

# Prospectus

November 2014



This document comprises a prospectus relating to Indivior PLC and the Indivior Ordinary Shares prepared in accordance with the Prospectus Rules of the Financial Conduct Authority made under section 73A of the Financial Services and Markets Act 2000. This Prospectus has been approved by the FCA in accordance with section 87A of FSMA and made available to the public as required by Rule 3.2 of the Prospectus Rules.

This Prospectus has been prepared in connection with the admission of the Indivior Ordinary Shares to the premium listing segment of the Official List and to trading on the London Stock Exchange's main market for listed securities. It is proposed that Admission will take place shortly following the Demerger of the Indivior Business from RB and, unless the context requires otherwise, this document has been prepared on the assumption that the ordinary resolution proposed in connection with the Demerger which is set out in the RB Shareholder Circular will be passed at the RB General Meeting and that the Demerger will become effective as proposed.

The Directors, whose names appear on page 49 of this Prospectus, and the Company accept responsibility for the information contained in this Prospectus. To the best of the knowledge of the Directors and the Company (each of whom has taken all reasonable care to ensure that such is the case) such information is in accordance with the facts and this Prospectus does not omit anything likely to affect the import of such information.

Application will be made to the FCA for all the Indivior Ordinary Shares to be admitted to the premium listing segment of the Official List and to the London Stock Exchange for such Indivior Ordinary Shares to be admitted to trading on the London Stock Exchange's main market for listed securities. It is expected that Admission of the Indivior Ordinary Shares will become effective and that dealings in the Indivior Ordinary Shares will commence on the London Stock Exchange at 8.00 a.m. on 23 December 2014. No application has been, or is currently intended to be, made for the Indivior Ordinary Shares to be admitted to listing or trading on any other stock exchange.

**All the Indivior Ordinary Shares are to be issued to existing shareholders of RB and no Indivior Ordinary Shares have been marketed to, nor are any available for purchase, in whole or in part, by the public in the UK or elsewhere in connection with the Demerger or Admission. This document is not an offer or invitation to the public to subscribe for or purchase Indivior Ordinary Shares but is issued for the purposes of the admission of the Indivior Ordinary Shares to the premium listing segment of the Official List and to trading on the London Stock Exchange's main market for listed securities.**

**You should read the whole of this Prospectus and any information incorporated into it by reference including, in particular, the factors described in Part II (*Risk Factors*) of this Prospectus.**

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## **INDIVIOR PLC**

*(Incorporated under the Companies Act 2006 and registered in England and Wales with registered number 9237894)*

### **Admission to the premium listing segment of the Official List and to trading on the main market of the London Stock Exchange**

*Joint Sponsor*  
**Deutsche Bank**

*Joint Sponsor*  
**Morgan Stanley**

*Financial Adviser*  
**Jefferies**

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You should rely only on the information contained in this Prospectus. No person has been authorised to give any information or make any representations other than those contained in this Prospectus and, if given or made, such information or representations must not be relied upon as having been so authorised by the Company, the Directors, Deutsche Bank, Morgan Stanley or Jefferies. The Company will comply with its obligation to publish a supplementary prