 and 2013, Dr. Greenstreet was Senior Vice President and Head of Medicines Development at Pfizer Inc. and a member of the global executive team for the \$16 billion specialty business, with accountability for a portfolio which included the immuno-inflammation, vaccine, specialty neuroscience and rare disease areas. Prior to Pfizer, she was at GlaxoSmithKline plc for 18 years where she was Senior Vice President and Chief of Strategy for Research and Development, serving on the corporate executive investment committee. She was responsible for enabling strategy development and execution to achieve GSK’s goal of delivering five to seven new medicines per year while reducing research and development spend. Dr. Greenstreet previously held various positions of increasing responsibility at GSK, including Senior Vice President for Medicine Development and Chief Medical Officer for Europe.

Dr. Greenstreet trained as a physician and obtained her MBChB from Leeds University in England and her MBA from INSEAD, France. She was recognized by Fast Company as one of the 100 most creative people in business in the United States in 2013 and by FierceBiotech as one of the top 10 women in biotechnology in 2012.

**Dr. A. Thomas McLellan — *Non-Executive Director***

Dr. McLellan has been a career researcher for 35 years with the Treatment Research Institute (which he co-founded in 1992) and the University of Pennsylvania. In his career, Dr. McLellan has published over 400 articles and chapters on addiction research. He has received several awards including Life Achievement Awards from the American, Swedish, Italian

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and British Societies of Addiction Medicine and from the American Public Health Association in 2010.

Between 2009 and 2011, Dr. McLellan was unanimously confirmed by the U.S. Senate to serve as Deputy Director of the White House Office of National Drug Control Policy, where he was one of the principal authors of the President’s National Drug Control Strategy.

Dr. McLellan holds a BA from Colgate University and his MS and PhD from Bryn Mawr College. He received postgraduate training in psychology at The University of Oxford.

**Lorna Parker — *Non-Executive Director***

Ms. Parker is a senior adviser at BC Partners Ltd., a leading private equity firm. As an independent consultant, she conducts board-effectiveness reviews for UK public companies.

She has an active not-for-profit portfolio: she is a Trustee of the Royal Horticultural Society, a Director of Future Academies, a Governor of Pimlico Academy, a Trustee of BC Partners Foundation and was until recently a Trustee of Place2Be.

Ms. Parker’s executive career was primarily in executive search, as a partner at Spencer Stuart. Ms. Parker created and led their private equity practice across Europe, co-led the legal search practice globally, was a member of the UK board practice and was managing director of the UK business. Prior to joining Spencer Stuart, Inc., Ms. Parker worked for Advent Venture Partners LLP (venture capital) and Kleinwort Benson (investment banking).

Ms. Parker has an MA in Economics from Cambridge University and an MBA from Stanford Business School, where she was

a Harkness Fellow.

**Daniel J. Phelan — *Non-Executive Director***

Mr. Phelan is a Board Director of TE Connectivity Ltd. (formerly Tyco Electronics Ltd.) and serves on the Management Development & Compensation Committee. He is a member of the Health Care and Life Sciences Advisory Board of Computer Sciences Corporation and the Advisory Board of RiseSmart, Inc.. He is also an Executive Director of Executive Networks and is a member of the Board of Trustees of Rutgers University.

Mr. Phelan retired from GlaxoSmithKline plc in December 2012 after 31 years, during which time he was an adviser to three chief executives and a member of the Corporate Executive Team. Prior to his retirement, he was Chief of Staff with global responsibility for Corporate Strategy and Development, Human Resources, Information Technology, Real Estate and Facilities, Environmental, Health and Safety, and Security. Before that, he was Senior Vice-President, Human Resources for fourteen years.

Mr. Phelan is a graduate of Rutgers College. He holds a Masters degree from The Ohio State University and a Law degree from Rutgers University School of Law. He is admitted to practice in New Jersey and Pennsylvania.

Mr. Phelan served as an officer on active duty and in the reserves of the U.S. Army Medical Service Corps. He has published on CEO succession planning and onboarding and public sector collective bargaining.

**Christian Schade — *Non-Executive Director***

Since June 2016, Mr. Schade currently serves as the President and CEO of Aprea AB, a privately held clinical-stage biopharmaceutical company.

Prior to that, Mr. Schade was CEO of Novira Therapeutics Inc., formerly a privately held biopharmaceutical company until acquisition by Johnson & Johnson in December 2015. He is a board director of Integra LifeSciences Holdings Corporation, a member of its Audit Committee and a member and chair of its Finance committee.

Mr. Schade was previously Executive Vice President and Chief Financial Officer of Omthera Pharmaceuticals, Inc., a specialty pharmaceutical company, prior to its acquisition in July 2013 by AstraZeneca PLC. He was EVP and CFO at NRG Energy, Inc. from April 2010 to September 2011. Mr. Schade joined Medarex, Inc. in 2000 and helped it to grow into a leading pharmaceutical development company and, as Senior Vice President, Administration and Chief Financial Officer, played a lead role in the negotiations for Bristol-Myers Squibb Company’s \$2.4 billion acquisition of Medarex, Inc. in September 2009 and the subsequent merger-integration process.

Prior to Medarex, Mr. Schade served as Managing Director and head of the European Corporate Funding Group at Merrill Lynch in London and also held various capital markets and corporate finance positions in New York and London for both Merrill Lynch & Co., Inc. and JP Morgan Chase & Co.

Mr. Schade received an AB from Princeton University, and an MBA from the Wharton School at the University of Pennsylvania.

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**Daniel Tassé — *Non-Executive Director***

Mr. Tassé was appointed Chairman and CEO of Alcresta Pharmaceuticals, Inc in April 2016, Alcresta is a speciality pharmaceutical company specializing in products for people living with gastrointestinal disorders and rare diseases. Mr. Tassé was Chairman and CEO of Ikaria, Inc., until its acquisition by Mallinckrodt PLC in April 2015. He had served as Ikaria Inc.’s President and CEO since 2008 and was appointed Chairman of the Board of Directors in October 2009. Mr. Tassé oversaw the spin-out of Bellerophon Therapeutics, Inc. from Ikaria in 2013, creating two companies to best leverage the scientific, financial and marketing strengths of the company. Mr. Tassé is a director of Bellerophon Therapeutics which is listed on NASDAQ.

Until the sale of Ikaria, Mr. Tassé was a member of the Healthcare Leadership Council, a member of the Board of Directors and Health Section Governing Board of the Biotechnology Industry Organization (BIO), where he co-chaired the Bioethics Committee,

and sat on the Regulatory Environment and Reimbursement Committees. Mr. Tassé was a Board Director of the Pharmaceutical Research and Manufacturers of America (PhRMA), where he participated in the FDA and Biomedical Research Committee. Mr. Tassé currently sits on the Business Advisory Council of the Children’s National Medical Center (Sheikh Zayed Institute) in Washington DC.

Prior to joining Ikaria, Mr. Tassé served as General Manager of the Pharmaceuticals and Technologies Business Unit of Baxter International Inc.. Earlier in his career, he held a number of senior management positions at GlaxoSmithKline plc and was Vice President and Regional Director for Australasia from 2001 to 2004. Mr. Tassé is currently a Senior Advisor to two private equity firms specializing in Health Care.

Mr. Tassé holds a B.S. in Biochemistry from the University of Montreal.

**Shaun Thaxter — *Chief Executive Officer***

Mr. Thaxter was appointed Chief Executive Officer of Indivior in November 2014. Since 2009, Mr. Thaxter had led the Reckitt Benckiser Pharmaceuticals, Inc. (RBP) business as CEO with a remit to build a global company through the acquisition of the global marketing rights from Merck, and he ensured its successful integration to accelerate RBP (subsequently renamed, Indivior, Inc.) towards its vision. He spearheaded the successful growth and development of RBP since launching the U.S. SUBOXONE® business in 2003. Following his formal appointment as President of RBP in 2005, Mr. Thaxter led RBP through sustained growth, building a lifecycle management pipeline and expanded addiction franchise that grew from zero to a peak of \$1.5 billion in net revenue. Today, under his leadership, Indivior successfully operates in 46 countries around the world.

Mr. Thaxter joined Reckitt & Colman plc (now Reckitt Benckiser plc) in 1995 as Senior Brand Manager and advanced to Category Manager within the UK Healthcare business. Following the 1999 merger with Benckiser, he was appointed Global Category Manager for the prescription product portfolio.

Mr. Thaxter graduated from King’s College, London with a Joint Honours BSc in Biochemistry and Physiology and undertook his early career with Proctor & Gamble and London International Group.

**Debby Betz - *Chief Corporate Affairs & Communications Officer***

Ms. Betz was appointed to her current role with the Company as Chief Corporate Affairs and Communications Officer in October 2014. Ms. Betz has more than 27 years of industry experience. She began her career with Purdue Pharma L.P. and Stuart Pharmaceuticals and has held various commercial roles in sales management, marketing, training, and sales.

Since joining Reckitt Benckiser in January 2004, she has successfully held a number of Director level roles in Marketing, Commercial Development and Strategic Planning, and Global Corporate Affairs and Communications, which she continues to lead today.

Ms. Betz holds a B.S.B.A. from State University of New York at Oswego.

**Mark Crossley — *Chief Strategy Officer***

Mr. Crossley joined the Company in 2012 as the Global Finance Director with responsibilities for Finance, Information Systems and Procurement. In October 2014, he was appointed to his current position as Chief Strategy Officer.

Prior to joining RBP, Mr. Crossley spent 13 years at Procter & Gamble in both corporate and current business roles including Associate Director Strategic and Business Planning Female Beauty, Associate Director Corporate Portfolio Finance, as well as multiple roles in Corporate Treasury and its Baby Care division. He also enjoyed an eight-year career with various operational and staff assignments in the U.S. Coast Guard.

Mr. Crossley graduated from the U.S. Coast Guard Academy with a BS in Management and Economics,

## **Jon Fogle - *Chief Human Resources Officer***

Mr. Fogle was appointed Chief Human Resources Officer for the Company in October 2014. Mr. Fogle joined Reckitt Benckiser as Human Resources Director for the United States in 2007. In 2010, he was promoted to Global Human Resources Director.

Under his leadership, the Company has grown rapidly from just over 200 employees in three countries to approximately 800 employees in more than 30 countries. Working with the entire leadership team, Mr. Fogle has fostered a strong commitment to developing both RBP's culture and talent.

Prior to joining RBP, Mr. Fogle was Senior Vice President of Human Resources, North America for Capmark Finance Inc. (formerly GMAC Commercial Mortgage Corporation).

Mr. Fogle holds a BS in psychology from Ursinus College and is a SHRM Senior Certified Professional.

## **Tony Goodman - *Chief Business Development Officer***

Mr. Goodman was appointed as the Chief Business Development Officer of the Company in October 2014. Since joining Reckitt Benckiser in May 2006, he has successfully held a number of key positions in Marketing, Managed Care and Global Category; and in Licensing, Mergers and Acquisitions, which he continues to lead today.

Mr. Goodman has more than 22 years of industry experience. Prior to joining RBP, Mr. Goodman held various strategic marketing roles, including Group Product Manager and Director of Managed Health Strategies with Purdue Pharma L.P., and Director of Strategic Marketing and Business Development with PRA International.

Mr. Goodman holds a B.B.A. from Marshall University.

## **Dr. Christian Heidbreder — *Chief Scientific Officer***

Dr. Heidbreder combines 25 years' leadership experience in the neurosciences spanning the academic, governmental, and industrial sectors across Europe and the United States. During his career, Dr. Heidbreder has published over 350 peer-reviewed scientific publications, reviews, book chapters, and published conference proceedings.

Dr. Heidbreder began his career as a researcher at the National Institute on Drug Abuse in Baltimore, at Princeton University, and at the Swiss Federal Institute of Technology in Zürich. Dr. Heidbreder subsequently held positions of increasing responsibility at SmithKline-Beecham Limited's Neuroscience Department in Harlow, GlaxoSmithKline plc's R&D Centre of Excellence for Drug Discovery in Psychiatry in Verona, and Altria Client Services Inc.'s Health Sciences Department in Richmond, Virginia.

Dr. Heidbreder was appointed Global R&D Director at RBP in 2009 with a remit to lead global strategies to drive the development of new pharmacotherapies in the area of addiction and related co-morbidities.

Dr. Heidbreder holds BA, MA, and PhD degrees from the University of Louvain and a Certificate in Strategic Innovation from the Wharton Business School. He is also an Affiliate Professor in the Department of Pharmacology & Toxicology of the Virginia Commonwealth University School of Medicine.

## **Javier Rodriguez — *Chief Legal Officer***

Mr. Rodriguez has been practicing law for over 15 years and has spent more than 10 of those years as in-house counsel in the pharmaceuticals industry.

Mr. Rodriguez began his legal career in 2000 as a litigation associate at the law firm of Thelen Reid & Priest LLP in New York City. In 2004, he joined the legal department at Berlex Laboratories, Inc., a subsidiary of Schering AG, which was subsequently acquired by Bayer AG in 2006. While at Berlex/Bayer, Mr. Rodriguez served as Corporate Counsel to the clinical development function, the U.S. diagnostic imaging business and the oncology and specialized therapeutics global business units. In 2008, Mr. Rodriguez joined Reckitt Benckiser LLC as Senior Counsel to the healthcare category and helped successfully manage the integration of Adams Respiratory Therapeutics, Inc. and its portfolio of over the counter products into the core Reckitt Benckiser business. He also took on increasing responsibility for the legal affairs of RBP as the business and operations of the company grew and evolved. In 2010, he worked alongside Shaun Thaxter on the acquisition of the global (ex-US) marketing rights to the buprenorphine franchise from Merck & Co., Inc. Following the integration of the buprenorphine business and establishment of RBP as a global business, Mr. Rodriguez was appointed VP General Counsel of RBP in 2011, and subsequently took on his current role as Chief Legal Officer of Indivior PLC in

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Mr. Rodriguez obtained his BS in Civil Engineering from Rutgers University and MSE in Structural Engineering from the University of Michigan. He graduated from the University of Pennsylvania with a JD and is admitted to practice law in New York, New Jersey and Virginia (corporate counsel).

**Richard Simkin — *Chief Commercial Officer***

Mr. Simkin has over 20 years’ global commercial business experience. He began his career with Reckitt & Colman plc (now Reckitt Benckiser plc) in 1987 and has held various roles in operations, sales and marketing with increasing responsibility.

Prior to his role with RBP, Mr. Simkin held the position of Global Category Director for one of the core categories within the RB Group where he was responsible for driving strategy and new product development. In addition, he has extensive experience in the healthcare markets ranging from over the counter to prescription products in multiple categories and countries. Mr. Simkin has also held a number of general manager positions within the RB Group, most recently as General Manager, Portugal in 2008.

In 2012, Mr. Simkin was appointed President, North America of RBP and moved to the United States where he has led the U.S. and Canadian teams in successfully navigating the introduction of market competition along with the preparation of pre-launch activities related to the product pipeline.

Mr. Simkin holds an MBA from the University of Lincoln (formerly known as the University of Lincolnshire and Humberside).

**Frank Stier - *Chief Supply Officer***

Mr. Stier was appointed Chief Supply Officer for the Company in October 2014. Mr. Stier joined Reckitt Benckiser in 1996 with roles including Deputy Site Manager and Industrial Customer Service Manager at the Ladenburg factory. He moved to Mannheim in 2003 and held the position of Supply Services Director, Central Europe. In 2010, he joined RBP as Supply Services Director, Europe. In 2011, he was promoted to Global Supply Services Director, then to Global Supply Director in January 2013.

He is the functional head of logistics, demand planning, manufacturing, direct procurement and QA.

Prior to joining RB, Mr. Stier held a variety of positions related to manufacturing and supply with Colgate-Palmolive GMBH, Hamburg.

Mr. Stier holds a degree in Engineering and Business Administration from the University of Hamburg.

**Ingo Elfering - *Chief Information Officer***

Mr. Elfering joined Indivior in November 2014, assuming the role of Chief Information Officer prior to the IPO and demerger from Reckitt Benckiser Group PLC (‘RB’) in November 2015, and was appointed to the Indivior Executive Committee on July 1, 2016.

Mr. Elfering was instrumental in leading the timely and efficient separation from RB’s services and systems, implementing an independently operated IT platform through innovative new initiatives such as Office365, Skype for Business and SAP worldwide. Mr. Elfering’s appointment to the Executive Committee has further reinforced Indivior’s commitment to leveraging strategic IT solutions to further business growth and achieve our vision of ensuring all patients have access to high-quality addiction treatment services.

Mr. Elfering started his career having successfully founded, run and sold an entrepreneurial Digital Health business. He then joined GlaxoSmithKline plc (‘GSK’) holding various roles of increasing responsibility in IT setting strategy for and operating various global IT & Digital Services, then leading Business Transformation in GSK’s cross functional shared services group and lastly driving Disruptive Innovation with a focus on Digital and new Business Models.

## B. Compensation

### Total Compensation for the Chairman and Non-Executive Directors

The table below sets out the total remuneration received by the Chairman and the Non-Executive Directors for the year ended December 31, 2015.

	2015 £'000	2015(1) \$'000
Howard Pien	275.0	404.3
Rupert Bondy	95.0	139.7
Dr. Yvonne Greenstreet	85.0	125.0
A. Thomas McLellan	70.0	102.9
Lorna Parker	70.0	102.9
Daniel J. Phelan	80.0	117.6
Christian Schade	85.0	125.0
Daniel Tassé	75.0	110.3

(1) The amounts have been translated into U.S. dollars from pounds Sterling based upon the exchange rate as certified by the Federal Reserve Bank of New York for customs purposes as of December 31, 2015. These translations are merely for the convenience of the reader and should not be construed as representations that the pounds Sterling amounts actually represent such U.S. dollar amounts or could be converted into U.S. dollars at the rate indicated.

### Compensation of Executive Directors and Senior Managers

The table below sets the remuneration of each of the Executive Directors and Senior Managers for the financial year ended December 31, 2015.

	Base Salary \$'000	Taxable Benefits(1) \$'000	Annual Bonus(2) \$'000	LTIP(3) \$'000	Pension Benefit(4) \$'000	Total \$'000
Shaun Thaxter	730.0	48.9	1,379.7	3,134.8	139.7	5,433.1
Cary Claiborne	465.0	221.7	527.3	—	19.8	1,233.8
All other Senior Managers	2,812,336	378,335	2,657,657	4,907,864	270,176	10,140,048

(1) Taxable benefits consist primarily of healthcare. For Cary Claiborne benefits included \$194,000 of relocation costs incurred and agreed by the Company as part of the terms of his appointment in November 2014.

(2) Cash payment for performance during the year.

(3) Value of the 2012 RB LTIP which was converted into Indivior shares upon completion of the Demerger. Performance was assessed up to December 31, 2015 and the value shown has been based on the three-month average share price to December 31, 2015 and has been converted to US\$ using the US\$/GB£ fx rate on December 31, 2015 of GB£1 = \$1.5285. The actual value of awards will be determined when the awards vest in May 2016.

(4) Pension benefits in the year comprised profit sharing contributions into the U.S. qualified 401(K) plan, 401(K) matching, contributions to a non-qualified plan and cash.

### Indivior Long-Term Incentive Plan ("LTIP")

Conditional awards were made under the LTIP to the Executive Directors on March 11, 2015.

	Date of award	Maximum number of shares under award	Market price at date of award	Face value(1) \$'000	Performance period	Normal vesting date
Shaun Thaxter	March 11, 2015	1,659,091	175p	4,278.4	Jan 2015 – Dec 2017	March 11, 2018
Cary Claiborne	March 11, 2015	1,056,818	175p	2,725.3	Jan 2015 – Dec 2017	March 11, 2018

1. The face value of the awards has been calculated using the market price at the date of the award and converted to US\$ using the US\$/GB£ exchange rate on December 31, 2015 of GB£1 = \$1.5285.
2. Shaun Thaxter and Cary Claiborne received awards with a face value of 600% of salary; for Cary Claiborne this included an enhanced award of 100% salary as part of the terms of his appointment.

## Pensions

Prior to the Demerger, the RB Group operated a number of defined benefit and defined contribution pension schemes around the world covering many of its employees, which are principally funded. Following the Demerger, we operated pension schemes which are mainly defined contribution schemes. The cost of providing pensions to employees who

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are members of defined contribution schemes is charged to the income statement as contributions are made. The Group has no further payment obligations once the contributions have been made. An exception is a defined benefit scheme in Germany operating as a book reserve scheme.

Executive Directors may receive contributions into a defined contribution scheme, including a cash allowance and pension benefits in the form of profit-sharing contributions into the U.S. qualified 401(K) plan, with the Company matching on 401(K) elected deferrals, or a combination thereof.

In 2015, the Chief Executive Officer received pension contributions of 17.5% of salary plus any Company matching on 401K elected deferrals. The Chief Financial Officer received pension contributions of profit-sharing contributions of 4% of pay, plus any Company match of 75% on elected deferrals up to 4.5% of pay.

## Indivior Share Plans

We have established the following plans, the key terms of which are summarized below. However, Indivior intends to review its existing employee share arrangements in 2016 and may, accordingly, seek shareholder approval of a new arrangement as a result.

### *The Indivior LTIP*

The LTIP was adopted by the Board on November 5, 2014.

### *Administration of the LTIP*

The LTIP is administered by the Remuneration Committee or, in the case of awards not being made to directors, such other committee as authorized by the Company.

### *Eligibility*

The committee may select any employee of the Indivior Group, including any executive director, to participate in the LTIP.

### *Awards*

Awards may be granted over ordinary shares and will normally take one of three forms:

- a conditional award, which is a deferred right to receive ordinary shares;
- an option to acquire ordinary shares at a price set by reference to their market value at the grant date; or
- an option to acquire ordinary shares for no cost or a nominal amount.

Awards may be satisfied by the issue of new ordinary shares, the transfer of ordinary shares held in treasury or the purchase of ordinary shares in the market.

Awards are personal to the participant and may not be transferred except on death. No payment is required for the grant of an award.

Awards may only be granted within 42 days following: the announcement of the Company's results for any period; the removal of any restrictions imposed on the Company which have previously prevented an award from being granted; any date on which changes to legislation or regulations affecting share plans are announced or made; or at any other time if the committee considers that exceptional circumstances exist. No awards may be granted under the LTIP after November 5, 2024.

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*Individual limit*

There is a limit on the market value (measured at the time of grant) of ordinary shares over which awards may be granted to an individual in any financial year of the Company of ten times the individual's basic salary.

*Plan limits*

The LTIP is subject to the limit that on any date, the aggregate nominal amount of ordinary shares that may be allocated under the LTIP may not, when added to the nominal amount of ordinary shares allocated in the previous 10 years under all employee share plans of the Indivior Group, exceed 10% of the then equity share capital of the Company.

For these purposes, ordinary shares are treated as allocated when rights to acquire or obtain them are granted and otherwise when they are issued or transferred. Rights which lapse, by reason of non-exercise or otherwise, cease to count. No account will be taken of (i) ordinary shares which are acquired by purchase in the market (rather than by subscription or from treasury); and (ii) ordinary shares which an employee purchases at market value using his own funds.

*Performance targets*

Each award may, or in the case of Executive Directors of the Indivior Group must, be subject to one or more performance targets which will determine whether and to what extent the participant will receive ordinary shares. Performance targets are normally measured over a period of not less than three years. For executive directors the performance targets are measured on one occasion only; there is no re-testing.

The committee may change a performance target from time to time if events happen as a result of which the committee considers it fair and reasonable to make the change. Any change to an existing performance target must not have the effect, in the opinion of the committee, of making the target materially easier or more difficult to achieve.

The committee may set different performance targets from year to year and for different awards.

*Vesting of awards*

Awards will normally only vest in accordance with the performance targets at the end of the performance period or, if later, three years after the date of grant.

Each award may, to the extent that it vests, be adjusted by the committee to reflect the dividends paid on the vested shares during the period starting with the start of the performance period and ending with the date on which the award vests or the option is exercised. The adjustment will be made, as the committee may decide, either by paying an amount equal to the dividends in cash or by applying that amount in purchasing additional Shares.

In the case of conditional awards, the ordinary shares are released automatically upon vesting while in the case of options, the award becomes exercisable on vesting and may be exercised during such period as the committee may have specified at the time of grant.

Alternatively, the committee may decide to satisfy awards on vesting by a cash payment.

The LTIP includes clawback and *malus* provisions under which the committee may reduce and/or recover awards. Awards may be adjusted prior to their exercise if there is a material misstatement of our results for any of the financial years during a performance

period or there is misconduct by any person which affects the extent to which the performance target would be satisfied (*malus*). Where LTIP awards have vested, the Remuneration Committee has the discretion to ‘claw back’ awards up to the fifth anniversary of the grant of the awards in the circumstances described above.

*Termination of employment*

If a participant ceases to be employed within the Indivior Group for any reason other than misconduct, he is entitled to retain any awards which have vested.

If a participant ceases to be employed within the Indivior Group, his unvested awards lapse unless he leaves for a permitted reason. A permitted reason is death, injury, ill-health, disability, redundancy, retirement with his employer’s

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agreement, the sale of the company or business in which the participant works and such other reason as the committee may decide.

Where a participant leaves for a permitted reason, his award will be reduced on a time-apportioned basis by reference to the proportion of the performance period during which the participant was in employment unless the committee decides otherwise. The award will then vest (if at all) according to the performance targets measured over the normal performance period unless the committee decides otherwise.

In the case of death, the performance targets will not apply but the award will be reduced on a time pro-rated basis. If the award is not subject to a performance target, the award will vest on the normal vesting date unless the committee decides otherwise. Options that have already vested, or which vest following termination of employment, may be exercised within the 12 months following termination or, if later, vesting.

*Change of control*

Special rules apply in the event of a change of control, including a change of control resulting from a plan of arrangement pursuant to Part 26 of the Companies Act or a takeover.

Unless the committee decides otherwise, awards will vest (if at all) by measuring the performance targets up to the date of the relevant event and then reducing the resulting number of ordinary shares on a time-apportioned basis by reference to the proportion of the performance period prior to the date of the relevant event.

In the event of a change of control, participants may surrender their awards in return for substitute awards over shares in the acquiring company or another company. The committee may allow awards to vest on a similar basis in the event of a demerger or other important events.

*Listing*

The Company will apply for any new ordinary shares issued under the LTIP to be admitted to the Official List and for permission to trade in those ordinary shares. Ordinary shares issued under the LTIP will rank equally in all respects with existing ordinary shares except for any rights attaching to the ordinary shares by reference to a record date prior to the date of allotment.

*Variation of Capital*

On any variation of the Company’s share capital, or in the event of a demerger, special dividend or other similar event which affects the market price of ordinary shares, awards may be adjusted in such manner as the committee considers appropriate.

*Benefits non-pensionable*

Benefits under the LTIP will not form part of a participant’s remuneration for pension purposes.

*Amendments*

The committee may amend the LTIP, or the terms of awards, to take account of changes to any applicable legislation or to obtain or maintain favorable tax, exchange control or regulatory treatment for participants or for any company in the Indivior Group including, if appropriate, setting up separate sub-plans.

Except as described above or for minor amendments designed to ease the administration of the LTIP, no amendment which is to the advantage of existing or future participants may be made, without the prior approval of the Company in general meeting, to those provisions dealing with eligibility, individual or plan limits, the terms of awards, the adjustment of awards or the power of amendment.

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*Hm Revenue & Customs in the United Kingdom (“HMRC”) registered options*

The LTIP contains a part which allows options to be granted in satisfaction of the conditions of Schedule 4 of the Income Tax (Earnings and Pensions Act) 2003, as amended (the “ITEPA”).

***The Indivior Savings-Related Share Option Plan (the “Sharesave Plan”)***

The Sharesave Plan was adopted by the Board on November 5, 2014.

*Administration*

The Sharesave Plan is administered, in accordance with its rules, by the Board or a duly authorized committee thereof .

*Eligibility*

All UK resident employees (including Executive Directors working 25 hours or more per week) who have five or more years of continuous service with the Company, or any subsidiary nominated to join in the Sharesave Plan, are eligible to participate. The Board has the discretion to reduce or eliminate the period of qualifying service and/or to invite other employees of the Indivior Group to participate.

*Options*

Options will entitle the holder to acquire ordinary shares. Options will be personal to the participant and may not be transferred. No payment will be required for the grant of an option. No options will be granted under the Sharesave Plan after 30 November 2024.

*Timing*

Invitations to participate will normally be issued within 30 days (or 42 days if applications are scaled back) following: the announcement of the Company’s results for any period; the coming into force of any amendment to Schedule 3 to ITEPA which affect savings; the date of any general meeting of the Company; the issue of a new Save-As-You-Earn prospectus; or at any other time if the Board determines that the circumstances are sufficiently exceptional to justify the grant of an option.

*Exercise price*

The price payable per Ordinary Share on exercise of an option granted under the Sharesave Plan may not be less than an amount equal to 80% of the market value of an Ordinary Share for such dealing day or days as the Board may select in the 30 day period immediately preceding the date of grant, or, if greater, the nominal value of an Ordinary Share.

*Individual limit*

Each eligible employee will be given the opportunity to apply for an option, the total exercise price of which does not exceed the monthly contributions and bonus repayable under the Sharesave contract to be entered into as a condition of the grant of the option. The aggregate maximum monthly contribution payable by an employee under all Sharesave contracts linked to the Sharesave Plan may not exceed such sum as may from time to time be permitted by statute and approved by the directors.

On any date, the aggregate nominal amount of new ordinary shares in respect of which options may be granted may not, when added to the nominal amount of any new ordinary shares allocated in the previous 10 years under all employee share plans of the Indivior Group, exceed 10% of the equity share capital of the Company.

For these purposes, ordinary shares are allocated when they are issued or, if earlier, when the right to receive or acquire the ordinary shares is conferred on the employee. Rights which lapse, by reason of non-exercise or otherwise, cease to count. No account is taken of ordinary shares which are acquired by purchase rather than by subscription except where

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such ordinary shares were first issued to an employee trust for the purpose of satisfying a participant's rights. No account is taken of ordinary shares which an employee purchases using his own funds except on the exercise of an option under an option plan or where such ordinary shares are acquired for an amount which is less than the market value of a fully paid up share of the same class.

### *Exercise of options*

Options will normally be exercisable in whole or in part during the period of six months starting on the bonus date. The bonus date is the date on which the bonus under the related Sharesave contract is payable. In normal circumstances this will be the third or fifth anniversary of the starting date of the Sharesave contract and will depend upon the election made by the participant at the time of grant.

Whenever an option is exercised, it may only be exercised to the extent of the amounts then paid under the related Sharesave contract and any interest or bonus payable under the contract.

### *Termination of employment*

If the participant dies, his personal representatives may exercise his options in the 12 months following his death or, if earlier, the bonus date. If a participant ceases to be employed within the Indivior Group for a permitted reason, the participant may exercise his options in the six months following the termination of his employment. A permitted reason is injury, disability, redundancy, retirement, the sale outside the Indivior Group of the company or business in which the participant works or, in the case of any option which the participant has held for at least three years, where the employee does not return after maternity leave. If a participant ceases to be employed for any other reason, his option will lapse.

For these purposes, a participant will not be treated as ceasing to be employed within the Indivior Group for so long as he remains employed by a company which is an associated company of the Company.

### *Change of control*

The exercise of options will also be permitted in the event of a change in control, a reorganization, an amalgamation or a voluntary winding up of the Company. In the event of a change in control of the Company, participants may surrender their options in return for substitute options over shares in the acquiring company.

### *Listing*

Application will be made for admission to the Official List of new ordinary shares issued under the Sharesave Plan and for permission to trade in those ordinary shares. Ordinary shares issued on the exercise of options will rank equally in all respects with existing ordinary shares except for rights attaching to ordinary shares by reference to a record date prior to the date of allotment.

### *Variation of Capital*

If there is a variation in the share capital of the Company, the Board may adjust options in such manner as it determines to be appropriate.

### *Benefits non-pensionable*

Benefits under the Sharesave Plan will not form part of a participant's remuneration for pension purposes.

### *Amendments*

The Board may make such amendments to the Sharesave Plan as are either necessary or desirable to ensure the Sharesave Plan continues to satisfy the statutory requirements for such plans or to take account of changes to applicable legislation. The Board may also make such amendments to the Sharesave Plan and to any option as may be necessary or

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desirable to obtain or maintain favorable tax, exchange control or regulatory treatment for participants or for any company in the Indivior Group.

Except as described above or for amendments designed to ease the administration of the Sharesave Plan, no amendment which is to the advantage of employees or participants may be made to those provisions dealing with eligibility, individual or Sharesave Plan limits, the terms of options or the adjustment of options without the prior approval of the Company in general meeting.

### ***The Indivior PLC US Employee Stock Purchase Plan (the "ESPP")***

The ESPP was approved by shareholders at the Annual General Meeting of the Company held on May 11, 2016.

### *Administration*

The ESPP is operated and administered by our Board or a duly authorized committee thereof.

### *Eligibility*

All individuals who are employees of the Company or participating subsidiaries are eligible to participate in the ESPP. An employee is ineligible if (i) upon enrolment in the ESPP, they would own directly or indirectly an aggregate of 5% or more of the combined voting power or value of the Company or a subsidiary's shares; (ii) they work 20 hours a week or less; or (iii) they work for five months or less of the calendar year.

### *Options*

Under the ESPP participants are granted options to purchase shares from the Company. As of each enrolment date, each participant is automatically granted an option to purchase a number of shares representing their savings but subject to a maximum number of shares with a market value at the date of grant of \$10,000. Options may either be options to subscribe for newly-issued shares or for existing shares purchased in the market. The rights of the participant shall not be transferable. No option shall be granted under the ESPP after the date as of which the ESPP is terminated by the Board in accordance with the termination provisions or, in any event after March 31, 2026.

### *Timing*

Eligible employees will automatically be enrolled in the ESPP. Automatic enrolment will occur every six months, commencing with the first regular payroll period on or after each successive January 1 or July 1 (each an 'Accumulation Period') or at such other times as the Board may determine. Any eligible employee may consent to enrolment in the ESPP by completing and signing an enrolment form (which authorizes the payroll deductions).

### *Exercise Price*

The exercise price shall be eighty-five percent (85%) of the lower of (i) the fair market value of a share on the enrolment date on which the option is granted; or (ii) the fair market value of a share on the purchase date but, in the case of newly issued shares, not lower than the par value of a share. The Board may establish a different purchase price, though it may not be less than (i) the purchase price set forth above and (ii) in the case of newly issued shares, than the par value per share. The Board must determine a different purchase price at least thirty (30) days prior to the Accumulation Period for which it is applicable.

To participate in the ESPP, eligible employees must elect and authorize to have deductions made from his pay on each payday during the Accumulation Period to which the enrolment form relates. Each participant designates a percentage of their base earnings to be deducted. The minimum deduction is one percent (1%) and the maximum is ten percent (10%), of base earnings per Accumulation Period.

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*Plan limits*

The Plan will be subject to the limit that on any date, the aggregate number of new shares which may be issued (or Treasury shares transferred) under the Plan may not, when added to the number of new shares allocated in the previous 10 years under all employee share schemes of the Company, exceed 10% of the equity share capital of the Company. For these purposes, shares are allocated when rights to acquire or obtain them are granted and otherwise when they are issued. Rights which lapse, by reason of non-exercise or otherwise, cease to count.

*Exercise of awards*

An award will normally be deemed to have been exercised on the specific trading day during an Accumulation Period on which shares are purchased under the ESPP. Whenever an award is exercised it will be for the number of whole shares which the funds accumulated in their account at such purchase date will purchase at the applicable purchase price.

*Termination of employment*

Participation in the ESPP terminates immediately when a participant ceases to be employed with the Company or a participating subsidiary for any reason whatsoever, including but not limited to termination of employment, whether voluntary or involuntary, or on account of death, disability or retirement, or if the participating subsidiary employing the participant ceases to be a participating subsidiary. As soon as administratively practicable after termination, the Company shall pay the participant or legal representative all amounts accumulated in the participant's account.

*Change of Control*

A participant's accumulated savings at the relevant date will be used to exercise his options in the event of a change of control, scheme of arrangement or winding up of the Company.

*Listing*

Application will be made for admission to the Official List of any new shares issued under the ESPP and for permission to trade in those shares. Shares issued on the exercise of options will rank equally in all respects with existing shares except for rights attaching to shares by reference to a record date prior to the date of allotment.

*Variation of Capital*

In the event of any reorganization or variation of capital the Board shall make such adjustment to the number, kind and purchase price of the shares available under the ESPP as is deemed appropriate. In the event of liquidation of the Company, each option to purchase shares shall terminate but the participant holding such an option shall have the right to exercise their option prior to such termination.

*Benefits non-pensionable*

Benefits under the ESPP do not form part of a participant's remuneration for pension purposes.

*Amendments*

The Board may amend, alter or terminate the ESPP at any time, provided that no amendment would (i) amend or modify the

ESPP in a manner requiring stockholder approval under Code Section 423 or the requirements of any securities exchange on which the shares are traded; or (ii) amend the provisions relating to the persons to whom, or for whom, securities, cash or other benefit are provided under the Plan, limitations on the number or amount of the benefits subject to the scheme, the maximum entitlement for any one participant and the basis for determining a participant's entitlement to, and the terms of, the benefits to be provided and for the adjustment thereof if there is a capitalization issue, rights issue or open offer, sub-division or consolidation of shares or reduction of capital or any other variation of capital to the advantage of participants (except for minor amendments to benefit the administration of the Plan, to take account of a change in legislation or to obtain or maintain favorable tax, exchange control or regulatory treatment for participants in the Plan or for the Company or for members of its Group) unless in each case it has been approved by shareholders in general meeting. Subject to the preceding paragraph, the committee, appointed by the Board, shall have the power to amend the ESPP and perform such acts as it deems necessary to promote the best interests of the Company.

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***The Indivior Global Stock Profit Plan (the “GSPP”)***

The GSPP has been established as a global share purchase plan to provide benefits to employees outside of the United Kingdom, and was adopted by the Board on November 30, 2014.

*Administration*

The GSPP is administered, in accordance with its rules, by the Board or a duly authorized committee thereof.

*Eligibility*

All individuals who are employees or directors of the Company and participating subsidiaries are eligible to participate in the GSPP. The Board, however, may determine that certain employees will not be eligible to participate in the GSPP by virtue of the fact that their participation is prohibited under the laws and/or regulations of their jurisdiction or because the likely costs involved in order to enable participation are not considered justifiable by the Board.

*Awards*

Awards under the GSPP are either options or share appreciation rights. Options may be granted either to the individual participant or to a trustee on his behalf. Options will entitle the participant to acquire ordinary shares. Options may be either options to subscribe for new ordinary shares or options to purchase existing Shares.

Share appreciation rights will be granted in jurisdictions where the Company is unable to grant options due to the prohibitive laws and/or regulations of that jurisdiction. A SAR is a right to receive a cash sum equal in value to the number of ordinary shares that the participant could have acquired if the participant had been able to receive and exercise an option for Shares to that value.

Awards are personal to the participant and may not be transferred. No payment will be required for the grant of an award. No awards will be granted after 30 November 2024.

*Timing*

Invitations to participate will only be issued during the period of 30 days (or 42 days if applications are scaled back) following: the announcement by the Company of its results for any period or the issue by the Company of any prospectus, listing particulars or other document containing equivalent information relating to shares; the date of any general meeting of the Company or at other times in exceptional circumstances.

*Exercise price*

The exercise price (or, in the case of a SAR, the notional exercise price) may be not less than 80% of the average of the market values, as derived from the Daily Official List of the London Stock Exchange, of an Ordinary Share on the date of an invitation or, if so determined by the Board, on a prior day not earlier than five dealing days before such invitation or the average for the three or the five consecutive dealing days preceding the relevant date.

*The savings contract*

In order to participate in the GSPP, an eligible employee must enter into a savings contract with a local savings body approved by the Company, under which the employee agrees to make monthly contributions of between £5 and £500 (or the equivalent in local currency) (or such higher amount as the Board may determine) for a period of three years. Interest (if any) is payable at the end of the savings period.

*Plan limits*

On any date the aggregate nominal amount of new ordinary shares in respect of which awards may be granted may not, when added to the nominal amount of any new ordinary shares allocated in the previous 10 years under all employee share plans of the Indivior Group, exceed 10% of the equity share capital of the Company.

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For these purposes ordinary shares are allocated when they are issued or if earlier when the right to receive or acquire the ordinary shares is conferred on the employee. Rights which lapse by reason of non-exercise or otherwise cease to count. No account is taken of ordinary shares which are acquired by purchase rather than by subscription except where such ordinary shares were first issued to an employee trust for the purpose of satisfying a participant’s rights.

*Exercise of awards*

An award will normally only be exercisable for a period of six months commencing on the completion of the related savings contract (three years after its commencement) and, if not exercised by the end of that period, the award will lapse.

Whenever an award is exercised, it may normally only be exercised to the extent of the amounts then repayable under the savings contract together with any interest or bonus.

*Termination of employment*

If the participant dies, his personal representatives may exercise his awards in the 12 months following his death or, if earlier, the completion date of the savings contract. If a participant ceases to be employed within the Indivior Group for a permitted reason, the participant may exercise his awards in the six months following the termination of his employment. A permitted reason is injury, ill-health, disability, redundancy, retirement or the sale outside the Indivior Group of the company or business in which the participant works. If the participant ceases to be employed in other circumstances, his awards will lapse.

For these purposes, a participant will not be treated as ceasing to be employed for so long as he remains employed by a company which is an associated company of the Company.

*Change of control*

In the event of a change of control (whether as a result of an offer or a scheme of arrangement under Part 26 of the Companies Act) or a voluntary winding up of the Company all awards may be exercised and, if not exercised within the specified period, will lapse. In the event of a change of control, participants may surrender their awards in return for substitute awards over shares in the acquiring company.

If the change of control forms part of a transaction as a result of which at least 50% of the shareholders in the acquiring company will be the same as the shareholders of the Company and participants are offered compensation (whether in the form of awards over shares in the acquiring company or otherwise), the Board may decide that awards which have not yet become exercisable will not become exercisable as a result of the change of control.

*Listing*

Application will be made for admission to the Official List of new ordinary shares issued under the GSPP and for permission to trade in those ordinary shares. Ordinary shares issued on the exercise of options will rank equally in all respects with existing ordinary shares except for rights attaching to ordinary shares by reference to a record date prior to the date of allotment.

*Variation of Capital*

If there is a variation in the share capital of the Company, the Board may adjust options in such manner as it determines to be appropriate.

*Benefits non-pensionable*

Benefits under the GSPP will not form part of a participant’s remuneration for pension purposes.

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*Amendments*

The Board may make such amendments to the GSPP as are either necessary or desirable to ensure the GSPP continues to satisfy the statutory requirements for such schemes or to take account of changes to applicable legislation. The Board may also make such amendments to the GSPP and to any option as may be necessary or desirable to obtain or maintain favorable tax, exchange control or regulatory treatment for participants or for any company in the Group. In particular the Board may adopt sub-plans with particular rules for specific jurisdictions where necessary or desirable to take account of the laws in those jurisdictions.

Except as described above or for amendments designed to ease the administration of the GSPP, no amendment which is to the advantage of employees or participants may be made to those provisions dealing with eligibility, individual or GSPP limits, the terms of options or the adjustment of options without the prior approval of the Company in general meeting.

*Trust*

In 2016, we established an employee benefit trust with independent trustees to purchase and hold shares in Indivior in trust to be used to satisfy awards and/or options granted to eligible employees under our share plans established from time to time.

**C. Board Practices**

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the [·]’s rules for domestic U.S. issuers, provided that we disclose which requirements we are not following and describe the equivalent home country requirement. However, notwithstanding our ability to follow the corporate governance practices of our home country, the United Kingdom, we have elected to apply the corporate governance rules of the [·] that are applicable to U.S. domestic registrants that are not “controlled” companies.

**Board of Directors**

The Board is committed to the highest standards of corporate governance and maintaining a sound framework for the control and management of the business. The Board is responsible for leading and controlling the Indivior Group and has overall authority for the management and conduct of our business and our strategy and development. The Board is also responsible for ensuring the maintenance of a sound system of internal control and risk management (including financial, operational and compliance controls, and for reviewing the overall effectiveness of systems in place) and for the approval of any changes to the capital, corporate and/or management structure of the Indivior Group. As at the date of this registration statement, the Board comprises 10 members; the Chairman, seven Non-Executive Directors and two Executive Directors. The Board regards the Chairman and each of the other Non-Executive Directors as independent for the purposes of the rules of the [·] for domestic U.S. issuers. Rupert Bondy is the Company’s Senior Independent Director.

**Committees of the Board**

Our Board has established an Audit Committee, a Remuneration Committee, a Nomination & Governance Committee and a Science & Policy Committee. Each of the Board’s committees have Terms of Reference which are reviewed annually and agreed by the Board.

*Audit Committee*

The Audit Committee has responsibility for, among other things, the monitoring of the financial integrity of the financial statements of the Indivior Group and the involvement of our external auditors in that process. It focuses in particular on compliance with accounting policies and ensuring that an effective system of internal financial controls is maintained. The ultimate responsibility for reviewing and approving the annual report and accounts and the half-yearly reports remains with the Board. The Audit Committee normally meets at least four times a year at the appropriate times in the reporting and audit cycle.

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The responsibilities of the Audit Committee set out in its Terms of Reference cover external audit, internal audit, financial and narrative reporting, internal controls and risk management and the systems and procedures for whistleblowing and detecting fraud. The Terms of Reference also set out the authority of the Audit Committee to carry out its responsibilities.

SEC rules and regulations and the listing standards of the [·] require that the Audit Committee comprises at least three members who are all independent and possess requisite financial literacy and includes one member who qualifies as an “audit committee financial expert.” The members of the Audit Committee are Christian Schade, Dr. Yvonne Greenstreet and Daniel Tassé. Mr. Schade is the chair of the Audit Committee. Our Board has determined that each member is independent and possesses the required level of financial literacy. Our Board has determined that Mr. Tassé qualifies as an “audit committee financial expert” as defined in the SEC rules and satisfies the financial sophistication requirement of the [·].

***Remuneration Committee***

The Remuneration Committee is responsible for determining the specific remuneration packages for the Chairman. It is also responsible for determining general remuneration policy and recommending and monitoring the level and structure of remuneration for senior executives. The Remuneration Committee meets at least twice a year.

The responsibilities of the Remuneration Committee set out in its Terms of Reference cover setting levels of remuneration and determination and monitoring of the remuneration policy, approval of the design of, and determining targets for, performance-related pay schemes and approval of the design and implementation of all long-term incentive arrangements. The Terms of Reference also set out the reporting responsibilities and the authority of the Remuneration Committee to carry out its responsibilities.

The members of the Remuneration Committee are Daniel J. Phelan, Rupert Bondy, Lorna Parker and Daniel Tassé, each of whom is a non-executive director. Mr. Phelan is the chair of the Remuneration Committee. Our Board has determined that each member is independent under the listing standards of the [·] and the applicable rules and regulations of the SEC.

***Nomination & Governance Committee***

The Nomination & Governance Committee is responsible for considering and making recommendations to the Board in respect of appointments to the Board and the Board committees. It is also responsible for keeping the structure, size and composition of the Board under regular review, and for making recommendations to the Board with regard to any necessary changes. The Nomination & Governance Committee’s Terms of Reference cover succession planning, taking into account the skills and expertise that will be needed on the Board in the future. The Nomination & Governance Committee meets at least twice a year. The Nomination & Governance Committee also has responsibility for oversight of the Group’s Corporate Compliance Program.

The members of the Nomination & Governance Committee are Rupert Bondy, Dr. A. Thomas McLellan, Lorna Parker and Daniel J. Phelan. Rupert Bondy is the chair of the Nomination & Governance Committee. Our Board has determined that each member is independent under the listing standards of the [·] and the applicable rules and regulations of the SEC.

***Science & Policy Committee***

The Science & Policy Committee is responsible for providing assurance to the Board regarding the quality, competitiveness and integrity of the Company’s research and development activities. It is also responsible for reviewing the approaches adopted in respect of the Company’s chosen therapy area of addiction and its co-morbidities, reviewing the scientific technology and research and development capabilities deployed within the business, assessing the decision-making processes for research and development projects, reviewing benchmarking against industry and scientific best practices and reviewing relevant and important bioethical issues and

assisting in the formulation of appropriate policies in relation to such issues.

The members of the Science & Policy Committee are Dr. Yvonne Greenstreet, Dr. A. Thomas McLellan and Christian Schade. The Science & Policy Committee is chaired by Dr. Yvonne Greenstreet.

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**Code of Ethics and Ethical Guidelines**

Our Board has adopted a Code of Business Conduct that describes our commitment to, and requirements in connection with, ethical issues relevant to business practices and conduct.

**Indemnification of Directors and Senior Managers**

Each of the Directors and Senior Managers has the benefit of indemnity insurance maintained by the Indivior Group on their behalf indemnifying them against liabilities they may potentially incur to third parties as a result of their office as director or senior manager.

**D. Employees**

As at June 30, 2016, the Indivior Group employed 909 people worldwide. Of these, 563 were located in North America and 346 were located in the rest of the world. Of our 909 employees, approximately 408 were employed in commercial sales and marketing positions; 138 were employed full time in research and development, clinical and regulatory positions; 196 were employed in general management and other support positions; 86 were employed in medical affairs positions; and, 81 were employed in supply positions.

Certain of our employees are represented by unions or works councils. We believe that we have a good relationship with its employees and with the unions and works councils that represent certain employees.

**E. Share Ownership**

See “ Item 7. Major Shareholders and Related Party Transactions.”

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**ITEM 7: MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

**A. Major Shareholders**

The following table sets forth information with respect to the beneficial ownership of our ordinary shares, based on notifications made by such shareholders under the UK Financial Conduct Authority’s Disclosure and Transparency Rules as of June 30, 2016 by:

- each of our directors, executive officers and senior managers individually and as a group; and
- each person, or group of affiliated persons, who is known by us to own beneficially more than 3% of our ordinary shares

As of June 14, 2016, 326,351,657 of our shares were held in the United States, comprising 45.3% of our issued share capital. In addition, as of June 14, 2016, we had 84 shareholders of record in the United States.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security.

These shares, however, are not included in the computation of the percentage ownership of any other person.

All ordinary shares have the same voting rights.

NAME AND ADDRESS OF BENEFICIAL OWNER	NUMBER OF SHARES BENEFICIALLY OWNED	TOTAL PERCENTAGE
<b>Major Shareholders:</b>		
Scopia Capital Management LP	87,863,509	12.19%
Fidelity Management & Research LLC	36,483,568	5.07%
Artemis Investment Management	33,290,772	4.62%
Janus Capital Management LLC	35,318,654	4.92%
Harbor International Fund	48,650,545	6.77%
Prudential plc	37,217,232	5.17%
<b>Directors</b>		
Rupert Bondy	16,183	*
Cary Claiborne	85,780	*
Dr. Yvonne Greenstreet	4,598	*
Dr. A. Thomas McLellan	5,951	*
Lorna Parker	4,734	*
Daniel J. Phelan	8,056	*
Howard Pien	36,531	*
Christian Schade	4,680	*
Daniel Tassé	10,112	*
Shaun Thaxter	833,716	*
<b>Senior Management</b>		
Debby Betz	65,400	*
Mark Crossley	124,192	*
Jon Fogle	65,500	*
Tony Goodman	75,167	*
Dr. Christian Heidbreder	55,167	*
Javier Rodriguez	62,204	*
Richard Simkin	170,866	*
Frank Stier	33,087	*
Ingo Elfering	*	*
<b>All Directors and Senior Managers as a Group</b>	<b>1,671,924</b>	<b>0.23%(1)</b>

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\* Represents beneficial ownership of less than one percent of our outstanding ordinary shares.

(1) Based on 720,597,566 shares outstanding as of June 14, 2016, which comprise our entire issued and outstanding share capital as of that date.

On September 26, 2014, we acquired the specialty pharmaceutical business unit from RB as part of the Demerger in December 2014, following which it has been operated as a standalone business, resulting in a significant change in the percentage of our outstanding ordinary shares owned by major shareholders.

Changes in the percentage ownership by major shareholders since the Demerger are set out below. The information in the table below is based on the notifications made by such shareholders as of the dates indicated under the UK Financial Conduct Authority’s Disclosure and Transparency Rules.

	30, 2016	31, 2015	31, 2014
<b>Shareholder</b>			
Scopia Capital Management LP	12.19%	5.65%	*
Fidelity Management & Research LLC	5.06%	5.07%	*
Artemis Investment Management	4.62%	*	*
Janus Capital Management LLC	4.90%	7.99%	*
Harbor International Fund	6.75%	6.77%	*
Prudential plc	5.16%	5.17%	*
JAB Holdings B.V.	*	*	10.67%

\* Less than 3%

## B. Related Party Transactions

For the period prior to the Demerger, transactions with former owners include certain expenses that were allocated to the Group prior to the Demerger, transfers of cash to the former owner in accordance with the former owner’s cash pooling program, and dividends to former owners. Allocations from the former owners to the Group included corporate allocations in Selling, distribution and administrative expense of \$28 million and \$55 million in 2014 and 2013, respectively.

Historically, the RB Group has provided services to, and funded certain expenses of, the Indivior Group. These services and expenses include finance, legal, tax, treasury, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. These service charges and corporate expense allocations are based on a number of allocation measures including headcount, revenue and operating profit. Generally, such amounts have been deemed to have been paid by the Indivior Group in the year in which the costs are recorded. Please see “Item 10.C. — Material Contracts” for further information.

In connection with the Demerger, RB and the Group provided certain mutual indemnities relating to liabilities, including certain tax and legal liabilities, which relate to our respective businesses subsequent to the Demerger.

Also, the Group indemnified RB for taxes and related losses that may result from any organizational restructuring or sale of by the Group causing the Demerger to lose qualification as a tax-free transaction. This indemnity is effective for two years following the Demerger.

The notes to our consolidated historical financial information, included in “Item 18. Financial Statements,” set out the expenses included in our consolidated statement of income for corporate allocations.

## C. Interests of Experts and Counsel

Not applicable.

## ITEM 8: FINANCIAL INFORMATION

### A. Consolidated Statements and Other Financial Information

See “Item 18. Financial Statements” for a list of all financial statements filed as part of this registration statement.

On October 23, 2015, the Company paid an interim dividend relating to the financial year ending December 31, 2015. The first interim dividend of 3.2 cents per ordinary share (Sterling equivalent 2.08 pence per ordinary share) was paid to shareholders on the register as at September 18, 2015. The exchange rate applied to the first interim dividend was US\$1.53966 / £1.

On February 18, 2016, the Board announced the payment of a second interim dividend relating to the financial year ended December 31, 2015. The second interim dividend of 9.5 cents per ordinary share (Sterling equivalent 7.3 pence per ordinary share) will be paid on July 29, 2016 to shareholders on the register at June 17, 2016. The exchange rate applied to the second interim dividend was US\$1.2995 / £1.

The dividend payments are consistent with the commitment in the prospectus, issued for Demerger in November 2014, to pay 40% of net income as a dividend relating to the financial year ended December 31, 2015.

The Board, as indicated in the prospectus for the Demerger in November 2014, has considered future dividend policy in the

light of the Company's current financial position, strategy and prospects and has confirmed that it does not expect to pay ordinary dividends for the foreseeable future.

On May 3, 2016, we published our unaudited condensed consolidated interim financial statements for the three-month period ended March 31, 2016. We present such financials beginning on page F-2 of this registration statement.

## **Legal Proceedings**

Save as disclosed in this paragraph, there are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Company is aware), which may have, or have had during the 12 months prior to the date of this document, a significant effect on the Company's and/or our financial position or profitability. In addition to the proceedings set out in this section, the Company is involved in other legal proceedings and claims in the ordinary course of business.

### ***ANDA and related patent disputes***

Beginning in August 2013, the Indivior Group was informed of ANDA filings in the United States by Actavis, Par, Alvogen, Teva, Sandoz and Mylan for the approval by the FDA of generic versions of SUBOXONE® Film in the United States. The Indivior Group has filed patent infringement lawsuits against all six companies which triggered a 30-month stay for each of these competitors, starting on the date on which Indivior received the Paragraph IV Notice Letter from each of these six companies and which ends on the earliest of the expiration of the 30-month period or a court decision that the patent is not infringed, invalid or unenforceable. Teva's 30-month stay on ANDA No. 205806 expires on April 17, 2017, Alvogen's 30-month stay will expire on October 29, 2017, Mylan's 30-month stay will expire on March 24, 2018. In addition, Teva has challenged the applicability of the automatic 30-month stay to one of the two ANDA filings (ANDA No. 205299) it has made against the Company and, if it prevails in such challenge, it may be able to immediately launch the 8 mg/2 mg and 2 mg/0.5 mg dosage strengths of its generic product should it obtain FDA approval for that ANDA. The Company believes that the stay for this ANDA is applicable and expires on April 17, 2017.

The first of these ANDA proceedings, against Actavis and Par, involves the Orange Book-listed patents for SUBOXONE® Film, and went to trial in November and December 2015. As announced by the Company on June 3, 2016, in a judgment issued on June 3, 2016 in respect of the Company's first Orange Book patent infringement lawsuits against Actavis and Par, the District Court in Delaware found that Actavis' and Par's ANDA products infringe the asserted claims of U.S. Patent No. 8,603,514, one of Company's Orange Book listed patents for SUBOXONE® Film, and that the asserted claims of U.S. Patent No. 8,603,514 are not invalid. The Court also ruled that the asserted claims of U.S. Patent No. 8,017,150, which is set to expire in 2023, are valid, but that they are not infringed by Actavis or Par's ANDA product. The Court found that the asserted claims of U.S. Patent No. 8,475,832 are invalid, but that certain of the claims of this patent would be infringed by Actavis and Par's ANDA products if they were valid.

The trial against Teva in the lawsuit involving the Orange Book-listed patents is scheduled for November 2016. The trial against Par, Actavis, and Teva on the process patents is also scheduled for November 2016.

The trial against Alvogen in the lawsuit involving the Orange Book-listed patents for SUBOXONE® Film is scheduled for April 2017, with Alvogen's 30-month stay of FDA approval expiring October 29, 2017.

Trial against Mylan in the lawsuit involving the Orange Book-listed patents for SUBOXONE® Film is scheduled for September 2017, with Mylan's stay expiring March 24, 2018. There is also a second, stayed lawsuit between the Company and Mylan in the Northern District of West Virginia. In addition, Indivior received a Paragraph IV notification from Teva, dated February 8, 2016, indicating that Teva had filed a 505(b) (2) New Drug Application (NDA) for a 16mg/4mg strength of buprenorphine/naloxone sublingual film. Indivior filed suit against Teva within 45 days which triggered a 30-month stay of approval of Teva's 505(b)(2) NDA. The Indivior Group and Teva 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 its ANDA currently scheduled for trial in November 2016.

The USPTO declined to institute Teva's petitions for inter partes review of the three Orange Book-listed patents. Each of the three petitions were filed in December 2015. The Patent Trial and Appeal Board ("PTAB"), in a decision dated May 23, 2016, found that two of the petitions, as to U.S. Patent No. 8,603,514 and U.S. Patent No. 8,017,150, were untimely filed and rejected them on that basis. The third petition, as to U.S. Patent No. 8,475,832, was rejected based on the PTAB's finding, in a decision dated June 10, 2016, that the petition failed to establish a reasonable likelihood that the challenged claims are unpatentable.

***FTC and state investigations and civil antitrust litigation***

Beginning in December 2012, a series of antitrust complaints were filed in federal court against Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) (the “MDL Litigation”). Formerly-related RB Group entities have also been named as defendants in some of these complaints, as has Indivior PLC. These proceedings are now coordinated in the Eastern District of Pennsylvania. There are currently three operative complaints: one issued by plaintiffs who seek to represent a class of direct purchasers, one issued by plaintiffs who seek to represent a class of “End Payor” purchasers, and one issued by Amneal Pharmaceuticals LLC, a manufacturer of a generic alternative to SUBOXONE® Tablets. The complaints allege, inter alia, that the defendants violated federal antitrust laws, state unfair competition laws, and/or the Lanham Act by engaging in an alleged scheme to delay FDA approval of generic versions of SUBOXONE® Tablets, and by allegedly taking other steps to suppress sales of competing generic products in favor of SUBOXONE® Film. The complaints seek unspecified monetary damages and equitable relief. In addition, approximately 79 insurance companies have issued a writ from the Philadelphia County Court of Common Pleas. While this writ may relate to the same allegations as are being litigated in the MDL Litigation, these state-court plaintiffs have not served a complaint. Fact discovery is underway in the MDL Litigation.

In late 2012, the FTC commenced a non-public investigation of Indivior Inc. and various formerly-related RB Group entities by issuing a civil investigative demand, focusing on business practices relating to SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet, including those practices which are the subject of the MDL Litigation (the “FTC Investigation”). Indivior Inc. responded to the civil investigative demand by producing documents and other information to the FTC. The investigation is on-going, and as yet no decision has been made by the FTC on whether to pursue any legal action for enforcement.

Indivior Inc.’s response to the civil investigative demand included the production of hundreds of thousands of pages of documents. Indivior Inc. also withheld a significant number of documents on the basis of legal privilege, however, and the FTC has objected to the privilege claims made with respect to many of those documents. 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 on March 31, 2016. Indivior Inc. has filed objections to the Special Master’s report, and the Court ultimately will determine whether to adopt the Special Master’s recommendations in whole or in part, or to reject them in their entirety. The Court’s decision then may be subject to appeal in the U.S. Court of Appeals by either party, although it may be necessary to wait for a court decision on the remaining documents in dispute before any appeal.

In July 2013, the Attorney General of the State of New York commenced an antitrust investigation into the same conduct being investigated by the FTC. The State of New York issued a subpoena to which Indivior Inc. has responded by producing the same materials it has produced to the FTC. In August 2015, Indivior Inc. was informed that a contingent of additional states had initiated a coordinated investigation into the same conduct that is the subject of the FTC Investigation and the MDL Litigation. The existing investigation of these same issues by the State of New York has now been incorporated within this multi-state investigation. On July 1, 2016, Indivior Inc. was notified that 22 states and the District of Columbia intend to file a complaint in the Eastern District of Pennsylvania alleging violations of state and federal antitrust and consumer protection laws relating to the same conduct. The notice indicated that additional states may decide to join in any action and the Company has learned that as of July 7, 2016 three additional states had in fact joined.

***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 the process of responding by producing documents and other information in connection with this on-going investigation. It is not possible at this time to predict with any certainty or to quantify the potential impact of this investigation on us. We are cooperating fully with the relevant agencies and prosecutors and will continue to do so.

In July 2013, the Indivior Group was informed of the filing in the United States of a section 505(b)(2) NDA by BDSI for a branded buprenorphine/naloxone film. The Indivior Group filed a patent infringement lawsuit against BDSI in the U.S. District Court for the Eastern District of North Carolina in October 2013. That action was dismissed without prejudice on procedural grounds. Following confirmation in early September 2014 that BDSI was preparing to launch its competing film product, the Indivior Group filed a patent infringement lawsuit against BDSI in the U.S. District Court for the District of New Jersey on September 22, 2014, asserting an MSRX-licensed composition patent that is not Orange Book-listed for SUBOXONE® Film. The 30-month stay under the Hatch-Waxman Act does not apply in this case. This case was subsequently transferred to the U.S. District Court for the Eastern District of North Carolina (Western Division). The patent at issue in this case is also subject to on-going inter partes review proceedings. On March 24, 2016, the USPTO rejected BDSI's challenges to the patent. However, BDSI has continued to pursue relief in the USPTO through requests for rehearing, and has stated it will appeal if necessary. The North Carolina District Court action was stayed on May 5, 2016 pending resolution of these proceedings.

In anticipation of launching its product and being sued by the Indivior Group, BDSI filed a lawsuit against the Indivior Group and MSRX in the U.S. District Court for the Eastern District of North Carolina on September 20, 2014 seeking a declaratory judgment of non-infringement and invalidity of two patents relating to SUBOXONE® Film, one of which (U.S. Patent No. 8,475,832) is the subject of an appeal from an inter partes review before the USPTO and the other is a process patent that is the subject of reexamination and further prosecution at the USPTO. That case is also currently stayed.

This litigation may result in significant legal costs for the Indivior Group. If BDSI is successful in establishing that any of the patents in dispute are invalid, the Indivior Group will lose the patent protection offered by that patent. Alternatively, the scope of the patent rights might be narrowed as a result of the litigation or the inter partes review. Either could reduce the ability of the Indivior Group to maintain exclusivity for its products and result in increased competition for its products. It is possible that similar litigation might be brought in other jurisdictions.

In October 2014, BDSI sought an inter partes review by the U.S. Patent Office of claims 15-19 of our Orange Book-listed U.S. Patent No. 8,475,832. That proceeding was instituted and the Patent Trial and Appeal Board ruled the claims unpatentable. Briefing is complete in our appeal of that decision but the oral argument before the Court of Appeals for the Federal Circuit has not yet occurred.

#### ***USAO-NJ subpoena***

In 2011, the U.S. Attorney's Office for the District of New Jersey (the "USAO-NJ") issued a subpoena to Indivior, Inc. requesting production of certain documents in connection with a non-public investigation related, among other things, to the promotion, marketing and sale of SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet. Indivior, Inc. responded to the USAO-NJ by producing documents and other information. Indivior, Inc. has had no communication from USAO-NJ since March 2013. It is therefore not possible at this time to predict with any certainty the potential impact of, if any, this subpoena on the Indivior Group. Indivior, Inc. is cooperating fully with the USAO-NJ and will continue to do so.

#### ***French Competition Authority investigation***

In November 2012, the French competition authorities issued a statement of objections against the Indivior Group 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. The Indivior Group was subsequently fined €0.3 million in 2013 but has appealed against the ruling before the Paris Court of Appeal. That appeal was rejected in March 2015 and subsequently Indivior Group lodged an appeal against that judicial decision before the French Supreme Court in April 2015. The case is currently pending before the French Supreme Court and a hearing is expected to take place before the end of 2016. In addition, a private civil claim has been brought against a competitor of the Indivior Group as a result of the findings against the competitor, and it is therefore possible that a similar claim could be brought against the Indivior Group.

## **B. Significant Changes**

For information on any significant changes that may have occurred since the date of our annual financial statements, see "Item 5. Operating and Financial Review and Prospects."

ITEM 9: THE OFFER AND LISTING

A. Offering and Listing Details

The principal trading market for our ordinary shares is the London Stock Exchange, where our ordinary shares have been listed since December 23, 2014. The following table sets forth, for the periods indicated, the reported high and low closing prices on the London Stock Exchange for our ordinary shares in pounds Sterling. See “Exchange Rate Information” on page 4 for the exchange rates applicable to the periods set forth below.

	High £	Low £
<b>Annual:</b>		
<i>Fiscal year ended December 31,</i>		
2015	271.4	132.7
<b>Quarterly:</b>		
<i>Fiscal year ended December 31, 2016</i>		
Second quarter	252.8	136
First quarter	191.9	126.6
<i>Fiscal year ended December 31, 2015</i>		
Fourth quarter	236.2	181.9
Third quarter	271.4	205.3
Second quarter	243.9	188.3
First quarter	205.4	132.7
<b>Most Recent Six Months:</b>		
July 1, 2016 - July 13, 2016	281.6	241.2
June 2016	252.8	167.9
May 2016	178.4	136
April 2016	173.6	154.5
March 2016	171	155.6
February 2016	175.3	142.7
January 2016	191.9	150.3

For a description of the rights of our ADSs, see “Item 12.D. — American Depositary Shares.”

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are trading on the London Stock Exchange. We are in the process of applying to have our ADSs listed on the [·] under the symbol “[·].” We make no representation that such application will be approved or that our ADSs will trade on such market either now or at any time in the future.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10: ADDITIONAL INFORMATION

A. Share Capital

Current authorized share capital

Not applicable.

Current issued share capital

Our share capital as of March 31, 2016 consists of 718,577,618 ordinary shares with a nominal value \$0.10 per share.

As at June 30, 2016, the issued and fully paid share capital of Indivior was as follows:

Class of share	Issued and fully paid shares	Amount \$
Ordinary Shares	720,597,566	72,059,757

History of share capital

On September 26, 2014 (being the date of the Company’s incorporation) two ordinary shares of \$2.00 each in the capital of the Company were issued and were fully paid up in cash. Since that date, the following changes have been made to the share capital of the Company:

- on October 30, 2014, 50,000 redeemable fixed rate preference shares of £1 each (the “Redeemable Shares”) were issued and were fully paid up in cash. On November 4, 2014, the Redeemable Shares were redeemed by the Company. The Redeemable Shares were entitled to receive a fixed rate dividend but did not have any other right of participation in the profits of the Company;
- on October 30, 2014, the initial shareholders passed a special resolution (the “Reduction Resolution”) to reduce the share capital of Indivior by decreasing the nominal value of each ordinary share from \$2.00 to \$0.10 (the “Reduction of Capital”); the Reduction of Capital became effective as of January 21, 2015;

The Reduction of Capital, which required the confirmation of the Court under section 645 of the Companies Act, created distributable reserves on the balance sheet and became effective on January 21, 2015;

- on December 23, 2014, on completion of the Demerger, a total of 718,577,616 ordinary shares were allotted and issued at a price per share of \$2 each;
- on May 10, 2016, 1,743,510 shares were issued to the Indivior Employee Benefit Trust to be used to satisfy awards vesting under the LTIP;

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- on May 12, 2016, 210,619 shares were issued following the vesting of awards granted under the LTIP;
- on May 23, 2016, 65,819 shares were issued following the vesting of an award granted under the LTIP;
- there are currently 720,597,566 ordinary shares of \$0.10 each in issue.

Information about the Ordinary Shares

***Rights attached to the ordinary shares***

The ordinary shares rank pari passu for all dividends or other distributions made, paid or declared by the Company. Each ordinary share ranks equally in all respects with each other ordinary share and has the same rights and restrictions as each other ordinary share. Further details of the rights attached to the ordinary shares in relation to dividends, attendance and voting at general meetings, entitlements on a winding-up of the Company and transferability of shares are set out in “Item 10.B. Memorandum and Articles of Association.”

***Description of the type and class of securities***

The ordinary shares have a nominal value of \$0.10 each and the Company has one class of ordinary shares, the rights to which are detailed in the Articles, a summary of which is set out in “Item 10.B. Memorandum and Articles of Association.”

Except as described in this registration statement, the ordinary shares are credited as fully paid and free from all liens, equities, encumbrances and other interests. As described in “Item 5.A.—The Term Facility and Revolving Credit Facility,” there is a fixed charge covering all of our ordinary shares. The ordinary shares rank in full for all dividends and distributions on ordinary shares of the Company declared, made or paid after their issue.

The ordinary shares are in registered form and are capable of being held in uncertificated form. No temporary documents of title have been or will be issued in respect of the ordinary shares. As of July 13, 2016, the Company held no treasury shares. No ordinary shares have been issued other than fully paid.

***Rights attached to the ordinary shares***

Each ordinary share ranks equally in all respects with each other ordinary share and has the same rights (including voting and dividend rights and rights on a return of capital) and restrictions as each other ordinary share, as set out in the Articles.

Subject to the provisions of the Companies Act, any equity securities issued by the Company for cash must first be offered to Shareholders in proportion to their holdings of ordinary shares. The Companies Act and the Listing Rules allow for the disapplication of pre-emption rights which may be waived by a special resolution of the Shareholders, either generally or specifically, for a maximum period not exceeding five years.

Except in relation to dividends which have been declared and rights on a liquidation of the Company, the shareholders have no rights to share in the profits of the Company.

The ordinary shares are not redeemable. However, the Company may purchase or contract to purchase any of the ordinary shares on or off-market, subject to the Companies Act and the requirements of the Listing Rules. The Company may purchase ordinary shares only out of distributable reserves or the proceeds of a new issue of shares made to fund the repurchase.

Further details of the rights attached to the ordinary shares in relation to dividends, attendance and voting at general meetings, entitlements on a winding-up of the Company and transferability of shares are set out in “Item 10.A.—Information about the ordinary shares.”

***Description of restrictions on free transferability***

The ordinary shares are freely transferable and there are no restrictions on transfer in the United Kingdom.

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The Company may, under the Companies Act, send out statutory notices to those persons whom it knows or has reasonable cause to believe have an interest in its shares, asking for details of those who have an interest and the extent of their interest in a particular holding of shares. When a person receives a statutory notice and fails to provide any information required by the notice within the time specified in it, the Company can apply to the court for an order directing, among other things, that any transfer of shares which are the subject of the statutory notice is void.

**B. Memorandum and Articles of Association**

***Unrestricted objects***

The objects of the Company are unrestricted.

***Limited liability***

The liability of the Company’s members is limited to the amount, if any, unpaid on the shares in the Company held by them.

***Change of name***

The Articles allow the Company to change its name by resolution of the Board. This is in addition to the Company’s statutory ability to change its name by special resolution under the Companies Act.

***Share rights***

Subject to any rights attached to existing shares, shares may be issued with such rights and restrictions as the Company may by ordinary resolution decide, or (if there is no such resolution or so far as it does not make specific provision) as the Board may decide. Such rights and restrictions shall apply as if they were set out in the Articles. Redeemable shares may be issued, subject to any rights attached to existing shares. The Board may determine the terms and conditions and the manner of redemption of any redeemable share so issued. Such terms and conditions shall apply to the relevant shares as if they were set out in the Articles. Subject to the Articles, any resolution passed by the shareholders and other shareholders’ rights, the Board may decide how to deal with any shares in the Company.

***Voting rights***

Members will be entitled to vote at a general meeting or class meeting whether on a show of hands or a poll, as provided in the Companies Act. The Companies Act provides that:

- on a show of hands every member present in person has one vote and every proxy present who has been duly appointed by one or more members will have one vote, except that a proxy has one vote for and one vote against if the proxy has been duly appointed by more than one member and the proxy has been instructed by one or more members to vote for and by one or more other members to vote against. For this purpose the Articles provide that, where a proxy is given discretion as to how to vote on a show of hands, this will be treated as an instruction by the relevant member to vote in the way that the proxy decides to exercise that discretion; and
- on a poll every member has one vote per share held by him and he may vote in person or by one or more proxies. Where he appoints more than one proxy, the proxies appointed by him taken together shall not have more extensive voting rights than he could exercise in person.

This is subject to any special terms as to voting which are given to any shares or on which shares are held.

In the case of joint holders of a share the vote of the senior who tenders a vote, whether in person or by proxy, shall be accepted to the exclusion of the votes of the other joint holders and, for this purpose, seniority shall be determined by the order in which the names stand in the register in respect of the joint holding.

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***Restrictions***

No member shall be entitled to vote at any general meeting or class meeting in respect of any share held by him if any call or other sum then payable by him in respect of that share remains unpaid or if a member has been served with a restriction notice (as defined in the Articles) after failure to provide the Company with information concerning interests in those shares required to be provided under the Companies Act.

***Dividends and other distributions***

The Company may by ordinary resolution from time to time declare dividends not exceeding the amount recommended by the Board. Subject to the Companies Act, the Board may pay interim dividends, and also any fixed rate dividend, whenever the financial position of the Company, in the opinion of the Board, justifies its payment. If the Board acts in good faith, it is not liable to holders of shares with preferred or *pari passu* rights for losses arising from the payment of interim or fixed dividends on other shares.

The Board may withhold payment of all or any part of any dividends or other monies payable in respect of the Company's shares from a person with a 0.25% or greater holding, in number or nominal value, of the shares of the Company or of any class of such shares (in each case, calculated exclusive of any shares held as treasury shares) (in this paragraph, a "0.25% interest") if such a person has been served with a restriction notice (as defined in the Articles) after failure to provide the Company with information concerning interests in those shares required to be provided under the Companies Act.

Except insofar as the rights attaching to, or the terms of issue of, any share otherwise provide, all dividends shall be apportioned and paid *pro rata* according to the amounts paid up on the share during any portion of the period in respect of which the dividend is paid. Except as set out above, dividends may be declared or paid in any currency.

The Board may if authorized by an ordinary resolution of the Company offer ordinary shareholders (excluding any member holding shares as treasury shares) in respect of any dividend the right to elect to receive ordinary shares by way of scrip dividend instead of cash.

Any dividend unclaimed after a period of 12 years from the date when it was declared or became due for payment shall be forfeited and revert to the Company.

The Company may stop sending cheques, warrants or similar financial instruments in payment of dividends by post in respect of any shares or may cease to employ any other means of payment, including payment by means of a relevant system, for dividends if either (i) at least two consecutive payments have remained uncashed or are returned undelivered or that means of payment has failed or (ii) one payment remains uncashed or is returned undelivered or that means of payment has failed and reasonable enquiries have failed to establish any new postal address or account of the holder. The Company may resume sending dividend cheques, warrants or similar financial instruments or employing that means of payment if the holder requests such resumption in writing.

***Variation of rights***

Subject to the Companies Act, rights attached to any class of shares may be varied with the written consent of the holders of not less than three-fourths in nominal value of the issued shares of that class (calculated excluding any shares held as treasury shares), or with the sanction of a special resolution passed at a separate general meeting of the holders of those shares. At every such separate general meeting (except an adjourned meeting) the quorum shall be two persons holding or representing by proxy not less than one-third in nominal value of the issued shares of the class (calculated excluding any shares held as treasury shares) or by the purchase or redemption by the Company of any of its own shares.

The rights conferred upon the holders of any shares shall not, unless otherwise expressly provided in the rights attaching to those shares, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with them.

***Transfer of shares***

The shares are in registered form. Any shares in the Company may be held in uncertificated form and, subject to the Articles, title to uncertificated shares may be transferred by means of a relevant system. Provisions of the Articles do not apply to any uncertificated shares to the extent that such provisions are inconsistent with the holding of shares in

uncertificated form, with the transfer of shares by means of a relevant system, with any provision of the legislation and rules relating to uncertificated shares or with the Company doing anything by means of a relevant system.

Subject to the Articles, any member may transfer all or any of his certificated shares by an instrument of transfer in any usual form or in any other form which the Board may approve. The instrument of transfer must be signed by or on behalf of the transferor and (in the case of a partly paid share) the transferee.

The transferor of a share is deemed to remain the holder until the transferee's name is entered in the register.

The Board can decline to register any transfer of any share which is not a fully paid share. The Board may also decline to register a transfer of a certificated share unless the instrument of transfer:

- is duly stamped or certified or otherwise shown to the satisfaction of the Board to be exempt from stamp duty and is accompanied by the relevant share certificate and such other evidence of the right to transfer as the Board may reasonably require;
- is in respect of only one class of share; and
- if to joint transferees, is in favor of not more than four such transferees.

Registration of a transfer of an uncertificated share may be refused in the circumstances set out in the uncertificated securities rules (as defined in the Articles) and where, in the case of a transfer to joint holders, the number of joint holders to whom the uncertificated share is to be transferred exceeds four.

The Board may decline to register a transfer of any of the Company's certificated shares by a person with a 0.25% interest if such a person has been served with a restriction notice (as defined in the Articles) after failure to provide the Company with information concerning interests in those shares required to be provided under the Companies Act, unless the transfer is shown to the Board to be pursuant to an arm's length sale (as defined in the Articles).

### ***Sub-division of share capital***

Any resolution authorizing the Company to sub-divide any of its shares may determine that, as between the shares resulting from the sub-division, any of them may have a preference, advantage or deferred or other right or be subject to any restriction as compared with the others.

### ***General meetings***

The Articles rely on the Companies Act provisions dealing with the calling of general meetings. Under the Companies Act an annual general meeting must be called by notice of at least 21 days. The Company is a "traded company" for the purposes of the Companies Act and as such will be required to give at least 21 days' notice of any other general meeting unless a special resolution reducing the period to not less than 14 days has been passed at the immediately preceding annual general meeting or at a general meeting held since that annual general meeting or, pending the Company's first annual general meeting, at any general meeting.

Notice of a general meeting must be given in hard copy form, in electronic form, or by means of a website and must be sent to every member and every director. It must state the time and date and the place of the meeting and the general nature of the business to be dealt with at the meeting. As the Company will be a traded company, the notice must also state the website address where information about the meeting can be found in advance of the meeting, the voting record time, the procedures for attending and voting at the meeting, details of any forms for appointing a proxy, procedures for voting in advance (if any are offered), and the right of members to ask questions at the meeting. In addition, a notice calling an annual general meeting must state that the meeting is an annual general meeting.

Each director shall be entitled to attend and speak at any general meeting. The chairman of the meeting may invite any person to attend and speak at any general meeting where he considers that this will assist in the deliberations of the meeting.

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### ***Directors***

#### ***Number of Directors***

The Directors shall be not less than two and not more than 15 in number. The Company may by ordinary resolution vary the minimum and/or maximum number of Directors.

*Directors' shareholding qualification*

A Director shall not be required to hold any shares in the Company.

*Appointment of Directors*

Directors may be appointed by the Company by ordinary resolution or by the Board. A Director appointed by the Board holds office only until the next following annual general meeting of the Company and is then eligible for reappointment.

The Board or any committee authorized by the Board may from time to time appoint one or more Directors to hold any employment or executive office for such period and on such terms as they may determine and may also revoke or terminate any such appointment.

*Retirement of Directors*

At every annual general meeting of the Company any Director who has been appointed by the Board since the last annual general meeting, or who held office at the time of the two preceding annual general meetings and who did not retire at either of them, or who has held office with the Company, other than employment or executive office, for a continuous period of nine years or more at the date of the meeting, shall retire from office and may offer himself for reappointment by the members.

*Removal of Directors by special resolution*

The Company may by special resolution remove any Director before the expiration of his period of office.

*Vacation of office*

The office of a Director shall be vacated if:

- he resigns or offers to resign and the Board resolves to accept such offer;
- he is removed by notice given by all the other Directors and all the other Directors are not less than three in number;
- he is or has been suffering from mental or physical ill health and the Board resolves that his office be vacated;
- he is absent without the permission of the Board from meetings of the Board (whether or not an alternate Director appointed by him attends) for six consecutive months and the Board resolves that his office is vacated;
- he becomes bankrupt or compounds with his creditors generally;
- he is prohibited by a law from being a Director;
- he ceases to be a Director by virtue of the Companies Act; or
- he is removed from office pursuant to the Company's Articles.

If the office of a Director is vacated for any reason, he must cease to be a member of any committee or sub-committee of the Board.

*Alternate Director*

Any Director may appoint any person to be his alternate and may at his discretion remove such an alternate Director. If the alternate Director is not already a Director, the appointment, unless previously approved by the Board, shall have effect only upon and subject to being so approved.

*Proceedings of the Board*

Subject to the provisions of the Articles, the Board may meet for the dispatch of business, adjourn and otherwise regulate its meetings as it thinks fit. The quorum necessary for the transaction of the business of the Board may be fixed by the Board and, unless so fixed at any other number, shall be two. A meeting of the Board at which a quorum is present shall be competent to exercise all the powers, authorities and discretions vested in or exercisable by the Board.

The Board may appoint a Director to be the chairman or a deputy chairman and may at any time remove him from that office. Questions arising at any meeting of the Board shall be determined by a majority of votes. In the case of an equality of votes the chairman of the meeting shall have a second or casting vote.

All or any of the members of the Board may participate in a meeting of the Board by means of a conference telephone or any communication equipment which allows all persons participating in the meeting to speak to and hear each other. A person so participating shall be deemed to be present at the meeting and shall be entitled to vote and to be counted in the quorum.

The Board may delegate any of its powers, authorities and discretions (with power to sub-delegate) to any committee, consisting of such person or persons as it thinks fit, provided that the majority of persons on any committee or sub-committee must be Directors. The meetings and proceedings of any committee consisting of two or more members shall be governed by the provisions contained in the Articles for regulating the meetings and proceedings of the Board so far as the same are applicable and are not superseded by any regulations imposed by the Board.

*Remuneration of Directors*

Each of the Directors shall be paid a fee at such rate as may from time to time be determined by the Board, but the aggregate of all such fees so paid to the Directors shall not exceed £1,500,000 per annum or such higher amount as may from time to time be decided by ordinary resolution of the Company. Any Director who is appointed to any executive office shall be entitled to receive such remuneration (whether by way of salary, commission, participation in profits or otherwise) as the Board or any committee authorized by the Board may decide, either in addition to or in lieu of his remuneration as a Director. In addition, any Director who performs services which in the opinion of the Board or any committee authorized by the Board go beyond the ordinary duties of a Director may be paid such extra remuneration as the Board or any committee authorized by the Board may determine. Each Director may be paid his reasonable travelling, hotel and incidental expenses of attending and returning from meetings of the Board, or committees of the Board or of the Company or any other meeting which as a Director he is entitled to attend, and shall be paid all other costs and expenses properly and reasonably incurred by him in the conduct of the Company's business or in the discharge of his duties as a Director. The Company may also fund a Director's or former Director's expenditure and that of a Director or former Director of any holding company of the Company for the purposes permitted under the Companies Act and may do anything to enable a Director or former Director or a Director or former Director of any holding company of the Company to avoid incurring such expenditure as provided in the Companies Act.

*Pensions and gratuities for Directors*

The Board or any committee authorized by the Board may exercise the powers of the Company to provide benefits either by the payment of gratuities or pensions or by insurance or in any other manner for any Director or former Director or his relations, dependants or persons connected to him, but no benefits (except those provided for by the Articles) may be granted to or in respect of a Director or former Director who has not been employed by or held an executive office or place of profit with the Company or any of its subsidiary undertakings or their respective predecessors in business without the approval of an ordinary resolution of the Company.

*Directors' interests*

The Board may, subject to the provisions of the Articles, authorize any matter which would otherwise involve a Director breaching his duty under the Companies Act to avoid conflicts of interest. Where the Board gives authority in relation to a conflict of

interest or where any of the situations described in (i) to (v) below applies in relation to a Director, the Board may (a) require the relevant Director to be excluded from the receipt of information, the participation in discussion and/or the making of decisions related to the conflict of interest or situation; (b) impose upon the relevant Director such other terms for the purpose of dealing with the conflict of interest or situation as it may determine; and (c) may provide that the relevant Director will not be obliged to disclose information obtained otherwise than through his position as a Director of the Company and that is confidential to a third party or to use or apply the information in relation to the Company's affairs, where to do so would amount to a breach of that confidence. The Board may revoke or vary such authority at any time.

Subject to the provisions of the Companies Act, and provided he has declared the nature and extent of his interest to the Board as required by the Companies Act, a Director may:

- be party to, or otherwise interested in, any contract with the Company or in which the Company has a direct or indirect interest;
- hold any other office or place of profit with the Company (except that of auditor) in conjunction with his office of Director for such period and upon such terms, including remuneration, as the Board may decide;
- act by himself or through a firm with which he is associated in a professional capacity for the Company or any other company in which the Company may be interested (otherwise than as auditor);
- be or become a Director or other officer of, or employed by or a party to a transaction or arrangement with, or otherwise be interested in any holding company or subsidiary company of the Company or any other company in which the Company may be interested; and
- be or become a Director of any other company in which the Company does not have an interest and which cannot reasonably be regarded as giving rise to a conflict of interest at the time of his appointment as a Director of that other company.

A Director shall not, by reason of his office be liable to account to the Company or its members for any benefit realized by reason of having an interest permitted as described above or by reason of having a conflict of interest authorized by the Board and no contract shall be liable to be avoided on the grounds of a Director having any such interest.

*Restrictions on voting*

No Director may vote on or be counted in the quorum in relation to any resolution of the Board concerning his own appointment, or the settlement or variation of the terms or the termination of his own appointment, as the holder of any office or place of profit with the Company or any other company in which the Company is interested save to the extent permitted specifically in the Articles.

Subject to certain exceptions set out in the Articles, no Director may vote on, or be counted in a quorum in relation to, any resolution of the Board in respect of any contract in which he has an interest and, if he does so, his vote shall not be counted.

Subject to the Companies Act, the Company may by ordinary resolution suspend or relax to any extent the provisions relating to Directors' interests or the restrictions on voting or ratify any transaction not duly authorized by reason of a contravention of such provisions.

*Borrowing and other powers*

Subject to the Articles and any directions given by the Company by special resolution, the business of the Company will be managed by the Board who may exercise all the powers of the Company, whether relating to the management of the business of the Company or not. In particular, the Board may exercise all the powers of the Company to borrow money, to guarantee, to indemnify, to mortgage or charge any of its undertaking, property, assets (present and future) and uncalled capital and to issue debentures and other securities and to give security for any debt, liability or obligation of the Company or of any third party. The Board must restrict the

borrowings of the Company and exercise all voting and other rights or powers of control exercisable by the Company in relation to its subsidiary undertakings so as to secure that, save with the previous sanction of an ordinary resolution, no money shall be borrowed if the aggregate principal amount outstanding of all borrowings (as defined in the Articles) by the Indivior Group (exclusive of borrowings within the Indivior Group) then exceeds, or would as a result of such borrowing exceed, an amount equal to three times the adjusted capital and reserves (as defined in the Articles).

*Indemnity of Directors*

To the extent permitted by the Companies Act, the Company may indemnify any Director or former Director of the Company or any associated company against any liability and may purchase and maintain for any Director or former Director of the Company or any associated company insurance against any liability.

***Methods of service and communications with Shareholders***

Any notice, document (including a share certificate) or other information may be served on or sent or supplied to any Shareholder by the Company personally, by post, by means of a relevant system, by sending or supplying it in electronic form to an address notified by the Shareholder to the Company for that purpose, where appropriate, by means of a website and notifying the Shareholder of its availability, or by any other means authorized in writing by the Shareholder.

**C. Material Contracts**

Except as otherwise set forth below or as otherwise disclosed in this registration statement on Form 20-F (including the Exhibits), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of business.

**The Demerger Agreement**

The Demerger Agreement was entered into on November 17, 2014 between RB and Indivior to effect the Demerger and to govern the relationship between the RB Group and the Indivior Group following the Demerger. The Demerger Agreement took effect on December 23, 2014.

The Demerger Agreement contains mutual indemnities under which Indivior indemnified the RB Group against liabilities arising in respect of our business and RB indemnified the Indivior Group against liabilities arising in respect of the business carried on by the RB Group other than our business. These mutual indemnities are unlimited in terms of amount and duration and are customary for an agreement of this type.

The Demerger Agreement sets out how guarantees, indemnities or other assurances given by RB Group companies for the benefit of Indivior Group companies (or vice versa) are dealt with following the Demerger. The beneficiary of such a guarantee must generally seek to obtain the guarantor’s release from the guarantor’s obligations thereunder and, pending release, indemnify the guarantor against all amounts paid by it under the guarantee and ensure that the guarantor’s exposure under the guarantee is not increased.

Both the RB Group and the Indivior Group are permitted access to each other’s records for a period of eight years following the Demerger.

Both groups have agreed to keep certain information on the other group confidential, subject to certain customary exemptions.

**Transitional Services Agreement**

The Demerger Agreement required RB and RBP Global Holdings Limited to enter into a transitional services agreement in relation to the terms and conditions upon which the RB Group would provide various services to the Indivior Group after the Demerger. The Transitional Services Agreement is dated December 23, 2014.

Pursuant to the terms of the Transitional Services Agreement, RB (on behalf of the RB Group) agreed to provide RBP Global

Holdings Limited (on behalf of the Indivior Group) with certain services which are required to be provided on commercial terms and on an arms' length basis.

Otherwise than where the parties have agreed to provide certain services at a specific standard and level (as set out in the service schedules incorporated into the Transitional Services Agreement), the services are required to be provided to the same standard and level as during the 12-month period immediately preceding the Demerger. These services include (i) the continued provision by RB to RBP Global Holdings Limited of various back office services and support across finance, HR, regulatory, IS, office space and facilities, (ii) the continuation of manufacturing, distribution and sales and marketing services set out in certain existing intergroup agreements between certain members of the RB Group and certain members of the Indivior Group and (iii) the provision of services, (for example software support) pursuant to existing agreements entered into by a member of the RB Group and a third party from which a member of the Indivior Group derives a benefit. The agreement provides for a majority of these services to be provided for a maximum period of up to two years, with provision of office space in certain European countries for up to a maximum of three years. Each of the services may be extended by any period agreed in writing between the parties. The parties have covenanted for a period of one year from the cessation of the provision of the relevant services not to employ, solicit or contact with a view to employing employees of the other who are in a senior, technical or managerial role and are engaged in the provision of services to the other party pursuant to the Transitional Services Agreement.

RBP Global Holdings Limited may terminate the agreement in respect of any service(s) provided to it either on a country-by-country basis or an individual service-by-service basis under the agreement at any time on three months' written notice to RB. Either party may terminate the agreement with immediate effect (i) in case of a breach by the other party which, if capable of remedy, is not remedied within 30 days, (ii) if the other party suffers a material insolvency event or (iii) if a force majeure circumstance arises.

Currently, work on separation from RB continues under the Transitional Services Agreement and is fully on track. In April, formal operation of the FCP in Hull, United Kingdom, where buprenorphine is manufactured for our SUBOXONE® and SUBUTEX® products, was transferred to Indivior. On July 1, 2015, major operating companies changed their name to Indivior including the United States, the United Kingdom and Canada. Australia changed its operating name in February 2015. Subsequent to the Company name changes, product packaging and branded materials have been updated. The work on separation from RB is materially finished as of July 1, 2016. The project to implement a new, company-wide ERP system has finished. Eleven markets and manufacturing & supply are on ERP. Thirteen other countries' Finance and HR operations are outsourced to BDO. All work to transition to Indivior IT systems and applications has been done and Indivior now operates independently from RB with the exception of certain RB R&D systems which are still shared with RB until the move out of the RB facility in Hull targeted for end of 2017.

**Demerger Tax Deed**

The Demerger Agreement required RB and Indivior to enter into the Demerger Tax Deed dated December 23, 2014. The Demerger Tax Deed contains indemnities relating to taxation in the United Kingdom and elsewhere (excluding the United States). Subject to certain exceptions, RB indemnified Indivior against certain tax liabilities arising as a result of the Demerger or certain pre-Demerger reorganization steps. RB also indemnified Indivior against certain tax liabilities which are properly liabilities of the RB group being imposed on a member of the Indivior group and against certain tax liabilities arising as a result of a member of the RB group making a chargeable payment within the meaning of section 1088 of the Corporation Tax Act 2010 (a "Chargeable Payment") and against certain tax liabilities arising as a result of the Indivior group carrying on a non-pharma business at any time before the Demerger and against certain tax liabilities arising as a result of any non-U.S. controlled foreign company rules applying in relation to the RB group. Subject to certain exceptions, Indivior indemnified RB against certain tax liabilities which are properly liabilities of the Indivior group being imposed on a member of the RB group and against certain tax liabilities arising as a result of a member of the Indivior group making a Chargeable Payment or taking any other action after the Demerger which prevented the transfer of the shares in RBP Global Holdings Limited and the issue of ordinary shares by Indivior pursuant to the Demerger Agreement from being an exempt distribution for the purposes of section 1075 of the Corporation Tax Act 2010 and against certain tax liabilities arising as a result of the RB group carrying

on pharma business at any time before the Demerger and against certain tax liabilities arising as a result of any non-U.S. controlled foreign company rules applying in relation to the Indivior group. All these indemnities are subject to a de minimis of £100,000 but are otherwise unlimited in terms of amount. They do not cover liabilities which have not been notified by the indemnified party to the indemnifying party within three months after the expiry of the period specified by statute during which an assessment of the relevant tax liability may be issued by the relevant tax authority or, if there is no such period, within six years and 30 days after the end of the

accounting period in which the Demerger occurs.

**U.S. Tax Matters Agreement**

The Demerger Agreement required RB and Indivior to enter into the U.S. Tax Matters Agreement immediately prior to the Demerger effective time, December 23, 2014. The U.S. Tax Matters Agreement governs both Indivior’s and RB’s rights and obligations after the Demerger with respect to U.S. federal, state and local taxes for both pre-and post-Demerger periods. Under the U.S. Tax Matters Agreement, the Indivior Group and the RB Group generally are responsible for any taxes attributable to their respective operations for all taxable periods, except for transfer taxes imposed in connection with the internal restructuring and the Demerger, which are the RB Group’s responsibility, and income taxes resulting from the failure of the internal restructuring or the Demerger to qualify as a tax-free transaction, which are generally shared by Indivior and RB according to relative fault.

Indivior is generally required to indemnify RB against any tax resulting from the failure of the internal restructuring or the Demerger to qualify as a tax-free transaction (including such taxes of any third party for which any member of the RB Group is or becomes liable) if that tax results from (i) an issuance of a significant amount of equity securities of Indivior, a redemption of a significant amount of the equity securities of the Indivior Group or the involvement by the Indivior Group in other significant acquisitions of equity securities of Indivior (excluding the Demerger described in this document), (ii) other actions or failures to act by the Indivior Group (such as those described in the following paragraph) or (iii) any of the representations or undertakings of Indivior referred to in the U.S. Tax Matters Agreement being incorrect or violated. RB is generally required to indemnify Indivior for any tax resulting from the failure of the internal restructuring or the Demerger to qualify as a tax-free transaction (including such taxes of any third party for which any member of the Indivior Group is or becomes liable) if that tax results from (a) RB’s issuance of its equity securities, redemption of its equity securities or involvement in other acquisitions of its equity securities, (b) other actions or failures to act by RB or (c) any of RB’s representations or undertakings referred to in the U.S. Tax Matters agreement being incorrect or violated.

In addition, to preserve the tax-free treatment of the Demerger, for specified periods of up to 24 months following the Demerger, the Indivior Group is generally prohibited, except in specified circumstances, from:

- I. issuing, redeeming or being involved in other significant acquisitions of equity securities of the Indivior Group (excluding the Demerger described in the Demerger prospectus);
- II. transferring significant amounts of the assets of the Indivior Group;
- III. failing to comply with the tax requirement under Section 355 of the Code that the Indivior Group engages in the active conduct of a trade or business after the Demerger; or
- IV. engaging in other actions or transactions that could jeopardize the tax-free status of the Demerger.

Though valid as between the parties, the U.S. Tax Matters Agreement is not binding on the IRS and does not affect the several liability of the RB Group and the Indivior Group for all U.S. federal taxes relating to periods before the date of the Demerger.

**Existing Supply Agreement**

RB Health and RB Pharmaceuticals Limited entered into an amended and restated Supply Agreement on November 17, 2014, pursuant to which RB Health manufactures buprenorphine API and finished products (BUPRENEX®, SUBOXONE® Tablet, SUBUTEX® Tablet and TEMGESIC®) on behalf of RB Pharmaceuticals Limited and RB Pharmaceuticals Limited purchases the API and finished products for onward distribution. The parties agree that the existing Supply Agreement will remain in full force and effect until “Plant Day” (being April 1, 2015, the day that RB Pharmaceuticals took operational control of the FCP and therefore the manufacturing of the API) and will be replaced by the Copacker Supply Agreement).

Pursuant to the terms of the existing Supply Agreement, RB Health manufactures the API and the finished products exclusively for RB Pharmaceuticals Limited and RB Pharmaceuticals Limited purchases the API and the finished products

inspect RB Health’s premises and books and records relating to the manufacturing of the API and finished products, and (iii) manufacturing the API and finished products in accordance with the method of manufacture specifications set out in the relevant technical manual. RB Pharmaceuticals Limited’s obligations include (i) either supplying the raw materials to RB Health or authorizing RB Health to use an alternative third-party supplier and (ii) providing a rolling forecast for the volume of API and finished products it wishes to purchase from RB Health. The existing Supply Agreement may be terminated at any time by either party giving the other three months’ written notice if the other party commits a material breach which, if capable of remedy, has not been remedied within 30 days of receipt of the notice. It may also be terminated with immediate effect by either party giving written notice to the other if (i) the other party goes into liquidation, (ii) any distress, execution or sequestration process is levied against the property of the other party which is not discharged within 30 days or (iii) the other party is unable to pay its debts in the normal course.

**Copacker Supply Agreement**

The Demerger Agreement required RB and Indivior to procure that RB Health and Indivior UK Limited enter into a supply agreement dated December 23, 2014. The supply agreement commenced on April 1, 2015 (“Plant Day”), being the day that Indivior UK Limited took operational control of the FCP (and therefore the manufacturing of the API) and RB Health manufactures the finished products (BUPRENEX®, SUBOXONE® Tablet, SUBUTEX® Tablet and TEMGESIC®), on behalf of Indivior UK Limited pursuant to the agreement.

Pursuant to the terms of the Copacker Supply Agreement, RB Health agreed to manufacture the finished products exclusively for Indivior UK Limited and Indivior UK Limited agreed to purchase those products exclusively from RB Health for a period of seven years but either party may terminate the agreement early by giving the other 36 months’ written notice, such notice to expire no earlier than the sixth anniversary of Plant Day. RB Health’s and Indivior UK Limited’s obligations to each other are as set out in the Existing Supply Agreement, save that the references to the manufacturing and sale of the API by RB Health to Indivior UK Limited will not apply under the Copacker Supply Agreement. There is a restrictive covenant on RB Health and certain members of the RB Group for the duration of the Copacker Supply Agreement and for up to two years after its termination. The Copacker Supply Agreement contains a reciprocal indemnity whereby each party indemnifies the other for (i) any negligent act or omission in connection with its or its affiliates’ performance of the agreement and (ii) any breach of the warranties or obligations in the agreement. The Copacker Supply Agreement may be terminated by Indivior UK Limited giving RB Health 30 days’ written notice if, after 30 days, for of receipt of the notice, RB Health does not either (i) supply or deliver the finished products in accordance with the terms set out in Indivior UK Limited’s order or (ii) perform the services set out in the agreement. The Copacker Supply Agreement may also be terminated with immediate effect by either party given written notice to the other if (i) the other party goes into liquidation, (ii) any distress, execution or sequestration process is levied against the property of the other party which is not discharged within 30 days or (iii) the other party is unable to pay its debts in the normal course.

**The Lease of the FCP**

The Demerger Agreement required RB Health to grant to Indivior UK Limited a lease of the FCP dated December 1, 2014, in return for the payment of a premium for a term of 150 years at a peppercorn rent. Indivior UK Limited is required to contribute through a service charge to the cost of the upkeep of the communal areas of RB Health’s industrial estate in Hull of which the FCP forms part. The lease permits Indivior UK Limited to develop the FCP site without landlord consent. The lease contains rights of first refusal for the benefit of RB Health in the event that Indivior UK Limited or a future tenant proposes to assign or underlet the whole of the premises. In addition, there is a right of first refusal over the landlord’s reversionary interest in the premises for the benefit of Indivior UK Limited in the event that the landlord proposes to sell its interest in the FCP. Since the Demerger Indivior UK Limited has acquired an interest in an adjacent property (purchasing the remainder of a lease from RB Health to the previous tenant) and is entering into a surrender and grant of a new lease on substantially the same terms as the lease of the FCP to form a larger site.

**Research and Development Services Agreement**

The Demerger Agreement required RB and Indivior to procure that RB Health and Indivior UK Limited enter into an agreement dated December 23, 2014 which sets out the terms and conditions upon which RB Health and Indivior UK Limited provide to each other and any member of the RB Group and the Indivior Group after the Demerger (i) access to and use of research and development facilities located on the land owned by RB Health (the “R&D Facilities”), and (ii) various

The access to and use of the R&D Facilities and the related services are required to be provided to the same standard and level as the 12 month period preceding the Demerger and include the use of equipment owned by RB Health, materials purchased by RB Health, quality management and quality control services, use of controlled drug licenses, use of investigational medicinal product licenses and a controlled drugs store. The agreement sets out services provided by Indivior UK Limited to the RB Group which were to be provided for a maximum period of 12 months (and have therefore now ceased), while the access to and the use of the R&D Facilities and related services provided by RB Health to the Indivior Group were required to be provided for a maximum period of 3 years and are ongoing. RB Pharmaceuticals may request, by no later than the second anniversary of the agreement, that RB Health provide, or procure the provision of, services to RB Pharmaceuticals which are equivalent in standard and scope to the research and development services for a fourth year. RB Health may reasonably increase the relevant service charges in relation to such services.

Indivior UK Limited may terminate the agreement at any time on six months' written notice to RB Health. Either party may terminate the agreement with immediate effect (i) in case of a breach by the other party which, if capable of remedy, is not remedied within 30 days, (ii) if the other party suffers a material insolvency event or (iii) if a force majeure circumstance arises. The liability of RB Health and Indivior UK Limited is limited to £10 million in aggregate, less any amount already claimed under the Transitional Services Agreement. Indirect or consequential loss is excluded.

## **MSRX Agreement**

Under a commercial exploitation agreement dated August 15, 2008 between MSRX and RBP, RBP obtained exclusive global rights to MSRX Pharmfilm® technology in respect of buprenorphine and certain other products for the treatment of addiction used for the manufacturing of SUBOXONE® Film. MSRX manufactures and supplies RBP exclusively with the licensed products at a fixed price, subject to price adjustments and conditional rebates. MSRX and RBP may commercially exploit opportunities relating to SUBOXONE® Film, for which milestone payments and royalties on sales are payable by RBP, subject to price adjustments and a maximum royalty cap. RBP has the option to cease payment of annual royalties in exchange for a lump sum payment.

The agreement contains certain customary warranty and indemnity provisions, and after August 2015 the contract was automatically renewed and will continue to be automatically renewed on an annual basis (not to extend beyond the last to expire licensed patent), subject to RBP'S right to terminate the agreement on one year's notice. Both buprenorphine HCl and naloxone HCl are supplied free of charge by Indivior to MSRX to be used in the manufacture of SUBOXONE® Film.

MSRX has two manufacturing facilities located in Portage, Indiana. Manufacture and primary packaging of all SUBOXONE® Film output for the U.S. market is now approved at both facilities. Manufacture and primary packaging of SUBOXONE® Film output for the Rest of World is currently approved at one facility.

## **XenoPort Agreement**

Under a license agreement dated May 14, 2014 between XenoPort, Inc. and RBP, RBP obtained an exclusive worldwide license for the development and commercialization of XenoPort, Inc.'s oral product arbaclofen placarbil for all indications, which RBP plans to advance in a study for the treatment of alcohol use disorders. RBP's rights under the agreement are subject to certain rights by XenoPort, Inc. to negotiate with RBP on collaborations for non-addiction indications. The consideration for RBP's rights include: (i) an upfront, non-refundable cash payment of \$20,000,000, which we have already paid, plus \$5,000,000 on the transfer of certain technology and materials to RBP; (ii) payments of up to \$70,000,000 for certain development and regulatory milestones; (iii) payments of up to \$50,000,000 for commercial milestones; and (iv) tiered double-digit royalty payments of up to mid-teens on a percentage basis on potential future net sales in the United States and high single-digit royalty payments on potential future net sales outside the United States. The agreement contains certain customary warranty and indemnity provisions and continues, subject to certain termination rights, up until RBP has no further remaining payment obligations with respect to any product on a country-by-country basis.

## **D. Exchange Controls**

Other than certain economic sanctions which may be in place from time to time, there are currently no UK laws, decrees or regulations restricting the import or export of capital or affecting the remittance of dividends or other payment to holders of ordinary shares who are non-residents of the United Kingdom. Similarly, other than certain economic sanctions which may be in force from time to time, there are no limitations relating only to nonresidents of the United Kingdom under English law or Indivior's articles of

association on the right to be a holder of, and to vote in respect of, the ordinary shares.

E. Taxation

Taxation in the United States

The following summary of the material U.S. federal income tax consequences of the acquisition, ownership and disposition of the ADSs is based upon current law and does not purport to be a comprehensive discussion of all the tax considerations that may be relevant to a particular U.S. holder, as defined below, of the ADSs. This summary is based on current provisions of the Internal Revenue Code of 1986, as amended, or the Code, existing, final, temporary and proposed U.S. Department of the Treasury (“U.S. Treasury”) regulations (“U.S. Treasury Regulations”), administrative rulings and judicial decisions, in each case as available on the date of this Annual Report. All of the foregoing are subject to change, which change could apply retroactively and could affect the tax consequences described below.

This section summarizes the material U.S. federal income tax consequences to U.S. holders, as defined below, of an investment in the ADSs. This summary addresses only the U.S. federal income tax considerations for U.S. holders that acquire and hold the ADSs as capital assets. **Each prospective investor should consult a professional tax advisor with respect to the tax consequences of the acquisition, ownership or disposition of the ADSs.** This summary does not address tax considerations applicable to a holder of ADSs that may be subject to special tax rules including, without limitation, the following:

- banks or other financial institutions;
- insurance companies;

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- dealers or traders in securities, currencies, or notional principal contracts;
- tax-exempt entities, including an “individual retirement account” or “Roth IRA” retirement plan;
- regulated investment companies or real estate investment trusts;
- persons that hold the ordinary shares as part of a hedge, straddle, conversion, constructive sale or similar transaction involving more than one position;
- an entity classified as a partnership and persons that hold the ordinary shares through partnerships or certain other pass-through entities;
- holders (whether individuals, corporations or partnerships) that are treated as expatriates for some or all U.S. federal income tax purposes;
- persons who acquired the ADSs as compensation for the performance of services;
- persons holding the ADSs in connection with a trade or business conducted outside of the United States;
- a U.S. holder who holds the ADSs through a financial account at a foreign financial institution that does not meet the requirements for avoiding withholding with respect to certain payments under Sections 1471 through 1474 of the Internal Revenue Code of 1986, as amended, or the Code;
- holders that own (or are deemed to own) 10% or more of our voting shares; and
- holders that have a “functional currency” other than the U.S. dollar.

Further, this summary does not address alternative minimum tax, gift or estate consequences or the indirect effects on the holders of equity interests in entities that own the ADSs. In addition, this discussion does not consider the U.S. tax consequences to holders of ADSs that are not “U.S. holders” (as defined below). the purposes of this summary, a “U.S. holder” is a beneficial owner of ordinary shares or ADSs that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is either a citizen or resident of the United States;
- a corporation, or other entity that is treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States or any state of the United States or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust or has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

If a partnership holds ordinary shares or ADSs, the tax treatment of a partner will generally depend upon the status of the partner and upon the activities of the partnership. We will not seek a ruling from the IRS with regard to the U.S. federal income tax treatment of an investment in our ordinary shares or ADSs, and we cannot assure you that the IRS will agree with the conclusions set forth below.

### ***Ownership of ADSs***

For U.S. federal income tax purposes, a holder of ADSs generally will be treated as the owner of the ordinary shares represented by such ADSs. Gain or loss will generally not be recognized on account of exchanges of ordinary shares for ADSs, or of ADSs for ordinary shares. References to ordinary shares in the discussion below are deemed to include ADSs, unless context otherwise requires.

### ***Distributions***

Subject to the discussion under “*Passive Foreign Investment Company Considerations*” below, the gross amount of

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any distribution actually or constructively received by a U.S. holder with respect to ordinary shares will be taxable to the U.S. holder as a dividend to the extent of such U.S. holder’s pro rata share of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of such pro rata share of our earnings and profits will be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder’s adjusted tax basis in the ordinary shares. Distributions in excess of the sum of such pro rata share of our earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as capital gain from the sale or exchange of property. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. The amount of any distribution of property other than cash will be the fair market value of that property on the date of distribution. A corporate U.S. holder will not be eligible for any dividends-received deduction in respect of a dividend received with respect to ordinary shares.

Subject to the discussion below regarding the “Medicare tax,” qualified dividends received by non-corporate U.S. holders (*i.e.*, individuals and certain trusts and estates) are currently subject to a maximum income tax rate of 20%. This reduced income tax rate is applicable to dividends paid by “qualified foreign corporations” to non-corporate U.S. holders that meet the applicable requirements, including a minimum holding period (generally, at least 61 days without protection from the risk of loss during the 121-day period beginning 60 days before the ex-dividend date). A non-U.S. corporation (other than a corporation that is classified as a Passive Foreign Investment Company (“PFIC”) for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on shares of stock which are readily tradable on an established securities market in the United States. Our ADSs are listed on the [·], which is an established securities market in the United States, and we expect the ADSs to be readily tradable on the [·]. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in later years. The Company, which is incorporated under the laws of the United Kingdom, believes that it qualifies as a resident of the United Kingdom for the purposes of, and is eligible for the benefits of, the Convention between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on

Income and Capital Gains, signed on July 24, 2001, or the U.S.-UK Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-UK Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Based on the foregoing, we expect to be considered a qualified foreign corporation under the Code. Accordingly, dividends paid by us to non-corporate U.S. holders with respect to shares that meet the minimum holding period and other requirements are expected to be treated as “qualified dividend income.” However, dividends paid by us will not qualify for the 20% maximum U.S. federal income tax rate if we are treated, for the tax year in which the dividends are paid or the preceding tax year, as a “passive foreign investment company” for U.S. federal income tax purposes, as discussed below.

The U.S. Treasury has announced its intention to issue rules regarding when and to what extent holders of ADSs will be permitted to rely on certifications from issuers to establish that dividends paid on shares to which such ADSs relate are treated as qualified dividends. Because such procedures have not yet been issued, it is not clear whether we will be able to comply with them. Dividends received by a U.S. holder with respect to ordinary shares generally will be treated as foreign source income for the purposes of calculating that holder’s foreign tax credit limitation. For these purposes, dividends distributed by us generally will constitute “passive category income” (but, in the case of some U.S. holders, may constitute “general category income”).

***Sale or Other Disposition of Ordinary Shares***

A U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale or exchange of ordinary shares in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange and the U.S. holder’s tax basis for those ordinary shares. Subject to the discussion under “*Passive Foreign Investment Company Considerations*” below, this gain or loss will generally be a capital gain or loss and will generally be treated as from sources within the United States. Such capital gain or loss will be treated as long-term capital gain or loss if the U.S. holder has held the ordinary shares for more than one year at the time of the sale or exchange. Long-term capital gains of non-corporate U.S. holders may be eligible for a preferential tax rate; the deductibility of capital losses is subject to limitations. For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of the ADSs that

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are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer who does not make such election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and settlement date. Any foreign currency gain or loss a U.S. holder realizes will be U.S. source ordinary income or loss.

***Medicare Tax***

An additional 3.8% tax, or “Medicare Tax,” is imposed on all or a portion of the “net investment income” (which includes taxable dividends and net capital gains, adjusted for deductions properly allocable to such dividends or net capital gains) received by (i) U.S. holders that are individuals with modified adjusted gross income of over \$200,000 (\$250,000 in the case of joint filers, \$125,000 in the case of married individuals filing separately) and (ii) certain trusts or estates.

***Passive Foreign Investment Company Considerations***

A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying the applicable look-through rules, either: (i) at least 75% of its gross income is passive income, or (ii) on average at least 50% of the gross value of its assets is attributable to assets that produce passive income or are held for the production of passive income. In arriving at this calculation, a pro rata portion of the income and assets of each corporation in which we own, directly or indirectly, at least a 25% interest, as determined by the value of such corporation, must be taken into account. Passive income for this purpose generally includes dividends, interest, royalties, rents and gains from commodities and securities transactions.

We believe that we were not a PFIC for any previous taxable year. Based on our estimated gross income, the average value of our gross assets, and the nature of the active businesses conducted by our “25% or greater” owned subsidiaries, we do not believe that we will be classified as a PFIC in the current taxable year. Our status for any taxable year will depend on our assets and activities in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we

will not be considered a PFIC for the current taxable year or any future taxable year. The market value of our assets may be determined in large part by reference to the market price of the ADSs and our ordinary shares, which is likely to fluctuate after the offering (and may fluctuate considerably given that market prices of life sciences companies can be especially volatile). In addition, the composition of our income and assets will be affected by how, and how quickly, we spend the cash we raise in this offering. we were a PFIC for any taxable year during which a U.S. holder held ordinary shares, under the “default PFIC regime” (i.e., in the absence of one of the elections described below) gain recognized by the U.S. holder on a sale or other disposition (including a pledge) of the ordinary shares would be allocated ratably over the U.S. holder’s holding period for the ordinary shares. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed on the resulting tax liability for that taxable year. Similar rules would apply to the extent any distribution in respect of ordinary shares exceeds 125% of the average of the annual distributions on ordinary shares received by a U.S. holder during the preceding three years or the holder’s holding period, whichever is shorter. the event we were treated as a PFIC, the tax consequences under the default PFIC regime described above could be avoided by either a “mark-to-market” or “qualified electing fund” election. A U.S. holder making a mark-to-market election (if the eligibility requirements for such an election were satisfied) generally would not be subject to the PFIC rules discussed above, except with respect to any portion of the holder’s holding period that preceded the effective date of the election. Instead, the electing holder would include in ordinary income, for each taxable year in which we were a PFIC, an amount equal to any excess of (a) the fair market value of the ordinary shares as of the close of such taxable year over (b) the electing holder’s adjusted tax basis in such ordinary shares. In addition, an electing holder would be allowed a deduction in an amount equal to the lesser of (a) the excess, if any, of (i) the electing holder’s adjusted tax basis in the ordinary shares over (ii) the fair market value of such ordinary shares as of the close of such taxable year or (b) the excess, if any, of (i) the amount included in ordinary income because of the election for prior taxable years over (ii) the amount allowed as a deduction because of the election for prior taxable years. The election would cause adjustments in the electing holder’s tax basis in the ordinary shares to reflect the amount included in gross income or allowed as a deduction because of the election. In addition, upon a sale or other taxable disposition of ordinary shares, an electing holder would recognize ordinary income or loss (not to exceed the excess, if any, of (a) the amount included in ordinary income because of the election for prior taxable years over (b) the amount allowed as a deduction because of the election for prior taxable years).

Alternatively, a U.S. holder making a valid and timely “QEF election” generally would not be subject to the default PFIC regime discussed above. Instead, for each PFIC year to which such an election applied, the electing holder would be

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subject to U.S. federal income tax on the electing holder’s pro rata share of our net capital gain and ordinary earnings, regardless of whether such amounts were actually distributed to the electing holder. However, because we do not intend to prepare or provide the information that would permit the making of a valid QEF election, that election will not be available to U.S. holders. we were considered a PFIC for the current taxable year or any future taxable year, a U.S. holder would be required to file annual information returns for such year, whether or not the U.S. holder disposed of any ordinary shares or received any distributions in respect of ordinary shares during such year.

## ***Backup Withholding and Information Reporting***

U.S. holders generally will be subject to information reporting requirements with respect to dividends on ordinary shares and on the proceeds from the sale, exchange or disposition of ordinary shares that are paid within the United States or through U.S.-related financial intermediaries, unless the U.S. holder is an “exempt recipient.” In addition, U.S. holders may be subject to backup withholding (at a 28% rate) on such payments, unless the U.S. holder provides a taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder’s U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

## ***Foreign Asset Reporting***

In addition, certain individuals who are U.S. holders may be required to file IRS Form 8938 to report the ownership of “specified foreign financial assets” if the total value of those assets exceeds an applicable threshold amount (subject to certain exceptions). For these purposes, a specified foreign financial asset may include not only a financial account (as defined for these purposes) maintained by a non-U.S. financial institution, but also stock or securities issued by a non-U.S. corporation (such as the Company). Certain U.S. entities may also be required to file IRS Form 8938 in the future.

**Taxation in the United Kingdom**

The following paragraphs are intended as a general guide only to current UK tax law and HMRC published practice as of the date of this document both of which are subject to change at any time, possibly with retrospective effect. They relate only to certain limited aspects of the UK taxation treatment of the holders of ordinary shares or ADSs and apply only to holders of ordinary shares or ADSs who own their ordinary shares or ADSs legally and beneficially as an investment and who are resident and, in the case of individuals, domiciled in (and only in) the United Kingdom for tax purposes (except where the position of an overseas resident holder of ordinary shares or ADSs is expressly referred to). Certain categories of holders of ordinary shares or ADSs, such as traders, broker-dealers, insurance companies and collective investment schemes, and holders of ordinary shares or ADSs who have (or are deemed to have) acquired their ordinary shares by virtue of an office or employment, may be subject to special rules and this summary does not apply to such holders. Any person who is in any doubt about his own tax position, or is subject to taxation in a jurisdiction other than the United Kingdom, should consult an appropriate independent professional adviser.

This summary further assumes that a holder of an ADS is the beneficial owner of the underlying ordinary share for UK direct tax purposes.

INVESTORS IN THE ADSs SHOULD SATISFY THEMSELVES PRIOR TO INVESTING AS TO THE OVERALL TAX CONSEQUENCES, INCLUDING, SPECIFICALLY, THE CONSEQUENCES UNDER UK TAX LAW AND HMRC PRACTICE OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF THE ORDINARY SHARES OR ADSs, IN THEIR OWN PARTICULAR CIRCUMSTANCES BY CONSULTING THEIR OWN TAX ADVISERS.

***Taxation of Dividends***

Under current UK tax legislation, the Company is not required to withhold tax at source when paying a dividend.

*UK resident individual holders of ordinary shares or ADSs*

A holder who is an individual resident in the United Kingdom for tax purposes and who receives a dividend from the Company during the 2016/17 tax year will be subject to a dividend allowance in the form of a 0% tax rate on the first £5,000 of dividend income received in a year. The dividend tax rates for any additional dividend income above £5,000 will be set at 7.5% for basic rate taxpayers, 32.5% for higher rate taxpayers and 38.1% for additional rate taxpayers. Dividend income that is within the dividend allowance will still count towards an individual’s basic or higher rate limits. Dividend income will be treated as the top slice of a holder’s income.

*UK resident corporate holders of ordinary shares or ADSs*

Corporate holders resident in the United Kingdom for tax purposes will not normally be subject to UK corporation tax on any dividend received from the Company. In general, a corporate holder resident in the United Kingdom for tax purposes should not normally be subject to

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corporation tax on any dividend payments by the Company. A broad tax exemption applies, with separate conditions for holders that are small companies. If the conditions for exemption are failed or, in the case of holders who are not small companies, specific anti-avoidance provisions apply, a corporate holder will be subject to corporation tax on income on the dividend payment. Where a dividend payment qualifies for exemption, it is possible for the holder to elect for the dividend to be taxable. Companies should seek specific professional advice on whether a dividend payment qualifies for exemption.

*Non-UK resident holders of ordinary shares or ADSs*

A holder who is not resident in the United Kingdom for tax purposes will generally not be subject to UK tax on dividend receipts. Non-UK resident holders may be treated as having suffered the 7.5% ‘basic rate’ charge on their dividend income but this attributed credit will not be repayable.

***Taxation of Disposals***

A disposal or deemed disposal of an ordinary share or ADS by an individual resident in the United Kingdom may, depending on his or her individual circumstances, give rise to a chargeable gain or to an allowable loss for the purpose of UK capital gains tax. The principal factors that will determine the capital gains tax position on a disposal of an ordinary share or an ADS are the extent to which the holder realizes any other capital gains in the tax year in which the disposal is made, the extent to which the holder has incurred capital losses in that or any earlier tax year and the level of the annual exemption for tax-free gains in that tax year (the “annual exemption”). The annual exemption for the 2016/2017 tax year is £11,100. If, after all allowable deductions, a UK-resident individual holder’s total taxable income for the year exceeds the basic rate income tax limit, a taxable capital gain accruing on a disposal of an ordinary share or an ADS is taxed at the rate of 20%. In other cases, a taxable capital gain accruing on a disposal of an ordinary share or ADS may be taxed at the rate of 10% or the rate of 20% or at a combination of both rates.

A UK-resident individual holder who ceases to be resident in the United Kingdom (or who fails to be regarded as resident in a territory outside the United Kingdom for the purposes of double taxation relief) for a period of five tax years or less than five years and who disposes of an ordinary share or an ADS during that period of temporary non-residence may be liable to UK capital gains tax on a chargeable gain accruing on such disposal on his or her return to the United Kingdom (or upon ceasing to be regarded as resident outside the United Kingdom for the purposes of double taxation relief) (subject to available exemptions or reliefs).

A disposal (or deemed disposal) of an ordinary share or ADS by a corporate holder resident in the United Kingdom may give rise to a chargeable gain or an allowable loss for the purpose of UK corporation tax. Such a holder should be entitled to an indexation allowance, which applies to reduce a capital gain to the extent that such a gain arises due to inflation. The allowance may reduce a chargeable gain but will not create or increase an allowable loss. A gain or loss in respect of currency fluctuations over the period of holding an ordinary share or an ADS are also brought into account on a disposal.

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*Non-UK resident holders of ordinary shares or ADSs*

An individual holder of an ordinary share or ADS who is not resident in the United Kingdom will not be liable to UK capital gains tax on capital gains realized on the disposal of an ordinary share or ADS unless such holder carries on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency in the United Kingdom to which the ordinary share or ADS is attributable. In these circumstances, such holder may, depending on his or her individual circumstances, be chargeable to UK capital gains tax on chargeable gains arising from a disposal of his or her ordinary share or ADS.

A corporate holder of an ordinary share or ADS that is not resident in the United Kingdom will not be liable for UK corporation tax on chargeable gains realized on the disposal of an ordinary share or ADS unless it carries on a trade in the United Kingdom through a permanent establishment to which the ordinary share or ADS is attributable. In these circumstances, a disposal (or deemed disposal) of an ordinary share or ADS by such holder may give rise to a chargeable gain or an allowable loss for the purposes of UK corporation tax.

***Inheritance Tax***

An individual who is neither domiciled nor deemed domiciled in the United Kingdom (under certain UK rules relating to previous domicile or long residence) is only chargeable to UK inheritance tax to the extent the individual owns assets situated in the United Kingdom. As a matter of UK law, it is not clear whether the situs of an ADS for UK inheritance tax purposes is determined by the place where the depositary is established and records the entitlements of the deposit holders, or by the situs of the underlying share which the ADS represents, but the UK tax authorities may take the view that the ADSs, as well as the ordinary shares, are or represent UK-situs assets.

However, an individual who is domiciled in the United States (for the purposes of the Estate and Gift Tax Convention (the “Convention”), and is not a UK national as defined in the Convention, will not be subject to UK inheritance tax (to the extent UK inheritance tax applies) in respect of the ordinary shares or ADSs on the individual’s death or on a transfer of the ordinary shares or ADSs during their lifetime, provided that any applicable U.S. federal gift or estate tax is paid, unless the ordinary shares or ADSs are part of the business property of a UK permanent establishment or pertain to a UK fixed base of an individual used for the performance of independent personal services. Where the ordinary shares or ADSs have been placed in trust by a settlor, they may be subject to UK inheritance tax unless, when the trust was created, the settlor was domiciled in the United States and was not a UK national. If no relief

is given under the Convention, inheritance tax may be charged on death and also on the amount by which the value of an individual's estate is reduced as a result of any transfer made by way of gift or other undervalue transfer, broadly within seven years of death, and in certain other circumstances. Where the ordinary shares or ADSs are subject to both UK inheritance tax and to U.S. federal gift or estate tax, the Convention generally provides for either a credit against U.S. federal tax liabilities for UK inheritance tax paid or for a credit against UK inheritance tax liabilities for U.S. federal tax paid, as the case may be.

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***Stamp Duty and Stamp Duty Reserve Tax***

No UK stamp duty will generally be payable on the acquisition or transfer of ADSs or beneficial ownership of ADSs, provided that any instrument of transfer or written agreement to transfer remains at all times outside the United Kingdom, and provided further that any instrument of transfer or written agreement to transfer is not executed in the United Kingdom and the transfer does not relate to any matter or thing done or to be done in the United Kingdom. An agreement for the transfer of ADSs or beneficial ownership of ADSs should not give rise to a liability to stamp duty and stamp duty reserve tax (“SDRT”).

UK legislation does however provide for stamp duty (in the case of transfers) or SDRT to be payable at the rate of 1.5% on the amount or value of the consideration (or, in some cases, the value of the ordinary shares) where ordinary shares are issued or transferred to a person (or a nominee or agent of a person) whose business is or includes issuing depositary receipts or the provision of clearance services. In accordance with the terms of the deposit agreement, any tax or duty payable on deposits of ordinary shares by the depositary or by the custodian of the depositary will typically be charged to the party to whom ADSs are delivered against such deposits.

Following litigation on the subject, HMRC has accepted that it will no longer seek to apply the 1.5% SDRT charge when new shares are issued to a clearance service or depositary receipt system on the basis that the charge is not compatible with EU law. In HMRC's view, the 1.5% SDRT or stamp duty charge will continue to apply to transfers of shares into a clearance service or depositary receipt system unless they are an integral part of an issue of share capital. This view is currently being challenged in further litigation. Accordingly, specific professional advice should be sought before paying the 1.5% SDRT or stamp duty charge in any circumstances.

A transfer of an ordinary share will generally be subject to UK stamp duty at 0.5% of the value of any consideration provided (rounded up to the nearest £5). An agreement to transfer an ordinary share will normally give rise to a charge to SDRT at the rate of 0.5% of the amount or value of the consideration payable for the transfer. Any such stamp duty or SDRT is, in general, payable by the purchaser.

A transfer of ordinary shares from a nominee to its beneficial owner, including the transfer of underlying ordinary shares from the depositary to an ADS holder, under which no beneficial interest passes, will generally not be subject to stamp duty or SDRT.

***The Proposed Financial Transactions Tax (FTT)***

On February 14, 2013, the European Commission published a proposal for a Directive for a common FTT in Belgium, Germany, Estonia, Greece, Spain, France, Italy, Austria, Portugal, Slovenia and Slovakia (the participating Member States).

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The proposed FTT has very broad scope and could, if introduced in the current form as proposed on February 14, 2013, apply to certain dealings in ordinary shares (including secondary market transactions) in certain circumstances.

Under the proposals, the FTT could apply in certain circumstances to persons both within and outside of the participating Member States. Generally, it would apply to certain dealings in ordinary shares where at least one party is a financial institution, and at least one party is established in a participating Member State. A financial institution may be, or be deemed to be, “established” in a participating Member State in a broad range of circumstances, including (a) by transacting with a person established in a participating Member State or (b) where the financial instrument which is subject to the dealings is issued in a participating Member State. Prospective holders of ordinary shares should therefore note, in particular, that if the FTT is introduced, financial transactions relating to

ordinary shares may be subject to the FTT at a minimum rate of 0.1% provided certain conditions are met.

The FTT proposal remains subject to negotiation between the participating Member States, and the legality and scope of the proposal is uncertain. It may therefore be altered prior to any implementation, the timing of which remains unclear. Additional EU Member States may decide to participate. In December 2015 it was announced that Estonia had withdrawn and a joint statement was issued by several participating Member States, indicating an intention to make decisions on the remaining open issues by the end of June 2016. However, at the 3,475<sup>th</sup> Council meeting held on June 17, 2016, it was decided that work on the remaining open issues will continue during the second half of 2016. Therefore, prospective holders of the ordinary shares or ADSs are advised to seek their own professional advice in relation to the FTT.

## **F. Dividends and Paying Agents**

For a discussion of the declaration and payment of dividends on our ordinary shares, see “Item 10.B.—Dividends and other distributions.”

The paying agent for Indivior PLC’s shares is Computershare Investor Services PLC.

## **G. Statements by Experts**

The financial statements of Indivior PLC as of December 31, 2015 and 2014 and for each of the three years in the period ended December 31, 2015 included in this Registration Statement have been so included in reliance on the audit report of PricewaterhouseCoopers LLP, independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. PricewaterhouseCoopers LLP is a member of the Institute of Chartered Accountants of England and Wales.

## **H. Documents on Display**

When this registration statement on Form 20-F becomes effective, we will be subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers, and under those requirements will file reports with the SEC. Those other reports or other information and this registration statement may be inspected without charge and copied at the public reference facilities of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains a website at <http://www.sec.gov> from which certain filings may be accessed.

As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, for so long as we are listed on the [·], or any other U.S. exchange, and are registered with the SEC, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the SEC, on a Form 6-K, unaudited quarterly financial information for the first three quarters of each year.

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We will maintain a corporate website. Information contained on, or that can be accessed through, our website does not constitute a part of this registration statement on Form 20-F.

## **I. Subsidiary Information**

Not applicable.

## **ITEM 11: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

In addition to the risks inherent in our operations, we are exposed to a variety of financial risks, such as market risk (including foreign currency exchange, cash flow and interest rate risk), credit risk and liquidity risk, and further information can be found in Note 15 to the audited, consolidated financial statements included elsewhere in this registration statement.

## ITEM 12: DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

### A. Debt Securities

Not applicable.

### B. Warrants and Rights

Not applicable.

### C. Other Securities

Not applicable.

### D. American Depositary Shares

JPMorgan Chase Bank, N.A., as depositary, will register and deliver American Depositary Shares (“ADSs”). Each ADS represents five ordinary shares having a nominal value of \$0.10 per share (or a right to receive five ordinary shares) and is deposited with a custodian appointed by the depositary. The ADSs are administered at the depositary’s principal executive office located at 4 New York Plaza, Floor 12, New York, New York 10004.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an American Depositary Receipt (“ADR”) holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

The Direct Registration System, or DRS, is a system administered by The Depository Trust Company, also referred to as DTC, pursuant to which the depositary may register in book-entry form the ownership of uncertificated ADSs, which ownership is confirmed by periodic statements sent by the depositary to the registered holders of uncertificated ADSs. Unless certificated ADRs are specifically requested by you, all ADSs will be issued on the books of our depositary in book-entry form.

As an ADR holder, we will not treat you as one of our shareholders and you will not have shareholder rights. English law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADR holder rights. A deposit agreement among us, the depositary and you, as an ADR holder, and all other persons directly or indirectly holding ADSs sets out ADR holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. Under the deposit agreement, as an ADR holder, you agree that any legal suit, action or proceeding against or involving us or the depositary, arising out of or based upon the deposit agreement, the ADSs or the transactions contemplated thereby, may only be instituted in a state or federal court in New York, New York, and you irrevocably waive any objection which you may have to the laying of venue of any such proceeding and irrevocably submit to the exclusive jurisdiction of such courts in any such suit, action or proceeding.

The following is a summary of what we believe to be the material provisions of the deposit agreement. Because it is a summary, it does not contain all the information that may be important to you. For more complete information, you should read the entire deposit agreement and the form of ADR which summarizes certain terms of your ADSs. A copy of the deposit agreement is incorporated by reference to this registration statement on Form 20-F. You may also obtain a copy of the deposit agreement at the SEC’s Public Reference Room which is located at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-732-0330. You may also find the registration statement and the deposit agreement on the SEC’s website at <http://www.sec.gov>.

#### Voting Rights

You may instruct the depositary to vote the number of deposited ordinary shares your ADSs represent. The depositary will not itself exercise any voting discretion in respect of the ordinary shares. The depositary will notify you of shareholders’ meetings and distribute our voting materials to you or provide instructions on how to retrieve such materials. For your voting instructions to be valid, they must reach the depositary by a date established by the depositary.

The depositary will attempt, as far as practical, subject to the laws of England and our Articles of Association or similar documents, to vote the shares represented by your ADSs. The depositary will only vote or attempt to vote as instructed by you.

We cannot assure you that you will receive the notice or voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise your right to vote.

#### Dividends and Other Distributions

The depositary has agreed to pay to you the cash dividends or other distributions it or the custodian receives on shares or other

deposited securities, after deducting its fees and expenses. The depositary may utilize a division, branch or affiliate of JPMorgan Chase Bank, N.A. to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent.

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- **Cash.** The depositary will pay any cash dividend or other cash distribution or net proceeds of sales we pay on the shares in U.S. dollars.
- Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. The depositary will distribute only whole U.S. dollars and cents and will withhold any fractional cents.
- **Shares.** The depositary will distribute additional ADRs evidencing whole ADSs representing any shares we distribute as a dividend or free distribution consisting of shares, and U.S. dollars available to it resulting from the net proceeds received in such a distribution if such shares would give rise to fractional ADSs.
  - **Rights to purchase additional shares.** If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may make these rights available to you. If the depositary decides it is not legal and practical to make the rights available but that it is practical to sell the rights, the depositary will sell the rights and distribute the proceeds in the same way as it does with cash. The depositary will allow rights that are not distributed or sold to lapse. In that case, you will receive no value for such rights.
  - **Other Distributions.** The depositary will send to you anything else we distribute on deposited securities by any means it determines is equitable and practical. It may decide to sell what we distributed and distribute the net proceeds in the same way as it does with cash.

If the depositary determines in its discretion that any distribution described above is not practicable with respect to any specific registered ADR holder, the depositary may choose any method of distribution that it deems practicable for such ADR holder, including the distribution of foreign currency, securities or property, or it may retain such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items.

Any U.S. dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

**Notices**

The depositary will send to you any notices, reports or proxy soliciting material by first class mail, postage prepaid, to your address as listed on the ADR register.

**Exercise of Rights**

ADR holders may exercise their voting rights with respect to the ordinary shares underlying the ADSs only in accordance with the provisions of the deposit agreement.

**Payment of Taxes**

If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, such tax or other governmental charge shall be paid by the holder thereof to the depositary and by holding or having held an ADR the holder and all prior holders thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect thereof. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split-up or combination of deposited securities or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto.

By holding an ADR or an interest therein, you will be agreeing to indemnify us, the depositary, its custodian and any of our or

their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained.

**Changes Affecting the Ordinary Shares**

The depositary may, in its discretion, and shall if reasonably requested by us, amend the ADRs or distribute additional or amended ADRs, cash, securities or property to reflect any (i) changes in nominal value, splits, consolidation, cancellation or reclassification of the ordinary shares, (ii) distributions not distributed to the holders or (iii) any cash, securities or property received by the depositary in respect of the ordinary shares from any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of our assets. If the depositary does not amend the ADRs, each ADS evidenced by an ADR will automatically represent its pro rata interest in the ordinary shares.

**Amendment and Termination**

The deposit agreement may be amended by us and the depositary. You will be notified of any amendment that imposes or increases any fees or charges, and such amendment will become effective 30 days after notice of such amendment. Any amendment made in accordance with new laws, rules or regulations may become effective before you are notified or within any other period of time that is required for compliance.

The depositary may, and shall at our written direction, terminate the deposit agreement and the ADRs. The depositary will mail you a notice of such termination at least 30 days prior to the date of termination. After termination, the depositary will perform no further acts under the deposit agreement, but will continue to receive and hold (or sell) distributions on the ordinary shares and deliver any ordinary shares that are being withdrawn. The depositary will sell the ordinary shares as soon as practicable after six months of termination and hold the net proceeds in trust for the pro rata benefit of the holders of ADRs that have not been surrendered, after which the depositary will be discharged from all obligations under the deposit agreement. After the termination date, our

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obligations under the deposit agreement will be discharged except for our obligations to the depositary and its agents.

**Restrictions on Transfers and Withdrawals**

The withdrawal of the ordinary shares by holders may be restricted only for the reasons set forth in General Instruction I.A. (1) of Form F-6 under the Securities Act of 1933. Any withdrawals or transfers may require the payment of any stock transfer fees, taxes or charges applicable under the deposit agreement. Holders requesting withdrawals or transfers may need to present proof of identity and genuineness of any signature and any other information including, but not limited to, citizenship, residence, exchange control approval, beneficial ownership of securities and compliance with laws and any regulations of the depositary.

**Books of Depositary**

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register may be closed at any time or from time to time, when deemed expedient by the depositary.

**Limitations on Depositary's Liability**

The depositary is not liable if (i) any laws, provisions of our charter or any circumstance beyond its control prevents or delays, or causes the depositary to be subject to any civil or criminal penalty in connection with any act that the depositary is obligated to perform under the deposit agreement or the form of ADR or (ii) by reason of any exercise or failure to exercise any discretion given to the depositary under the Deposit Agreement or the form of ADR. The depositary assumes no liability for its performance so long as it does not engage in gross negligence or willful misconduct and has no obligation to appear in, prosecute or defend any action in respect of any of the ordinary shares or the ADRs.

The depositary is not liable for (i) any action or inaction if it relied upon the advice of legal counsel, accountants, any person presenting the ordinary shares for deposit, any holder or any other person that the depositary believes to be competent to give such

advice, (ii) any acts or omissions by any securities depository, clearing agency or settlement system, (iii) the insolvency of any custodian that is not an affiliate of the depository or (iv) the price received in connection with any sale of securities or the timing of such sale or any delay in action or omission to act. In addition, the depository and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions.

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**Fees and Expenses**

Category (as defined by SEC)	Depository Actions	Associated Fee
(a) Depositing or substituting the underlying shares	Each person to whom ADRs are issued against deposits of Shares, including deposits and issuances in respect of: <ul style="list-style-type: none"><li>Share distributions, stock split, rights, merger</li><li>Exchange of securities or any other transaction or event or other distribution affecting the ADSs or the Deposited Securities</li></ul>	US\$ 5.00 for each 100 ADSs (or portion thereof) evidenced by the new ADRs delivered
(b) Receiving or distributing dividends	Distribution of dividends	US\$ 0.05 or less per ADS
(c) Selling or exercising rights	Distribution or sale of securities, the fee being in an amount equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities	US\$ 5.00 for each 100 ADSs (or portion thereof)
(d) Withdrawing an underlying security	Acceptance of ADRs surrendered for withdrawal of deposited securities	US\$ 5.00 for each 100 ADSs (or portion thereof) evidenced by the ADRs surrendered
(e) Transferring, splitting or grouping receipts	Transfers, combining or grouping of depository receipts	US\$ 1.50 per ADS
(f) General depository services, particularly those charged on an annual basis	<ul style="list-style-type: none"><li>Other services performed by the depository in administering the ADRs</li><li>Provide information about the depository’s right, if any, to collect fees and charges by offsetting them against dividends received and deposited securities</li></ul>	US\$ 0.05 per ADS (or portion thereof) not more than once each calendar year and payable at the sole discretion of the depository by billing Holders or by deducting such charge from one or more cash dividends or other case distributions
(g) Expenses of the depository	Expenses incurred on behalf of Holders in connection with <ul style="list-style-type: none"><li>Compliance with foreign exchange control regulations or any law or regulation relating to foreign investment</li><li>The depository’s or its custodian’s compliance with applicable law, rule or regulation</li><li>Stock transfer or other taxes and other governmental charges</li></ul>	

- Cable, telex, facsimile transmission/delivery
- Expenses of the depositary in connection with the conversion of foreign currency into U.S. dollars (which are paid out of such foreign currency)
- Any other charge payable by depositary or its agents

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We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary. The charges described above may be amended from time to time by agreement between us and the depositary.

The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

The depositary anticipates reimbursing us for certain expenses related to the establishment and maintenance of the ADR program upon such terms and conditions as agreed upon between us and the depositary.

## **PART II**

### **ITEM 13 DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

None.

### **ITEM 14: MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS**

None.

### **ITEM 15: CONTROLS AND PROCEDURES**

Not applicable.

### **ITEM 16A: AUDIT COMMITTEE FINANCIAL EXPERT**

Not applicable.

### **ITEM 16B: CODE OF ETHICS**

Not applicable.

**ITEM 16C: PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Not applicable.

**ITEM 16D: EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**ITEM 16E: PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

None.

**ITEM 16F: CHANGE IN REGISTRANTS CERTIFYING ACCOUNTANT**

None.

**ITEM 16G: CORPORATE GOVERNANCE**

Not applicable.

**ITEM 16H: MINE SAFETY DISCLOSURE**

Not applicable.

**PART III**

**ITEM 17: FINANCIAL STATEMENTS**

We have elected to furnish financial statements and related information specified in Item 18.

**ITEM 18: FINANCIAL STATEMENTS**

See the Financial Statements beginning on page F-1.

**ITEM 19: EXHIBITS**

Exhibit No.	Description
1.1	Memorandum and Articles of Association of Indivior PLC.
2.1*	Deposit Agreement dated December 23, 2014 among Indivior PLC, JPMorgan Chase Bank, N.A., as Depositary and Owners and Holders from time to time of the American Depositary Receipts issued thereunder, including the Form of American Depositary Receipt.
2.2*	Amendment No. 1 to Deposit Agreement among Indivior PLC, JPMorgan Chase Bank, N.A. as Depositary and Holders from time to time of the American Depositary Receipts issued thereunder, including the Form of American Depositary Receipt.
4.1*†	Credit Agreement, by and among Morgan Stanley Senior Funding, Inc., Indivior Finance S.à.r.l., Indivior Finance (2014) LLC, RBP Global Holdings Limited and the other Loan Parties, dated December 19, 2014.

4.2*	First Amendment to the Credit Agreement, Credit Agreement, by and among Morgan Stanley Senior Funding, Inc., Indivior Finance S.à.r.l., Indivior Finance (2014) LLC, RBP Global Holdings Limited and the other Loan Parties, dated March 16, 2015.
4.3*	Demerger Agreement, by and among Reckitt Benckiser Group PLC, Indivior PLC, Reckitt Benckiser Healthcare (UK) Limited, RB Pharmaceuticals Limited and RBP Global Holdings Limited, dated November 17, 2014.
4.4*	Transitional Services Agreement by and between Reckitt Benckiser PLC and RBP Global Holdings Limited, dated December 23, 2014.
4.5*	Deed of Tax Covenant by and between Reckitt Benckiser Group plc and Indivior PLC, dated December 23, 2014.
4.6*	United States Tax Matters Agreement by and between Reckitt Benckiser Group PLC and Indivior PLC, dated December 23, 2014.
4.7*	Amended and Restated Supply Agreement by and between Reckitt Benckiser Healthcare (UK) Limited and RB Pharmaceuticals Limited, as amended and restated on November 17, 2014.
4.8*	Copacker Supply Agreement by and between Reckitt Benckiser Healthcare (UK) Limited and RB Pharmaceuticals Limited, dated December 23, 2014.
4.9*	Lease of Land and Buildings at Dansom Lane, Hull HU8 7DS, by and between Reckitt Benckiser Healthcare (UK) Limited and RB Pharmaceuticals Limited, dated December 1, 2014.
4.10*	Research and Development Services Agreement by and between Reckitt Benckiser Healthcare (UK) Limited and RB Pharmaceuticals Limited, dated December 23, 2014.
4.11*	Commercial Exploitation Agreement by and between MonoSol Rx, LLC and Reckitt Benckiser Pharmaceuticals Inc., dated August 15, 2008 (as amended on August 19, 2009, November 13, 2009, March 30, 2010, October 13, 2010, December 15, 2010, December 9, 2011, December 1, 2012, October 14, 2013 (by Addendum A), and July 30, 2014 (by Addendum B).
4.12*	License Agreement by and between XenoPort, Inc. and Reckitt Benckiser Pharmaceuticals Inc., dated May 14, 2014.
8.1	List of Subsidiaries.
15.1	Consent of PricewaterhouseCoopers LLP.

## Signatures

Indivior PLC

Shaun Thaxter  
*Chief Executive Officer*

# INDIVIOR PLC

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Unaudited condensed consolidated interim income statements

For the three months to March 31	Notes	Unaudited 2016 \$m	Unaudited 2015 \$m
<b>Net Revenues</b>	2	258	251
Cost of Sales		(21)	(24)
<b>Gross Profit</b>		237	227
Selling, distribution and administrative expenses	3	(105)	(92)
Research and development expenses	3	(31)	(20)
<b>Operating Profit</b>		101	115
Finance expense		(15)	(13)
Net finance expense		(15)	(13)
<b>Profit before taxation</b>		86	102
Taxation	4	(36)	(25)
<b>Net income</b>		50	77
<b>Earnings per ordinary share (cents)</b>			
Basic earnings per share	5	7	11
Diluted earnings per share	5	7	11

Unaudited condensed consolidated interim statements of comprehensive income

For the three months to March 31	Unaudited 2016 \$m	Unaudited 2015 \$m
Net income	50	77
<b>Other comprehensive income</b>		
<i>Items that may be reclassified to profit or loss in subsequent years</i>		
Net exchange adjustments on foreign currency translation	(3)	(9)
Other comprehensive income	(3)	(9)
<b>Total comprehensive income</b>	47	68

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

Unaudited condensed consolidated interim balance sheets

	Notes	Unaudited Mar 31, 2016 \$m	Audited Dec 31, 2015 \$m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		55	62
Property, plant and equipment		36	32
Deferred tax assets		100	122
		191	216
<b>Current assets</b>			
Inventories		48	48
Trade and other receivables		241	206
Cash and cash equivalents		543	467
		832	721
<b>Total assets</b>		1,023	937
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	6	(52)	(34)
Trade and other payables	8	(570)	(528)
Current tax liabilities		(61)	(54)
		(683)	(616)
<b>Non-current liabilities</b>			
Borrowings	6	(542)	(571)
Provisions for liabilities and charges		(41)	(42)
		(583)	(613)
<b>Total liabilities</b>		(1,266)	(1,229)
<b>Net liabilities</b>		(243)	(292)
<b>EQUITY</b>			
<b>Capital and reserves</b>			
Share capital	9	72	72
Other Reserves		(1,295)	(1,295)
Foreign currency translation reserve		(26)	(23)
Retained Earnings		1,006	954
<b>Total equity</b>		(243)	(292)

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

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Unaudited condensed consolidated interim statements 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
<b>At January 1, 2015</b>		1,437	—	(1,295)	(16)	(601)	(475)
<b>Comprehensive income</b>							
Net income		—	—	—	—	77	77
Other comprehensive income		—	—	—	(1)	(9)	(10)
<b>Total comprehensive income</b>		—	—	—	(1)	68	67

<b>Transactions recognised directly in equity</b>						
Capital reduction	(1,365)	—	—	—	1,365	—
<b>Balance at March 31, 2015</b>	<u>72</u>	<u>—</u>	<u>(1,295)</u>	<u>(17)</u>	<u>832</u>	<u>(408)</u>
<b>Unaudited</b>						
<b>At January 1, 2016</b>	<u>72</u>	<u>—</u>	<u>(1,295)</u>	<u>(23)</u>	<u>954</u>	<u>(292)</u>
<b>Comprehensive income</b>						
Net income	—	—	—	—	50	50
Other comprehensive income	—	—	—	(3)	—	(3)
<b>Total comprehensive income</b>	<u>—</u>	<u>—</u>	<u>—</u>	<u>(3)</u>	<u>50</u>	<u>47</u>
<b>Transactions recognised directly in equity</b>						
Share-based plans	—	—	—	—	3	3
Deferred taxation on share-based plans	—	—	—	—	(1)	(1)
<b>Total transactions recognised directly in equity</b>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>2</u>	<u>2</u>
<b>Balance at March 31, 2016</b>	<u>72</u>	<u>—</u>	<u>(1,295)</u>	<u>(26)</u>	<u>1,006</u>	<u>(243)</u>

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

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#### Unaudited condensed consolidated interim cash flow statements

	Unaudited 2016 \$m	Unaudited 2015 \$m
<b>For the three months to March 31</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit	101	115
Depreciation and amortization	6	6
Share-based payments	2	—
Impact from foreign exchange movements	(2)	1
(Increase)/decrease in trade and other receivables	(35)	26
Decrease in inventories	—	1
Increase in trade and other payables and provisions	43	64
<b>Cash generated from operations</b>	<u>115</u>	<u>213</u>
Interest paid	(11)	(11)
Transaction costs related to loan	—	(23)
Taxes paid, net	(7)	(14)
<b>Net cash inflow from operating activities</b>	<u>97</u>	<u>165</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(4)	—
<b>Net cash (outflow) from investing activities</b>	<u>(4)</u>	<u>—</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Cash movements on overdraft	—	(9)
Cash movements in borrowings	(17)	(9)
<b>Net cash (outflow) from financing activities</b>	<u>(17)</u>	<u>(18)</u>
<b>Net increase in cash and cash equivalents</b>	76	147
Cash and cash equivalents at beginning of the period	467	331
<b>Exchange differences</b>	—	(12)
<b>Cash and cash equivalents at end of the period</b>	<u>543</u>	<u>466</u>

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

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## Notes to the unaudited condensed consolidated interim Financial Statements

### 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

Indivior PLC (the ‘Company’) is a public limited company incorporated on September 26, 2014 and domiciled in the United Kingdom. In these unaudited condensed consolidated interim financial statements (‘Interim Financial Statements’), reference to the ‘Group’ means the Company and all its subsidiaries.

These unaudited 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, 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 issued by the International Accounting Standards Board. In preparing these unaudited condensed consolidated interim financial statements, the significant judgments made by management in applying the Group’s accounting policies and the key sources of estimation uncertainty were the same as those that applied to the consolidated financial statements for the year ended December 31, 2015, with the exception of changes in estimates that are required in determining the provision for income taxes.

The unaudited 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, 2015. These unaudited condensed consolidated interim financial statements have been approved for issue as at April 29, 2016.

### 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.

#### Net revenues

Net revenues are attributed to countries based on the country where the sale originates. The following table represents net revenues 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. Net revenues and non-currents assets for the three months to March 31, 2016 and 2015 were as follows:

Net revenues from sale of goods:

For the three months to March 31	2016 \$m	2015 \$m
United States	211	200
ROW	47	51
<b>Total</b>	<b>258</b>	<b>251</b>

Non-current assets:

	Mar 31 2016 \$m	Dec 31 2015 \$m
United States	82	80
ROW	9	14
<b>Total</b>	<b>91</b>	<b>94</b>

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### 3. OPERATING COSTS AND EXPENSES

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

For the three months to March 31	2016 \$m	2015 \$m
Research and development expenses	(31)	(20)
Marketing, selling and distribution expenses	(32)	(38)
Administrative expenses	(66)	(47)
Depreciation and amortisation	(6)	(6)
Operating lease rentals	(1)	(1)
<b>Total</b>	<b>(105)</b>	<b>(92)</b>

### 4. TAXATION

In the three months ended March 31, 2016, tax on total profits amounted to \$36m and represented a quarterly effective tax rate of 42% (Q1 2015: 25%). The Group's balance sheet at March 31, 2016 included a tax payable liability of \$61m and deferred tax asset of \$100m.

The increase in the effective tax rate, to 42% was primarily driven by income mix between countries in the quarter, but this income mix is expected to change in the full year.

### 5. EARNINGS PER SHARE

For the three months to March 31	2016 cents	2015 Cents
Basic earnings per share	7	11
Diluted earnings per share	7	11

#### 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. 718,577,618 shares were issued on the demerger.

#### 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. The weighted average number of shares is adjusted for the number of shares granted assuming the exercise of stock options.

	2016 Average number of shares	2015 Average number of shares
On a basic basis	718,577,618	718,577,618
Dilution for Long Term Incentive Plan	12,692,955	5,307,010
On a diluted basis	<b>731,270,573</b>	<b>723,884,628</b>

### 6. FINANCIAL LIABILITIES — BORROWINGS

	Mar 31 2016 \$m	Dec 31 2015 \$m
<b>Current</b>		

Bank loans	(52)	(34)
	(52)	(34)
	<b>Mar 31 2016 \$m</b>	<b>Dec 31 2015 \$m</b>
<b>Non-current</b>		
Bank loans	(542)	(571)
	(542)	(571)

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	<b>Mar 31 2016 \$m</b>	<b>Dec 31 2015 \$m</b>
<b>Analysis of net debt</b>		
Cash and cash equivalents	543	467
Borrowings*	(626)	(641)
	(83)	(174)

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

	<b>Mar 31 2016 \$m</b>	<b>Dec 31 2015 \$m</b>
<b>Reconciliation of net debt</b>		
The movements in the period were as follows:		
Net debt at beginning of period	(174)	(428)
Increase in cash and cash equivalents	76	136
Net repayment of borrowings and overdraft	17	121
Exchange adjustments	(2)	(3)
Net debt at end of period	(83)	(174)

The carrying value less 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 are as follows:

	<b>Currency</b>	<b>Nominal interest margin</b>	<b>Maturity</b>	<b>Scheduled repayments*</b>	<b>Issuance cost \$m</b>	<b>Face value \$m</b>	<b>Carrying amount \$m</b>
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 net secured 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.

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

In 2011, the USAO-NJ issued a subpoena to RBP requesting production of certain documents in connection with a non-public investigation related, among other things, to the promotion, marketing and sale of Suboxone® Film, Suboxone® Tablet and Subutex Tablet. RBP responded to the USAO-NJ by producing documents and other information and has had no communication from USAO-NJ since March 2013.

In late 2012, the FTC commenced a non-public investigation of Indivior Inc. and various formerly-related Reckitt Benckiser Group entities by issuing a civil investigative demand, focusing on business practices relating to SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet, including those practices which are the subject of the series of antitrust complaints filed in federal court against Indivior Inc. (the “MDL Litigation”) (collectively, the “FTC Investigation”). Indivior responded to the civil investigative demand by producing documents and other information to the Federal Trade Commission (the “FTC”). The investigation is on-going, and as yet no decision has been made by the FTC on whether to pursue any legal action for enforcement.

Indivior’s response to the civil investigative demand included the production of hundreds of thousands of pages of documents. The Company also withheld a significant number of documents on the basis of legal privilege, however, and the FTC has objected to the privilege claims made with respect to many of those documents. 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 on March 31, 2016. The Company has filed objections to the Special Master’s report, and the Court ultimately will determine whether to adopt the Special Master’s recommendations in whole or in part, or to reject them in their entirety. The Court’s decision then may be subject to appeal in the United States Court of Appeals by either party, although it may be necessary to wait for a court decision on the remaining documents in dispute before any appeal.

In July 2013, the Attorney General of the State of New York commenced an antitrust investigation into the same conduct being investigated by the FTC. The State of New York issued a subpoena to which the Company has responded by producing the same materials it has produced to the FTC. In August 2015, the Company was informed that a contingent of additional states had initiated a coordinated investigation into the same conduct that is the subject of the FTC Investigation and the MDL Litigation. The existing investigation of these same issues by the State of New York has now been incorporated within this multi-state investigation. On July 1, 2016, Indivior was notified that twenty-two states and the District of Columbia intend to file a complaint in the Eastern District of Pennsylvania alleging violations of state and federal antitrust and consumer protection laws relating to the same conduct. To date, New York has not joined the notice or otherwise expressed its intention to sue. The notice indicates, however, that additional states may decide to join in any action.

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 United States Attorney for the Western District of Virginia has served a number of subpoenas relating to Suboxone® Film, Suboxone® Tablet, Subutex® Tablet, Buprenorphine and the Group’s competitors, among other issues. Indivior is in the process of responding by producing documents and other information in connection with this ongoing investigation. It is not possible at this time to predict with any certainty or to quantify the potential impact of this investigation on the Company. Indivior is cooperating fully with the relevant agencies and prosecutors and will continue to do so.

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It is not possible at this time to predict with any certainty if there will be a liability associated with these investigations nor, if one were to occur, is there an ability to quantify the potential impact on the financial statements of the Indivior Group.

**ANDA Litigation**

Beginning in August 2013, we have been informed of ANDA applications filed by six competitors for the FDA approval of generic versions of SUBOXONE® Film in the United States. We have filed patent infringement lawsuits against all six companies as summarized below:

- Trial in the lawsuits against Actavis and Par involving the Orange Book-listed patents for Suboxone® Film, November and December 2015, and the post-trial briefing concluded in March 2016. In a judgment issued on June 3, 2016, the District Court in Delaware found that Actavis’ and Par’s ANDA products infringe the asserted claims of U.S. Patent No. 8,603,514, one of the

Company's Orange Book listed patents for SUBOXONE® Film, and that the asserted claims of that patent are not invalid. The Court also ruled that the asserted claims of U.S. Patent No. 8,017,150, which is set to expire in 2023, are valid, but that they are not infringed by Actavis' or Par's ANDA products. The Court found that the asserted claims of U.S. Patent No. 8,475,832 are invalid, but that certain of the claims of this patent would be infringed by Actavis and Par's ANDA products if they were valid.

- Trial against Teva, Actavis and Par in the lawsuits involving the two recently granted process patents (US Patent No. 8,906,277 and US Patent No. 8,900,497) scheduled for November 2016.
- Trial against Teva in the lawsuit involving the Orange Book-listed patents for Suboxone® Film scheduled for November 2016, with Teva's 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17, 2017. Indivior believes Teva's 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17, 2017, however, Teva disputes the applicability of the stay to this ANDA.
- Trial against Alvogen in the lawsuit involving the Orange Book-listed patents and process patents for Suboxone® Film scheduled for April 2017, with Alvogen's 30-month stay of FDA approval expiring October 29<sup>th</sup>, 2017.
- Trial against Mylan in the lawsuit involving the Orange Book-listed patents for Suboxone® Film is scheduled for September 25<sup>th</sup>, 2017, with Mylan's stay expiring March 24, 2018. There is also a second, stayed lawsuit between the Company and Mylan in the Northern District of West Virginia. We and Sandoz have each submitted a proposed order to dismiss their patent litigation suit which are pending before the court.
- Indivior received a Paragraph IV notification from Teva, dated February 8, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16 mg/4 mg strength of buprenorphine/naloxone sublingual film. Indivior filed suit against Teva within 45 days, triggering a 30-month stay of approval of Teva's 5-05(b)(2) NDA. The Indivior Group and Teva 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 its ANDA currently scheduled for trial in November 2016.
- The USPTO declined to institute Teva's petitions for inter partes review of the three Orange Book-listed patents.

## 8. TRADE AND OTHER PAYABLES

	Mar 31 2016 \$m	Dec 31 2015 \$m
Sales returns and rebates	(321)	(287)
Trade payables	(102)	(113)
Accruals	(132)	(116)
Other tax and social security payables	(15)	(12)
Total	(570)	(528)

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
At March 31, 2016	718,577,618	\$ 0.10	72

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

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The holders of ordinary shares (nominal value \$0.10) are entitled to receive dividends as declared from time to time and are entitled to one vote per share at meetings of the Parent Company.

The initial shareholders resolved, by a special resolution, passed on October 30, 2014, to reduce Indivior’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 which will provide Indivior with, among other things, capacity for the payment of future dividends.

As required under section 645 of the Companies Act, 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.

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. In 2015, Adrian Hennah, the RB CFO, also sat on the Indivior PLC Board of Directors. He did not stand for re-election in the May 2016 Annual General Meeting of Shareholders, and consequently stood down from the Board. The amount included within administrative expenses in respect of these services is \$2m.

11. POST BALANCE SHEET EVENTS

In April and May of 2016, the Company repurchased an additional \$20m and \$16m, respectively of its syndicated debt in the market at a discount, retiring this debt early. Refer also to Note 7 for post balance sheet events impacting contingent liabilities.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Indivior PLC:

In our opinion, the accompanying consolidated balance sheets and the related consolidated income statements, statements of comprehensive income, statements of changes in equity and statements of cash flows present fairly, in all material respects, the financial position of Indivior PLC and its subsidiaries at December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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Consolidated income statements

For the years ended December 31	Notes	2015 \$m	2014 \$m	2013 \$m
<b>Net revenues</b>	3	1,014	1,115	1,216
Cost of sales		(97)	(95)	(104)
<b>Gross profit</b>		917	1,020	1,112
Selling, distribution and administrative expenses	4	(423)	(343)	(341)
Research and development expenses	4	(148)	(115)	(76)
<b>Operating profit</b>		346	562	695
Finance expense	7	(61)	(1)	—
Net finance expense	7	(61)	(1)	—
<b>Profit before taxation</b>		285	561	695
Taxation	8	(70)	(158)	(206)
<b>Net income</b>		215	403	489
<b>Earnings per ordinary share (cents)</b>	9			
Basic earnings per share		30	56	68
Diluted earnings per share		29	56	68

Consolidated statements of comprehensive income

For the year ended December 31	Notes	2015 \$m	2014 \$m	2013 \$m
Net income		215	403	489
<b>Other comprehensive income</b>				
<i>Items that may be reclassified to profit or loss in subsequent years:</i>				
Net exchange adjustments on foreign currency translation		(14)	(16)	—
Other comprehensive income		(14)	(16)	—
<b>Total comprehensive income</b>		201	387	489

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

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Consolidated balance sheets

As at December 31	Notes	2015 \$m	2014 \$m
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets	10	62	91
Property, plant and equipment	11	32	13
Deferred tax assets	12	122	77
Other receivables	14	—	1
		216	182
<b>Current assets</b>			
Inventories	13	48	41

Trade and other receivables	14	206	193
Cash and cash equivalents	16	467	331
		721	565
<b>Total assets</b>		<b>937</b>	<b>747</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Borrowings	17	(34)	(17)
Trade and other payables	21	(528)	(383)
Current tax liabilities		(54)	(62)
		(616)	(462)
<b>Non-current liabilities</b>			
Borrowings	17	(571)	(719)
Provisions for liabilities and charges	18	(42)	(41)
		(613)	(760)
<b>Total liabilities</b>		<b>(1,229)</b>	<b>(1,222)</b>
<b>Net liabilities</b>		<b>(292)</b>	<b>(475)</b>
<b>Equity</b>			
<b>Capital and reserves</b>			
Share capital	22	72	1,437
Other reserves	23	(1,295)	(1,295)
Foreign currency translation reserve	23	(23)	(16)
Retained earnings	23	954	(601)
		(292)	(475)
<b>Total equity</b>		<b>(292)</b>	<b>(475)</b>

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

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### Consolidated statements of changes in equity

	Notes	Share capital \$m	Share premium \$m	Other reserves \$m	Foreign currency translation reserve \$m	Retained earnings \$m	Total equity \$m
<b>Balances at January 1, 2013</b>		1,437	—	(1,295)	—	3	145
<b>Comprehensive income</b>							
Net income		—	—	—	—	489	489
Other comprehensive income		—	—	—	—	—	—
<b>Total comprehensive income</b>		—	—	—	—	489	489
Payments to former owners, recognized directly in equity	23	—	—	—	—	(967)	(967)
Charges from former owners, recognized directly in equity	23	—	—	—	—	267	267
<b>Total transactions with former owners</b>	23	—	—	—	—	(700)	(700)
<b>Balances at December 31, 2013</b>		1,437	—	(1,295)	—	(208)	(66)
<b>Balances at January 1, 2014</b>		1,437	—	(1,295)	—	(208)	(66)
<b>Comprehensive income</b>							
Net income		—	—	—	—	403	403

Other comprehensive income		—	—	—	(16)	—	(16)
<b>Total comprehensive income</b>		—	—	—	(16)	403	387
Payments to former owners, recognized directly in equity	23	—	—	—	—	(991)	(991)
Charges from former owners, recognized directly in equity	23	—	—	—	—	195	195
<b>Total transactions with former owners</b>	23	—	—	—	—	(796)	(796)
<b>Balances at December 31, 2014</b>		1,437	—	(1,295)	(16)	(601)	(475)
<b>Balances at January 1, 2015</b>		1,437	—	(1,295)	(16)	(601)	(475)
<b>Comprehensive income</b>							
Net income		—	—	—	—	215	215
Other comprehensive income		—	—	—	(7)	(7)	(14)
<b>Total comprehensive (expense)/income</b>		—	—	—	(7)	208	201
<b>Transactions with owners</b>							
Share based plans	23	—	—	—	—	8	8
Deferred taxation on share-based plans	23	—	—	—	—	(3)	(3)
Dividends paid	23	—	—	—	—	(23)	(23)
Capital reduction	23	(1,365)	—	—	—	1,365	—
Total transactions recognized directly in equity		(1,365)	—	—	—	1,347	(18)
<b>Balances at December 31, 2015</b>		72	—	(1,295)	(23)	954	(292)

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

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Consolidated cash flow statements

For the years ended December 31	Notes	2015 \$m	2014 \$m	2013 \$m
<b>Cash flows from operating activities</b>				
Operating profit		346	562	695
Depreciation amortization and impairment		32	26	28
Impairment and write-offs		8	—	—
Share-based payments	10,11	5	—	—
Impact from foreign exchange impacts		—	(13)	—
Trade and other receivables	14	(9)	3	110
Inventories		(9)	(5)	(2)
Payables and provisions	18,21	145	(50)	63
<b>Cash generated from operations</b>		518	523	894
Interest paid	17	(44)	—	—
Transaction costs related to loan	17	(23)	(24)	—
Taxes paid, net		(131)	(59)	(103)
<b>Net cash inflow from operating activities</b>		320	440	791
<b>Cash flows from investing activities</b>				
Purchase of property, plant and equipment	11	(27)	—	(3)
Purchase of intangible assets	10	(4)	(26)	—
<b>Net cash (outflow) from investing activities</b>		(31)	(26)	(3)

<b>Cash flows from financing activities</b>				
Cash movement on overdraft	17	(9)	9	—
Cash movement in borrowings	17	(112)	750	—
Dividends paid	23	(23)	(500)	(239)
Net transfers to former owners		—	(349)	(567)
<b>Net cash (outflow) from financing activities</b>		<b>(144)</b>	<b>(90)</b>	<b>(806)</b>
Net increase in cash and cash equivalents	16	145	324	(18)
Cash and cash equivalents at beginning of the year	16	331	7	25
Exchange difference		(9)	—	—
<b>Cash and cash equivalents at end of the year</b>	<b>16</b>	<b>467</b>	<b>331</b>	<b>7</b>

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

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Notes to the consolidated Financial Statements

1. General information

Indivior PLC (the “Company”) and its subsidiaries (together, “the Group”) is engaged in the development, manufacture, and sale of buprenorphine-based prescription drugs for the treatment of opioid dependence (the “Indivior Business”).

The Company was incorporated and domiciled in the United Kingdom on September 26, 2014. It was incorporated to serve as the holding company for the various entities of the pharmaceutical business (the “Pharmaceutical Business”) of Reckitt Benckiser Group plc (“RB”). The consolidated financial statements of the Company for periods prior to the Demerger (defined below) accounted for the transfers of such entities to the Company as a reorganization of entities under common control, retroactively at the book values of RB, including allocated costs from RB. On December 23, 2014, the Company was demerged from RB (the “Demerger”). Upon the Demerger, each shareholder of the former owner received one ordinary share in the Company for each ordinary share in the former owner that they held at the time of the Demerger. The Company and RB entered into a transition services agreement, which took effect on the date of the Demerger. Refer to Note 26 for related disclosures.

The subsidiary undertakings as at December 31, 2015, all of which are included in the consolidated financial statements, are shown below.

	Principal activity	Country of incorporation or registration and operation	Effective % of share capital held by the Group
Indivior Global Holdings Limited	Holding company	England and Wales	Ordinary 100
RBP Global Holdings Limited	Holding and Finance company	England and Wales	Ordinary 100
Indivior Finance S.à.r.l	Finance company	Luxembourg	Ordinary 100
Indivior Finance (2014) LLC	Finance company	Luxembourg	Ordinary 100
Indivior US Holdings Inc.	Holding company	United States	Ordinary 100
Indivior Finance LLC	Finance company	England and Wales	Ordinary 100
Indivior Finance (2015) S.à.r.l	Finance company	Luxembourg	Ordinary 100
Indivior Pty Ltd	Operating company	Australia	Ordinary 100
Indivior UK Limited	Operating company	England and Wales	Ordinary 100
Reckitt Benckiser Pharmaceuticals Healthcare South Africa Propriety Ltd	Operating company	South Africa	Ordinary 100
Indivior EU Limited	Operating company	England and Wales	Ordinary 100
Indivior France SAS	Operating company	France	Ordinary 100
RB Pharmaceuticals (Italia) S.r.l	Operating company	Italy	Ordinary 100
RB Pharmaceuticals (Deutschland) GmbH	Operating company	Germany	Ordinary 100
Indivior Solutions Inc.	Operating company	United States	Ordinary 100

Indivior Inc.	Operating company	United States	Ordinary 100
Indivior Ireland (Investments) Limited	Finance company	Ireland	Ordinary 100
Indivior Canada Ltd	Operating company	Canada	Ordinary 100
Indivior España S.L.U	Operating company	Spain	Ordinary 100
Indivior Nederland B.V.	Operating company	Netherlands	Ordinary 100
Indivior Portugal Unipessoal LDA.	Operating company	Portugal	Ordinary 100
Indivior Österreich GmbH	Operating company	Austria	Ordinary 100
Indivior Schweiz AG	Operating company	Switzerland	Ordinary 100
Indivior Hrvatska d.o.o.	Operating company	Croatia	Ordinary 100
Indivior Nordics ApS (Denmark)	Operating company	Denmark	Ordinary 100

With the exception of Indivior Global Holdings Ltd, none of the above subsidiaries is held directly by Indivior PLC.

The principal accounting policies adopted in the preparation of these Financial Statements are set out below. Unless otherwise stated, these policies have been consistently applied to all the years presented.

The consolidated financial statements have been authorized for issue by the Board of Directors on July 13, 2016.

## 2. The basis of preparation and changes in accounting policy

The consolidated Financial Statements have been prepared in accordance with International Financial Reporting Standards (IFRS) and IFRS Interpretations Committee (IFRS IC) interpretations as issued by the International Accounting Standards Board. These Financial Statements have been prepared under the historical cost convention.

The Financial Statements are presented in millions (m) of US\$ unless otherwise indicated.

The introduction of Indivior PLC as the new ultimate holding company of the Group does not meet the IFRS 3 definition of a business combination and as such falls outside the scope of that standard. Following the guidance regarding the selection of an appropriate accounting policy in IAS 8, the introduction of the Company as the new ultimate holding company of the Group has been accounted for as a group reconstruction using merger accounting principles. This policy, which does not conflict with IFRS, reflects the economic substance of the transaction. This means that although the reorganization did not become effective until December 23, 2014, the consolidated Financial Statements are presented as if the current Group structure had always been in place. Accordingly, the results of the Group for the comparative period are presented as if the Group had been in existence throughout the period presented.

The share capital issued as consideration in the exchange is treated as if it had existed from the earliest year presented. This presentation of share capital results in the creation of the Other Reserves in the consolidated balance sheet. The Other reserves represents the difference between the nominal value of the shares issued by the Company and the net investment in the Group by the former owner.

When recognizing the share capital issued, the Company has applied the provisions for merger relief under s.612 of the Companies Act. Accordingly, no premium has been recognized on the shares issued by the Company.

During the period prior to the Demerger, in the Financial Statements include expense allocations for certain functions provided to the Group during the period before the Demerger from the former owner, including, but not limited to, general corporate expenses related to finance, legal, tax, treasury, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. These costs have historically been allocated to the Group. The former owner had allocated these general corporate expenses to the Group on the basis of direct usage when identifiable, with the remainder allocated on a pro-rata basis of net revenues, operating profit, headcount or other measures of the Company and the former owner. These costs are included within administrative expenses in the consolidated income statements. Both Indivior and the former owner consider the basis on which the expenses have been allocated to reasonably reflect the utilization of services provided to or the benefit received by the Group during the periods presented. The former owner used the “tax incurred” approach in preparing the Indivior carve out financials. In doing so, they considered the actual tax incurred by the carve out business (and therefore reflected the benefits, reliefs and charges arising as a result of membership of the wider group) as adjusted for the tax effect of carve-out adjustments. To the extent that no charge was made by the former owner for the services provided, the expenses incurred by the former owner represent an increase in the former owner’s investment in the Group (that is, in substance, a capital contribution) and accordingly have been reflected as such in the Pharmaceutical Business Financial Statements.

In the period prior to the Demerger, the former owner performed cash management functions for the Indivior Business. This included certain cash pooling activities which resulted in the transfer of excess cash to the former owners. Such transfers of cash to the former owners have been recorded in equity for the comparative period as a reduction in the former owner’s investment in the Group (that is, in

substance, a distribution).

After making appropriate enquiries, the Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future.

A number of new standards, amendments to standards and interpretations are effective for the Group’s annual periods beginning on or after January 1, 2016, and have not been applied in preparing these consolidated financial statements. With the exception of IFRS 16 Leases, IFRS 9 Financial Instruments and IFRS 15 Revenue, which the Group does not intend to early adopt and for which the extent of the impact is still being determined, none of these is expected to have a significant effect on the consolidated financial statements of the Group.

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**2. The basis of preparation and changes in accounting policy (continued)**

**Comparative financial information**

Prior to the Demerger, consolidated Financial Statements were not prepared for the Indivior Group. The accompanying consolidated Financial Statements present the results of the Company and its subsidiaries as if the Indivior Group had been in existence throughout the period presented and as if the Demerger had occurred as at January 1, 2013.

**New accounting requirements**

IFRS 15 Revenue from contracts with customers is effective for annual periods beginning on or after January 1, 2018. The IASB has issued a new standard for the recognition of revenue. This will replace IAS 18 which covers contracts for goods and services. The new standard is based on the principle that revenue is recognized when control of a good or service transfers to a customer — so the notion of control replaces the existing notion of risks and rewards.

Management has considered the impact of the new rules and has not concluded on the significance of the impact, A more detailed assessment will be performed in the near future.

Management is in the process of assessing the impact of the revised issuance of IFRS 9 Financial instruments and IFRS 16 Leases, which will be effective for annual periods beginning on or after January 1, 2018 and January 1, 2019 respectively.

**Basis of consolidation**

The Financial Statements include the results of the Company (after its incorporation) and all of its subsidiary undertakings made up to the same accounting date. Subsidiary undertakings are those entities controlled by the Group. Control exists where the Group is exposed to, or has the rights to variable returns from its involvement with the investee and has the ability to use its power over the investee to affect its returns.

Inter-company transactions, balances and unrealized income and expenses on transactions between Group companies have been eliminated on consolidation. All subsidiaries have year-ends which are co-terminus with the Group’s. Subsidiaries’ accounting policies have been changed where necessary to ensure consistency with the policies adopted by the Group.

**Foreign currency translation**

Items included in the financial statements of each of the Group’s entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in US dollars, which is the Group’s presentation currency.

Foreign currency transactions are translated into the functional currency using exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

The exchange rates used for the translation of currencies into US dollars that have the most significant impact on the Group results were:

	2015	2014	2013
GBP year-end exchange rate	1.4736	1.5577	1.6557
GBP average exchange rate	1.5285	1.6476	1.5649

The financial statements of overseas subsidiary undertakings are translated into US dollars on the following basis:

- Assets and liabilities at the rate of exchange ruling at the year-end date.
- Profit and loss account items at the average rate of exchange for the year.

Exchange differences arising from the translation of the net investment in foreign entities, borrowings and other currency instruments designated as hedges of such investments, are taken to equity (and recognized in the statement of comprehensive income) on consolidation.

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**2. The basis of preparation and changes in accounting policy (continued)**

**Accounting estimates and judgments**

The Directors make a number of estimates and assumptions regarding the future, and make some significant judgments in applying the Group’s accounting policies. These estimates and assumptions may affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses. Although these estimates are based on management’s best knowledge of the amount, events or actions, actual results may ultimately differ from those estimates. The key estimates and assumptions used in the Financial Statements are set out below.

**Provisions for returns, discounts, incentives and rebates**

The Company offers various types of price reductions on its products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions about the attainment of sales targets. They are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. The Company also estimates the amount of product returns, on the basis of contractual sales terms and reliable historical data; the same recognition principles apply to sales returns.

**Income taxes**

Judgment is required in determining the provision for income taxes. There are many transactions and calculations whose ultimate tax treatment is uncertain. The Company recognizes liabilities for anticipated tax issues based on estimates of whether additional taxes are likely to be due. The Company recognizes deferred tax assets and liabilities based on estimates of future taxable income and recoverability. Where a change in circumstance occurs, or the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the income tax and deferred tax balances in the year in which that change or outcome is known. For more details of income taxes see Note 8 to the consolidated Financial Statements.

**Impairment of assets**

The Company assesses impairment of non-financial assets at each reporting date by evaluating conditions specific to the Company and to the particular asset that may lead to impairment. If an impairment trigger exists, the recoverable amount of the asset is determined. This involves fair value less costs to sell or value-in-use calculations, which incorporate a number of key estimates and assumptions.

**Provisions for legal claims**

The Company may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims and tax assessment claims.

Provisions are estimated on the basis of events and circumstances related to present obligations at the statement of financial position date, of past experience, and to the best of management’s knowledge at the date of preparation of the Financial Statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from the Company’s estimates.

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**3. 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 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.

**Net revenues**

**Accounting policy**

Revenue arising from the sale of goods is presented in the consolidated income statement under net revenues. Net revenues comprise gross revenue from sales of pharmaceutical products, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities.

Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer at the point of delivery, usually when title passes to the customer either on shipment or on receipt of goods depending on local trading terms; the Company no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Company, in accordance with IAS 18.

Returns, discounts, incentives and rebates are estimated and recognized in the period in which the underlying sales are recognized as a reduction of sales revenue.

These amounts are calculated as follows:

- Provisions for rebates based on attainment of sales targets are estimated and accrued as each of the underlying sales transactions is recognized.
- Provisions for price reductions under government and state programs, largely in the US, are estimated on the basis of the specific terms of the relevant regulations and agreements, and accrued as each of the underlying sales transactions is recognized.
- Provisions for sales returns are calculated on the basis of management’s best estimate of the amount of product that will ultimately be returned by customers. In countries where product returns are possible, the Company has implemented a returns policy that allows the customer to return products within a certain period either side of the expiry date (usually three months before and six months after the expiry date). The provision is estimated on the basis of past experience of sales returns.

The Company also takes account of factors such as levels of inventory in its various distribution channels, product expiry dates, information about potential discontinuation of products and the entry of competing generics into the market. In each case, the provisions are subject to continuous review and adjustment as appropriate based on the most recent information available to management. The

Company believes that it has the ability to measure each of the above provisions reliably, using the following factors in developing its estimates:

- the nature and patient profile of the underlying product;
- the applicable regulations and/or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;
- historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;
- past experience and sales growth trends;
- actual inventory levels in distribution channels, monitored by the Company using internal sales data and externally provided data;
- the shelf life of the Company’s products; and
- market trends including competition, pricing and demand.

There may be adjustments to the provisions when the actual rebates are invoiced based on utilization information submitted to the Company (in the case of provisions for rebates related to sales targets or contractual rebates) and claims/invoices received (in the case of regulatory rebates and chargebacks). Management believes that the estimates made are reasonable; however such estimates involve judgments on aggregate future sales levels, distribution channel mix, distributor’s sales performance and market competition.

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3. Segment information (continued)

Net revenues are attributed to countries based on the country where the sale originates. The following table represents net revenues from continuing operations attributed to countries based on the country where the sale originates and non-current assets, net of accumulated depreciation and amortization, by country. Non-current assets for this purpose consist of property, plant and equipment and intangible assets.

	Net revenues from sale of goods \$m	Non-current assets \$m
January 1 – December 31, 2015		
United States	807	80
Rest of World	207	14
Total	1,014	94
January 1 – December 31, 2014	\$m	\$m
United States	855	63
Rest of World	260	41
Total	1,115	104
January 1 – December 31, 2013	\$m	\$m
United States	950	50
Rest of World	266	57
Total	1,216	107

Significant Customers

Net revenues include amounts derived from significant customers that amount to 10% or more of the Company’s net revenues as follows (in percentages of total net revenues):

Customer	2015 %	2014 %	2013 %
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Customer A	23%	22%	24%
Customer B	28%	28%	28%
Customer C	20%	19%	18%

4. Operating costs and expenses

Accounting policies

Research and Development

Research expenditure on internal activities is charged to the consolidated statement of income in the year in which it is incurred.

Development expenditure is written off in the year in which it is incurred, unless the following criteria are met:

- It must be technically feasible to complete the development project (or intangible asset) so that the related product will be available for use or sale;
- There is an intention to complete the intangible asset or development project and use or sell it;
- The Company has the ability to use the intangible asset or to sell it;
- The way in which the intangible asset will generate probable future economic benefits;
- The availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- Expenditure attributable to the intangible asset during its development is able to be reliably measured.

Amounts capitalized are amortized over the useful life of the developed product.

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4. Operating costs and expenses (continued)

An internally generated intangible asset arising from the Company’s development activities is recognized only if the following conditions are met:

- An asset is created that can be identified;
- It is probable that the asset created will generate future economic benefits; and
- The development cost of the asset can be measured reliably.

The Company has determined that filing for regulatory approval is the earliest point at which the probable threshold can be achieved. All development expenditure incurred prior to filing for regulatory approval is therefore expensed as incurred. The Company did not capitalize any development expenditure in 2015, 2014 or 2013.

Expenses

Expenses are recognized in respect of goods and services received when supplied in accordance with contractual terms. Provision is made when an obligation exists for a future liability in respect of a past event and where the amount of the obligation can be reliably estimated.

Marketing and promotional expenses are charged to the income statement as incurred.

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

	Notes	2015 \$m	2014 \$m	2013 \$m
Research and Development expenses		(148)	(115)	(76)
Marketing, selling, and distribution expenses		(166)	(147)	(160)
Administrative expenses		(227)	(167)	(151)
Depreciation and amortization	10, 11	(24)	(26)	(28)
Operating lease rentals	19	(6)	(3)	(2)
		(423)	(343)	(341)

## 5. Auditors’ remuneration

	2015 \$m	2014 \$m
Audit of parent company and consolidated Financial Statements:		
Audit of the Group’s Annual Report and Financial Statements	1.11	0.70
Audit of account of the Group’s subsidiaries	0.21	0.18
<b>Audit and audit-related services</b>	1.32	0.88
Taxation compliance	0.02	—
Other assurance services	0.05	—
<b>Total auditors’ remuneration</b>	1.39	0.88

No statutory audits were required by the Pharmaceutical business prior to the Demerger.

Total fees charged for non-audit services in the year relating to the Indivior Group or any of its subsidiaries were \$0.07m (2014: nil, 2013: nil).

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## 6. Employees

### Accounting policies

#### Employee benefits

##### *Short-term obligations*

Liabilities for wages and salaries, including non-monetary benefits, annual leave and accumulating sick leave expected to be settled within 12 months after the end of the period in which the employees render the related service, are recognized in respect of employees’ services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liability for annual leave and accumulating sick leave is recognized in the provision for employee benefits. All other short-term employee benefits are presented as payables.

##### *Post-retirement benefits other than pensions*

Some Group companies provide post-retirement medical care to their retirees. The costs of providing these benefits are accrued over the period of employment and the liability recognized in the balance sheet is calculated using the projected unit credit method and is discounted to its present value and the fair value of any related asset is deducted. Additional employer costs in respect of options and awards are charged to the income statement over the same period with the credit included in payables.

##### *Employee share schemes*

Incentives in the form of shares are provided to employees under share option and restricted share award schemes.

The fair values of these options and awards are calculated at their grant dates and any shortfall between the cost to the employee and the fair market value are charged to the income statement over the relevant vesting periods, with the credit taken directly to retained earnings.

The fair value at grant date is determined using a Monte Carlo simulation model that takes into account the exercise price, the term of the award, the vesting and performance criteria, the impact of dilution, the non-tradable nature of the award, the share price at grant date, the expected dividend yield and the risk-free interest rate for the term of the award.

The fair value of the awards excludes the impact of any non-market vesting conditions (e.g. earnings per share). Non-market vesting conditions are included in assumptions about the number of awards that are expected to become exercisable. At each balance sheet date, the entity revises its estimate of the number of awards that are expected to become exercisable. The employee benefit expense recognized each period takes into account the most recent estimate.

The proceeds received net of any directly attributable transaction costs are credited to share capital and share premium when the options are exercised.

*Pension commitments*

Some Group companies operate defined contribution and (funded and unfunded) defined benefit pension schemes. The cost of providing pensions to employees who are members of defined contribution schemes is charged to the income statement as contributions are made. The Group has no further payment obligations once the contributions have been paid.

The liability or surplus recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the balance sheet date, less the fair value of the plan assets. The defined benefit obligation is calculated annually by independent actuaries using the projected unit credit method. The present value of the defined benefit obligation is determined by discounting the estimated future cash flows by the yield on high-quality corporate bonds denominated in the currency in which the benefits will be paid, and that have a maturity approximating to the terms of the pension obligations. The costs of providing these defined benefit schemes are accrued over the period of employment. Actuarial gains and losses are recognized immediately in other comprehensive income.

Past-service costs are recognized immediately in the income statement.

The net interest amount is calculated by applying the discounted rate used to measure the defined benefit obligation at the beginning of the period to the net defined benefit liability/asset.

The net pension scheme interest is presented as finance income/expense.

*Termination benefits*

Termination benefits are payable when employment is terminated before the normal retirement date, or when an employee accepts voluntary redundancy in exchange for these benefits. The Group recognizes termination benefits at the earlier of the following dates: (a) when the Group can no longer withdraw the offer of these benefits; or (b) when the entity recognizes costs for a restructuring that is detailed in a formal plan that involves the payment of termination benefits and has, at a minimum, been announced to employees. In the case of an offer made to encourage voluntary redundancy, the termination benefits are measured based on the number of employees expected to accept the offer. Benefits falling due more than 12 months after balance sheet date are discounted to present value.

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6. Employees (continued)

	2015 \$m	2014 \$m	2013 \$m
(a) Staff costs			
The total employment costs, including Directors, were:			
Wages and salaries	(137)	(112)	(104)
Social security costs	(31)	(25)	(24)
Net pension costs	(2)	(2)	(2)

Share-based plans	(8)	(3)	(3)
	<u>(178)</u>	<u>(142)</u>	<u>(133)</u>

Compensation awarded to key management (the Executive Committee and Directors):

	2015 \$m	2014 \$m	2013 \$m
Short-term employee benefits	(9)	(6)	(5)
	<u>(9)</u>	<u>(6)</u>	<u>(5)</u>

## (b) Staff numbers

The monthly average number of people employed by the Group, including Directors, during the year was:

	2015	2014	2013
Operations	548	540	547
Management	172	116	74
Research and development	111	85	79
Average number of employees	<u>831</u>	<u>741</u>	<u>700</u>

## 7. Net finance expense

### Accounting policy

Finance costs of borrowings are recognized in the income statement over the term of those borrowings.

	2015 \$m	2014 \$m	2013 \$m
<b>Finance expense</b>			
Interest payable on borrowings	(52)	(1)	—
Amortization of finance charges	(9)	—	—
Total finance expense	<u>(61)</u>	<u>(1)</u>	<u>—</u>
<b>Net finance expense</b>	<u>(61)</u>	<u>(1)</u>	<u>—</u>

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## 8. Income tax expense

### Accounting policy

Income tax on the profit for the year comprises current and deferred tax. Income tax is recognized in the income statement except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case the tax is also recognized in other comprehensive income or directly in equity, respectively.

Current tax is the expected tax payable on the taxable income for the year, using tax rates enacted, or substantively enacted, at the balance sheet date, and any adjustment to tax payable in respect of previous years.

	2015 \$m	2014 \$m	2013 \$m
Current tax	118	157	224
Adjustments for current tax of prior years	(3)	(3)	(1)
Total current tax	<u>115</u>	<u>154</u>	<u>223</u>
Origination and reversal of temporary differences	(23)	4	(17)
Adjustments for prior year deferred tax	(22)	—	—
<b>Total deferred tax</b>	<u>(45)</u>	<u>4</u>	<u>(17)</u>
<b>Tax on profit</b>	<u>70</u>	<u>158</u>	<u>206</u>

The standard rate of corporation tax in the UK changed from 21% to 20% with effect from April 1, 2015. The Group’s profits for the year ended December 31, 2015 are taxed at an effective rate of 24.5% (2014: 28.2%, 2013:29.6%). UK income tax of \$33m (2014: \$74m, 2013:\$94m) is included within current tax and is calculated at 20.25% (2014: 21.5%, 2013:23.25%) of the estimated assessable profit for the year. Taxation for other jurisdictions is calculated at the rates prevailing in the relevant jurisdictions.

The total tax charge for the year can be reconciled to the accounting profit as follows:

	2015 \$m	2014 \$m	2013 \$m
Profit on before taxation	285	561	695
Tax at the notional UK corporation tax rate of 20.25% (2014: 21.5%)	58	120	162
Effects of:			
Tax at rates other than the UK corporation tax rate	23	33	38
Permanent differences	(10)	10	—
R&D Tax Credit	(4)	(2)	—
Adjustments in respect of prior years	(25)	(3)	(1)
Adjustments to amounts carried in respect of unresolved tax matters	26	(3)	14
Impact of changes in tax rates	—	3	—
Other	2	—	(7)
<b>Income tax expense</b>	<b>70</b>	<b>158</b>	<b>206</b>

Taxation has been provided at current rates on the profits earned for the periods covered by the Group Financial Statements. The reported tax rate of 25% for the year ended December 31, 2015 benefited from a \$25m adjustment to estimates made in respect of prior periods. Revision to estimates were made to reflect actual tax expense incurred by certain UK and US subsidiaries following the completion of their statutory tax returns following the Demerger. These revisions primarily related to confirmation of group relief available through interest deductions and application of transfer prices. This tax benefit was offset by additional amounts recorded in respect of unresolved tax matters.

The company has provided for reserves on US State income tax nexus, intercompany transactions and certain manufacturer’s deductions claimed on its US federal income tax return. These are areas that require a significant amount of judgment and estimation. The company believes that the reserves are adequate to cover any assessments that may arise.

The Group continues to believe that it has made adequate provision for the liabilities likely to arise from periods which are open and not yet agreed by tax authorities. The ultimate liability for such matters may vary from the amounts provided and is dependent upon the outcome of agreements with relevant tax authorities or litigation where appropriate. In assessing these income tax uncertainties, management is required to make judgements in the determination of the unit of account, the evaluation of the circumstances, facts and other relevant information in respect of the tax position taken together with estimates of amounts that may be required to be paid in ultimate settlement with the tax authorities. As Indivior operates in a multinational tax environment, the nature of the uncertain tax positions is often complex

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and subject to change. Original estimates are always refined as additional information becomes known. Indivior has developed its probability assessment to review and measure uncertain tax positions using internal expertise, experience and judgement together with assistance and opinions from professional advisors. The group feels that the reserves are adequate to cover any assessments that may arise.

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 \$19m tax reserve for amounts claimed on all open periods as its best estimate of its expected settlement position for this issue.

9. Earnings per share

	2015 cents	2014 cents	2013 cents
Basic earnings per share	30	56	68
Diluted earnings per share	29	56	68

### Basic

Basic earnings per share (EPS) is calculated by dividing profit for the period attributable to the owners former owners of the Company by the weighted average number of ordinary shares in issue during the period. 718,577,618 shares were issued during the period ended December 31, 2015.

For the purpose of calculating EPS, the share capital for the Company in the period prior to the pre-demerger reorganization on December 23, 2014 and 2013 is calculated as if this re-organization was completed as at January 1, 2013.

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

	2015 Average Number of shares	2014 Average number of shares	2013 Average number of shares
On a basic basis	718,577,618	718,577,618	718,577,618
Dilution for Long Term Incentive Plan (LTIP)	14,507,535	5,307,010	5,307,010
On a diluted basis	733,085,153	723,884,628	723,884,628

## 10. Intangible assets

### Accounting policy

#### Intangible assets

Intangible assets are carried at cost less accumulated amortization and accumulated impairment.

Payments made in respect of acquired distribution rights are capitalized when it is probable that the expected future economic benefits that are attributable to the asset will flow to the Company. The useful life of the acquired distribution rights is determined based on legal, regulatory, contractual, competitive, economic or other relevant factors. Acquired rights with finite lives are subsequently amortized using the straight-line method over their defined useful economic lives. Amortization expense related to acquired distribution rights is included in selling, distribution and administrative expenses.

Payments related to the acquisition of rights to a product or technology are capitalized if it is probable that future economic benefits from the asset will flow to the Company. Amortization of the asset starts when it becomes available for use, at which point the asset is amortized over its useful economic life. Prior to that date, the intangible asset is tested for impairment annually, irrespective of whether any indication of impairment exists.

#### Impairment of intangible assets

The carrying values of intangible assets are reviewed for impairment either annually or when events or changes in circumstances indicate the carrying value may be impaired depending on the intangible asset type. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of impairment loss. Where it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash-generating unit to which it belongs.

An asset's recoverable amount is the higher of an asset's or cash-generating unit's fair value less costs to sell and its value-in-use. In assessing value-in-use, its estimated future cash flow is discounted to its present value using a pre-tax discount rate that reflects the current market assessments of the time value of money and the risks specific to the asset.

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In carrying out impairment reviews of intangible assets a number of significant assumptions have to be made when preparing cash flow projections. These include the future rate of market growth, discount rates, the market demand for the products acquired, the future profitability of acquired businesses or products, levels of reimbursement and success in obtaining regulatory approvals. If actual results should differ, or changes in expectations arise, impairment charges may be required which would adversely impact operating results.

	Acquired distribution rights \$m	Technology and licenses acquired \$m	Total \$m
<b>Cost</b>			
At January 1, 2015	220	56	276
Additions	—	4	4
Disposals and asset write-offs	—	(8)	(8)
Exchange adjustments	(2)	1	(1)
<b>At December 31, 2015</b>	<b>218</b>	<b>53</b>	<b>271</b>
<b>Accumulated amortization and impairment</b>			
At January 1, 2015	185	—	185
Amortization charge	23	—	23
Exchange adjustments	1	—	1
<b>At December 31, 2015</b>	<b>209</b>	<b>—</b>	<b>209</b>
<b>Net book amount at December 31, 2015</b>	<b>9</b>	<b>53</b>	<b>62</b>
	Acquired distribution rights \$m	Technology and licenses acquired \$m	Total \$m
<b>Cost</b>			
At January 1, 2014	222	30	252
Additions	—	26	26
Exchange adjustments	(2)	—	(2)
<b>At December 31, 2014</b>	<b>220</b>	<b>56</b>	<b>276</b>
<b>Accumulated amortization and impairment</b>			
At January 1, 2014	158	—	158
Amortization charge	25	—	25
Exchange adjustments	2	—	2
<b>At December 31, 2014</b>	<b>185</b>	<b>—</b>	<b>185</b>
<b>Net book amount at December 31, 2014</b>	<b>35</b>	<b>56</b>	<b>91</b>

### Acquired distribution rights

Acquired distribution rights are amortized over a period from six to seven years. The useful life of the acquired distribution rights was determined based on legal, regulatory, contractual, competitive, economic or other relevant factors. Amortization expense is included in selling, distribution and administrative expenses for all years presented.

There were no impairments recognised in the year.

### Technology and licenses acquired

The licenses acquired are not amortized as the Group has not yet filed for regulatory approval for the related products as at December 31, 2013. The licenses are assessed for impairment at the end of each reporting period. There were no impairments recognised in the year.

In May 2014, the Group exercised its rights to purchase the nasal naloxone technology under the co-development and asset purchase agreement with AntiOp, Inc. Additions recognized in the period for this exercise amounted to \$4m.

In December 2015, the Group received a non-approval letter from the FDA in response to the NDA application of its nasal naloxone spray. Consequently, the Group has taken the decision to discontinue any further development of this asset. The asset was fully written off. A write-off charge of \$8m was recognised in the period for this.

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## 11. Property, plant and equipment

### Accounting policies

#### Property, plant and equipment

Property, plant and equipment are stated at cost less accumulated depreciation and impairment, with the exception of freehold land, which is shown at cost less impairment. Cost includes expenditure that is directly attributable to the acquisition of the asset.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be reliably measured.

Except for freehold land and assets under construction, the cost of property, plant and equipment is written off on a straight-line basis over the period of the expected useful life of the asset. For this purpose, expected lives are determined within the following limits:

- Freehold buildings: not more than 50 years; and
- Owned plant and equipment: not more than 15 years.

In general, production plant and equipment and office equipment are written off over ten years or less; motor vehicles and computer equipment over five years or less.

Assets' residual values and useful lives are reviewed, and adjusted if necessary, at each balance sheet date. Property, plant and equipment are reviewed for impairment if events or changes in circumstances indicate that the carrying amount may not be appropriate. Freehold land is reviewed for impairment on an annual basis.

Gains and losses on the disposal of property, plant and equipment are determined by comparing the asset's carrying value with any sale proceeds, and are included in the income statement.

	Land and buildings \$m	Plant and equipment \$m	Total \$m
<b>Cost</b>			
At January 1, 2015	5	39	44
Additions	3	24	27
Exchange adjustment	—	1	1
<b>At December 31, 2015</b>	<b>8</b>	<b>64</b>	<b>72</b>
<b>Accumulated depreciation and impairment</b>			
At January 1, 2015	3	28	31
Charge for the year	—	9	9
<b>At December 31, 2015</b>	<b>3</b>	<b>37</b>	<b>40</b>
<b>Net book amount at December 31, 2015</b>	<b>5</b>	<b>27</b>	<b>32</b>

The opening balances have been adjusted to correct an incorrect prior period classification of the Fine Chemical Plant's PP&E balances between land and buildings and plant and equipment.

	Land and buildings \$m	Plant and equipment \$m	Total \$m
<b>Cost</b>			
At January 1, 2014	2	35	37
Additions	—	1	1
At December 31, 2014	2	36	38
<b>Accumulated depreciation and impairment</b>			
At January 1, 2014	1	23	24

Charge for the year	—	1	1
At December 31, 2014	1	24	25
Net book amount at December 31, 2014	1	12	13

Depreciation and amortization expense is included in selling, distribution and administrative expense within the income statement.

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**12. Deferred tax**

**Accounting policy**

Deferred tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. The deferred tax is not accounted for if it arises from the initial recognition of an asset or liability in a transaction (other than a business combination) that affects neither accounting nor taxable profit or loss at that time. Deferred tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the deferred tax asset or liability is settled. Deferred tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Deferred tax is provided on temporary differences arising on investments in subsidiaries except where the investor is able to control the timing of temporary differences and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets and liabilities within the same tax jurisdiction are offset where there is a legally enforceable right to offset current tax assets against current tax liabilities and where there is an intention to settle these balances on a net basis.

	Unrealized profit in inventory \$m	Intangible assets \$m	Short-term temporary differences \$m	Other \$m	Total \$m
<b>Deferred tax assets</b>					
At January 1, 2014	65	2	18	—	85
(Charged) to the income statement	(1)	(5)	(6)	—	(12)
Charged directly to equity	—	—	4	—	4
At December 31, 2014	64	(3)	16	—	77
Credited to the income statement	20	2	7	16	45
(Credited) directly to equity	—	—	—	(3)	(3)
Exchange differences	—	1	1	1	3
<b>At December 31, 2015</b>	<b>84</b>	<b>—</b>	<b>24</b>	<b>14</b>	<b>122</b>
	Unrealized profit in inventory \$m	Intangible assets \$m	Short-term temporary differences \$m	Other \$m	Total \$m
<b>Deferred tax liabilities</b>					
At January 1, 2014	—	(6)	—	—	(6)
Credited to the income statement	—	8	—	—	8
At December 31, 2014	—	2	—	—	2
(Charged) to the income statement	—	(2)	—	—	(2)
<b>At December 31, 2015</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>

Deferred tax assets and liabilities have been offset where they relate to income taxes levied by the same taxation authority. Unused tax credits of \$26m (2014: \$26m) have not been recognized at December 31, 2015 as the likelihood of future economic benefit is not sufficiently assured. These assets will be recognized if utilization of the credits becomes reasonably certain. No deferred tax liability has been recognized on the unremitted earnings of overseas subsidiaries as no tax is expected to be payable on them in the foreseeable future based on the current repatriation policy of the Group. No deferred tax liability has been recognized on unremitted earnings on overseas subsidiaries as such dividends are not taxable in the UK.

13. Inventories

Accounting policy

Raw materials, stores and consumables, work in progress and finished goods are stated at the lower of cost or net realizable value. Cost comprises materials, direct labor and an appropriate portion of overhead expenses (based on normal operating capacity) required to get the inventory to its present location and condition. Inventory valuation is determined on a first in, first out (FIFO) basis. Selling expenses and certain other overhead expenses are excluded. Net realizable value is the estimated selling price less applicable selling expenses.

Write down of inventory occurs in the general course of business. Impairments are recognized in cost of sales.

	2015 \$m	2014 \$m
Raw materials, stores and consumables	11	7
Work in progress	21	9
Finished goods and goods held for resale	16	25
<b>Total inventories</b>	<b>48</b>	<b>41</b>

The cost of inventories recognized as an expense and included as cost of sales amounted to \$97m (2014: \$95m). This includes inventory write-offs and losses of \$2m (2014: \$4m).

The Group inventory provision (reflected in the carrying amount above) at December 31, 2015 was \$2m (2014: \$2m).

14. Trade and other receivables

Accounting policy

Trade receivables are initially recognized at fair value and subsequently held at amortized cost, less provision for impairment.

If there is objective evidence that the Group will not be able to collect the full amount of the receivable, a provision is recognized on the balance sheet. Significant financial difficulties of the debtor, probability that a debtor will enter bankruptcy or financial reorganization, and default or delinquency in payments are considered indicators that the trade receivable is impaired. The impairment is calculated as the difference between the carrying value of the receivable and the present value of the related estimated future cash flows, discounted at the original interest rate.

	2015 \$m	2014 \$m
<b>Non-current assets</b>		
Prepayments	—	1
<b>Total non-current receivables</b>	<b>—</b>	<b>1</b>
<b>Current assets</b>		
Trade receivables	176	169
Less: Provision for impairment of receivables	(7)	(7)
Trade receivables — net	169	162
Other receivables	25	9
Prepayments	12	22
<b>Total current receivables</b>	<b>206</b>	<b>193</b>

Trade receivables consist of amounts due from customers, primarily wholesalers and distributors, for whom there is no significant history of default. The credit risk of customers is assessed, taking into account their financial positions, past experiences and other relevant factors. Individual customer credit limits are imposed based on these factors.

#### 14. Trade and other receivables (continued)

As at December 31, 2015, trade receivables of \$9m (2014: \$6m) were past due, but not impaired. The ageing analysis of trade receivables past due is as follows:

	2015 \$m	2014 \$m
Past due not more than three months	9	6
Past due more than three months and not more than six months	—	—
Past due more than six months and not more than one year	—	—
Past due more than one year	—	—
	9	6

As at December 31, 2015, trade receivables of \$11m (2014: \$10m) were considered to be impaired. The amount of provision at December 31, 2015 was \$7m (2014: \$7m). It was assessed that a portion of the receivables is expected to be recovered due to the nature and historical collection of trade receivables. The ageing analysis of these receivables is as follows:

	2015 \$m	2014 \$m
Up to three months	—	—
Over three months	11	10
	11	10

The movement in the provision for impaired receivables consists of increases for additional provisions offset by receivables written off and unused provision released back to the income statement. The gross movements in the provision are considered to be insignificant. The current other receivables balance does not contain impaired assets. They consist of items including reclaimable turnover tax and are from a broad range of countries within the Group.

The carrying amounts of the Group's trade and other receivables are denominated in the following currencies:

	2015 \$m	2014 \$m
Sterling	21	10
Euro	36	39
US dollar	125	130
Other currencies	24	14
	206	193

The maximum exposure to credit risk at the year-end is the carrying value of each class of receivable mentioned above. The Group does not hold any collateral as security.

	2015 \$m	2014 \$m
<b>Amounts falling due beyond one year</b>		
Prepayments	—	1
Total non-current receivables	—	1

Prepaid expenses relate to the Group's exclusive license and supply agreement with MSRX.

The other receivables do not contain impaired assets.

#### 15. Financial instruments and risk management

The Group’s financial assets and liabilities include cash and cash equivalents, borrowings, trade receivables and trade payables as set out in Notes 16, 17, 14 and 21 respectively. The carrying value less impairment provision of current borrowings, cash at bank, trade receivables and trade payables are assumed to approximate their fair values due to their short-term nature. The non-current borrowing, which is presented at amortised cost, is also assumed to approximate its fair value.

Financial risk management of the Group is mainly exercised and monitored at group level. The Group’s financing and financial risk management activities are centralized into the Global Treasury Group (GTG) to achieve benefits of scale and control with the ultimate goal of maximizing the Company’s liquidity and mitigating its operational and financial risks. GTG manages financial exposures of the Group centrally in a manner consistent with underlying business risks. GTG manages only those risks and flows generated by the underlying commercial operations and speculative transactions are not undertaken.

GTG operates under the close control of the CFO and is subject to periodic independent reviews and audits, both internal and external.

**Foreign exchange risk management**

The Group operates internationally and is exposed to foreign exchange risk arising from various currency exposures. Foreign exchange risk arises from future commercial transactions, recognized assets and liabilities and net investments in foreign operations. The Group’s policy is to align the interest costs and operating profit of its major currencies in order to provide some protection against the translation exposure on foreign currency profits after tax. The Group may undertake borrowings and other hedging methods in the currencies of the countries where most of its assets are located.

**Liquidity risk management**

Liquidity risk is the risk that the Group is not able to settle or meet its obligations on time or at a reasonable price. The Group’s policy is to ensure that there is sufficient funding and facilities in place to meet foreseeable borrowing requirements. The Group manages and monitors liquidity risk through regular reporting of current cash and borrowing balances and periodic preparation and review of short and medium term cash forecasts, while considering the maturity of its borrowing facility.

At December 31, 2015, Indivior had \$34m of borrowings repayable within one year and held \$467m of cash and cash equivalents.

Indivior regularly sweeps cash from a number of global subsidiaries to central Treasury accounts for liquidity management purposes.

**Credit risk management**

The Group has no significant concentrations of credit risk. The Group’s exposure to credit risk arises from cash and cash equivalents, deposits with banks and financial institutions, and trade receivables. Financial institution counterparties are subject to approval under the Group’s counterparty risk policy and such approval is limited to financial institutions with a BBB rating or above. Concentration of credit risk with respect to trade receivables are limited given that the balances consist of amounts due from customers, primarily wholesalers and distributors, for whom there is no significant history of default. The credit risk of customers is assessed, taking into account their financial positions, past experiences and other relevant factors. Individual customer credit limits are imposed based on these factors.

**Capital risk management**

The Group considers capital to be net debt plus total equity. Net debt is calculated as total borrowings less cash and cash equivalents, short-term available-for-sale financial assets and financing derivative financial instruments (refer to Note 17). Total equity includes share capital, reserves and retained earnings as shown in the consolidated balance sheet.

	Note	2015 \$m	2014 \$m
Net debt	17	(174)	(428)
Total equity		(292)	(475)
		(466)	(903)

The objectives for managing capital are to safeguard the Group’s ability to continue as a going concern, in order to provide returns for Shareholders and benefits for other stakeholders and to maintain an efficient capital structure to optimize the cost of capital.

The Group monitors net debt which at year-end amounted to net debt of (\$174m) (2014: (\$428m)). The Group seeks to pay down net debt using cash generated by the business to maintain an appropriate level of financial flexibility.

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## 16. Cash and cash equivalents

### Accounting policy

Cash and cash equivalents comprise cash in hand, current balances with banks and similar institutions and highly liquid investments with maturities of less than three months.

Bank overdrafts are included within borrowings in the balance sheet.

	2015 \$m	2014 \$m
Cash and cash equivalents	467	331
	467	331

## 17. Financial liabilities — borrowings

### Accounting policy

Interest-bearing borrowings are recognized initially at fair value less attributable transaction costs. Subsequent to initial recognition, interest-bearing borrowings are stated at amortized cost, with any difference between cost and redemption value being recognized in the income statement over the period of the borrowings on an effective interest basis.

Borrowings are classified as a current liability unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the reporting date.

Current	2015 \$m	2014 \$m
Bank loans and overdrafts	34	17
	34	17
Non-current	2015 \$m	2014 \$m
Bank loans	571	719
	571	719
Analysis of net debt	2015 \$m	2014 \$m
Cash and cash equivalents	467	331
Overdrafts	—	(9)
Borrowings (excluding overdrafts)*	(641)	(750)
	(174)	(428)

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

Reconciliation of net debt	2015 \$m	2014 \$m
Net debt at beginning of year	(428)	7
Net (decrease)/increase in cash and cash equivalents	136	324
Repayment of /(Proceeds from) borrowings and overdrafts	121	(759)
Exchange adjustments	(3)	—
Net debt at end of year	(174)	(428)

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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 are as follows:

	<u>Currency</u>	<u>Nominal interest margin</u>	<u>Maturity</u>	<u>Amortization</u>	<u>Issuance cost \$m</u>	<u>Face value \$m</u>	<u>Carrying amount \$m</u>
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

\*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 \$150m (defined as cash on hand plus the undrawn amount available under the Company's \$50m revolving credit facility).

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<u>Maturity of debt</u>	<u>2015 \$m</u>	<u>2014 \$m</u>
Bank loans and overdrafts payable due:		
Within one year or on demand	34	17
Bank loans payable due:		
Later than one and less than five years	607	30
Over five years	—	713
Gross borrowings (unsecured)	<u>641</u>	<u>760</u>

## 18. Provisions for liabilities and charges

### Accounting policy

Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events; it is more likely than not that there will be an outflow of resources to settle that obligation; and the amount can be reliably estimated.

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the reporting date. Provisions are reviewed regularly and amounts updated where necessary to reflect the latest assumptions. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from the Company's estimates.

	<u>Retirement Benefits \$m</u>	<u>Legal provisions \$m</u>	<u>Total provisions \$m</u>
At January 1, 2014	—	41	41
Charged to the income statement	1	—	1
Exchange adjustments	—	(1)	(1)
At December 31, 2014	<u>1</u>	<u>40</u>	<u>41</u>
Charged to income statement	<u>1</u>	<u>—</u>	<u>1</u>

At December 31, 2015, total provisions consisted of non-current legal provisions in the amount of \$40m (2014: \$40m) in relation to a number of regulatory investigations by various government authorities in a number of markets. These investigations involve primarily competition law inquiries. The legal provisions are classified as non-current liabilities.

19. Operating lease commitments

Accounting policy

Leases are classified as finance leases when the terms of the lease transfer substantially all the risks and rewards of ownership to the Group. All other leases are classified as operating leases.

Payments made under operating leases (net of incentives received from the lessor) are charged to the income statement on a straight-line basis over the term of the lease.

	2015 \$m	2014 \$m
Total future minimum lease payments under non-cancellable operating leases due:		
Within one year	4	1
Later than one and less than five years	7	2
More than five years	2	—
	13	3

Operating lease rentals charged to the income statement in 2015 were \$6m (2014: \$3m).

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20. Contingent liabilities

The Group is currently subject to other legal proceedings and investigations, including through subpoenas and other information requests, by various governmental authorities.

In 2011, the USAO-NJ issued a subpoena to Reckitt Benckiser Pharmaceuticals Inc. (RBP) requesting production of certain documents in connection with a non-public investigation related, among other things, to the promotion, marketing and sale of Suboxone® Film, Suboxone® Tablet and Subutex® Tablet. RBP responded to the USAO-NJ by producing documents and other information and has had no communication from USAO-NJ since March 2013.

In late 2012, the FTC commenced a non-public investigation of Indivior Inc. and various formerly-related Reckitt Benckiser Group entities by issuing a civil investigative demand, focusing on business practices relating to SUBOXONE® Film, SUBOXONE® Tablet and SUBUTEX® Tablet, including those practices which are the subject of the series of antitrust complaints filed in federal court against Indivior Inc. (the “MDL Litigation”) (collectively, the “FTC Investigation”). Indivior responded to the civil investigative demand by producing documents and other information to the Federal Trade Commission (the “FTC”). The investigation is on-going, and as yet no decision has been made by the FTC on whether to pursue any legal action for enforcement.

Indivior’s response to the civil investigative demand included the production of hundreds of thousands of pages of documents. The Company also withheld a significant number of documents on the basis of legal privilege, however, and the FTC has objected to the privilege claims made with respect to many of those documents. 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 on March 31, 2016. The Company has filed objections to the Special Master’s report, and the Court ultimately will determine whether to adopt the Special Master’s recommendations in whole or in part, or to reject them in their entirety. The Court’s decision then may be subject to appeal in the United States Court of Appeals by either party, although it may be necessary to wait for a court decision on the remaining documents in dispute before any appeal.

In July 2013, the Attorney General of the State of New York commenced an antitrust investigation into the same conduct being investigated by the FTC. The State of New York issued a subpoena to which the Company has responded by producing the same materials it has produced to the FTC. In August 2015, the Company was informed that a contingent of additional states had initiated a coordinated investigation into the same conduct that is the subject of the FTC Investigation and the MDL Litigation. The existing

investigation of these same issues by the State of New York has now been incorporated within this multi-state investigation. On July 1, 2016, Indivior was notified that twenty-two states and the District of Columbia intend to file a complaint in the Eastern District of Pennsylvania alleging violations of state and federal antitrust and consumer protection laws relating to the same conduct. To date, New York has not joined the notice or otherwise expressed its intention to sue. The notice indicates, however, that additional states may decide to join in any action.

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 United States Attorney for the Western District of Virginia has served a number of subpoenas relating to Suboxone Film, Suboxone Tablet, Subutex Tablet, Buprenorphine and the Group’s competitors, among other issues. Indivior is in the process of responding by producing documents and other information in connection with this ongoing investigation. It is not possible at this time to predict with any certainty or to quantify the potential impact of this investigation on the Company. Indivior is cooperating fully with the relevant agencies and prosecutors and will continue to do so.

It is not possible at this time to predict with any certainty if there will be a liability associated with these investigations nor, if one were to occur, is there an ability to quantify the potential impact on the Financial Statements of the Group.

**ANDA Litigation**

Beginning in August 2013, we have been informed of ANDA applications filed by six competitors for the FDA approval of generic versions of SUBOXONE® Film in the United States. We have filed patent infringement lawsuits against all six companies as summarized below:

- Trial in the lawsuits against Actavis and Par involving the Orange Book-listed patents for Suboxone® Film, November and December 2015, and the post-trial briefing concluded in March 2016. In a judgment issued on June 3, 2016, the District Court in Delaware found that Actavis’ and Par’s ANDA products infringe the asserted claims of U.S. Patent No. 8,603,514, one of the Company’s Orange Book listed patents for SUBOXONE® Film, and that the asserted claims of that patent are not invalid. The Court also ruled that the asserted claims of U.S. Patent No. 8,017,150, which is set to expire in 2023, are valid, but that they are not infringed by Actavis’ or Par’s ANDA products. The Court found that the asserted claims of U.S. Patent No. 8,475,832 are invalid, but that certain of the claims of this patent would be infringed by Actavis and Par’s ANDA products if they were valid.
- Trial against Actavis and Par in the lawsuits involving the two recently granted process patents (US Patent No. 8,906,277 and US Patent No. 8,900,497) scheduled for November 2016.
- Trial against Teva in the lawsuit involving the Orange Book-listed patents and process patents for Suboxone® Film scheduled for November 2016, with Teva’s 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17, 2017. Indivior believes Teva’s 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17, 2017, however, Teva disputes the applicability of the stay to this ANDA.
- Trial against Alvogen in the lawsuit involving the Orange Book-listed patents and process patents for Suboxone® Film scheduled for April 2017, with Alvogen’s 30-month stay of FDA approval expiring October 29, 2017.
- Trial against Mylan in the lawsuit involving the Orange Book-listed patents for Suboxone® Film is scheduled for September 25th, 2017, with Mylan’s stay expiring March 24, 2018. There is also a second, stayed lawsuit between the Company and Mylan in the Northern District of West Virginia. We and Sandoz have each submitted a proposed order to dismiss their patent litigation suit which are pending before the court.
- Indivior received a Paragraph IV notification from Teva, dated February 8, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16 mg/4 mg strength of buprenorphine/naloxone sublingual film. Indivior filed suit against Teva within 45 days, triggering a 30-month stay of approval of Teva’s 5-05(b)(2) NDA. The Indivior Group and Teva 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 its ANDA currently scheduled for trial in November 2016.
- The USPTO declined to institute Teva’s petitions for inter partes review of the three Orange Book-listed patents.

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**21. Trade and other payables**

	2015 \$m	2014 \$m
Sales returns and rebates	287	273
Trade payables	113	29

Accruals and other payables	116	74
Other tax and social security payable	12	7
	<u>528</u>	<u>383</u>

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.

The carrying amounts of total trade and other payables are denominated in the following currencies:

	2015 \$m	2014 \$m
Sterling	56	41
US dollar	442	314
Other currencies	30	28
	<u>528</u>	<u>383</u>

## 22. Share capital

### Accounting policy

Incremental costs directly attributable to the issue of ordinary shares, net of any tax effects, are recognized as a deduction from equity.

	Equity ordinary shares	Issue price	Nominal value \$m
<b>Issued and fully paid</b>			
At January 1, 2015	718,577,618	\$ 2.00	1,437
Nominal value reduction	—	\$ (1.90)	(1,365)
<b>At December 31, 2015</b>	<u>718,577,618</u>	<u>\$ 0.10</u>	<u>72</u>

	Equity ordinary shares	Issue price	Nominal value \$m
<b>Issued and fully paid</b>			
At January 1, 2014	718,577,618	\$ 2.00	1,437
At December 31, 2014	<u>718,577,618</u>	<u>\$ 2.00</u>	<u>1,437</u>

The holders of ordinary shares (nominal 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 which 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.

## 23. Other equity

	2015 \$m	2014 \$m
<b>Retained earnings</b>		

Opening balance at January 1	(601)	(208)
Net profit for the year	215	403
Capital reduction	1,365	—
Transactions with owners/former owners	(18)	(796)
Other comprehensive expense	(7)	—
Closing balance at December 31	954	(601)

## Nature and purpose of reserves

### Foreign currency translation

The foreign currency translation reserve contains the accumulated foreign exchange differences from the translation of the Financial Statements of the Group's foreign operations arising when the Group's entities are consolidated.

### Other reserves

The other reserves balance relates to the Group reconstruction in 2014. For details, refer to Note 2 of the Group Financial Statements.

### Transactions with former owners

As discussed in Note 2, transactions with former owners includes dividends to former owners, certain expenses that were allocated to the Group prior to the Demerger, transfers of cash to the former owner in accordance with the former owner's cash pooling program.

## 24. Dividends

	2015 \$m	2014 \$m
The following dividends were declared and paid in the year:		
Ordinary interim of 3.2 cents for 2015 (2014: nil) paid October 16, 2015	23	—
	23	—

The directors have approved a second interim dividend for 2015 of 9.5 cents per ordinary share. This is expected to be paid on July 29, 2016 to shareholders on the register of members on June 17, 2016. The estimated amount of this dividend on February 17 2016 was \$68m.

## 25. Share-based payments

### Accounting policy

The Group operates three equity-settled executive and employee share plans. For all grants of share options and awards, the fair value at the grant date is calculated using appropriate pricing models. The grant date fair value is recognized over the vesting period as an expense, with a corresponding increase in retained earnings

#### Employee Plans

#### Legacy Award — Indivior LTIP (formerly Reckitt Benckiser LTIP)

Upon Indivior demerging from the former parent and listing on the UK Main Market, awards under the Reckitt Benckiser 2007 Long-Term Incentive Plan granted in 2012 were exchanged on a value neutral basis for new awards over Indivior ordinary shares under the Indivior LTIP for a number of executives.

The Remuneration Committee considered the vesting of these awards taking into account the performance of the former parent and Indivior over the vesting period, weighted one-third on RB's performance and two-thirds on Indivior's performance. The Committee concluded that 93.33% of the Award would vest in May 2016. Further information can be found in the Directors' Remuneration Report.

Indivior LTIP

In 2015, a share based incentive plan was introduced for employees (including executive directors) of the company. An award under the plan can take the form of a nil-cost option, a market value option, or a conditional award.

The LTIP may comprise of grants of performance shares and/or share options which vest subject to the achievement of stretching performance targets.

The LTIP has a performance period of at least three years and a minimum vesting period of three years.

The LTIP opportunity is reviewed annually with reference to market data and the associated cost to the Company, calculated using an expected value methodology.

The performance condition is reviewed before each award cycle to ensure it remains appropriately stretching.

The fair values of awards granted under the long term incentive plans are calculated using a Monte Carlo simulation model. The key assumptions in the simulation model are stock price of the company, expected volatilities of the company, risk-free rate, and dividend yield.

For all plans, the inputs to the option pricing models are reassessed for each grant. The following assumptions were used in calculating the fair value of options granted:

	2015 \$m	2014 \$m
Dividend yield %	—	—
Expected volatility % (i)	38.2	—
Risk free interest rate % (ii)	0.7	—
Expected life in years	3	—

- (i) Given the short trading history as of the valuation dates, we relied on comparable set of guideline companies. We calculated the expected volatility based on equal weighting of historical volatility and the implied volatility of guideline public companies. This historical volatility was calculated based on a lookback period of three years.
- (ii) The risk free interest rate reflects the continuous risk-free yield based on the UK government interest rates as of the valuation date, based upon a maturity commensurate with the performance period.

At the end of the year, the maximum number of shares that could be awarded under the Group’s LTIP was:

	Legacy (LTIP) millions	LTIP millions	Total millions
Outstanding at January 2014	—	—	—
Awarded	5	—	5
Vested	—	—	—
Forfeited	—	—	—
Outstanding at December 2014	5	—	5
Awarded	—	10	10
Vested	—	—	—
Forfeited	—	—	—
Outstanding at December 2015	5	10	15

Charged to income statement:

The expense charged to the income statement for share-based payments is as follow:

	2015 \$m	2014 \$m
Granted in current year	6	3
Granted in prior years	2	—
Total share-based expense for the year	8	3

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## **26. Related party transactions**

For the period prior to the Demerger, transactions with former owners include certain expenses that were allocated to the Group prior to the Demerger, transfers of cash to the former owner in accordance with the former owner's cash pooling program, and dividends to former owners. Allocations from the former owners to the Group included corporate allocations in Selling, distribution and administrative expense of \$28m and \$55m in 2014 and 2013, respectively. For 2014 and 2013, \$53m and \$106m, respectively, related to cash taxes paid by RB on behalf of the Group, were included in the statement of cash flows as "Taxes paid, net".

RB, the former parent, and RBP Global Holdings Limited (RBP), the previous holding company of the Group, entered into a Transitional Services Agreement (TSA) prior to the demerger. Pursuant to the terms of the TSA, RB is providing Indivior with certain services on commercial terms and on an arm's length transaction. Services include, but are not limited to, sales and marketing services, and the provision of various back office services and support across finance, HR, regulatory, IS, office space and facilities. The amount included within administrative expenses in respect of these services is \$9m.

In connection with the Demerger, RB and the Group provided certain mutual indemnities relating to liabilities, including certain tax and legal liabilities, which relate to our respective businesses subsequent to the Demerger.

Also, the Group indemnified RB for taxes and related losses that may result from any organizational restructuring or sale of by the Group causing the Demerger to lose qualification as a tax-free transaction. This indemnity is effective for two years following the Demerger.

In 2015, Adrian Hennah, the RB CFO, also sat on the Indivior PLC Board of Directors. He did not stand for re-election in the May 2016 Annual General Meeting of Shareholders, and consequently stood down from the Board.

Key management compensation is disclosed in Note 6a.

## **27. Post balance sheet events**

Refer to Notes 8 and 20 for post balance sheet events impacting income taxes and contingent liabilities. In addition, the Company repurchased an additional \$20m and \$16m of its syndicated debt in the market at a discount in April and May 2016, respectively, retiring this debt early.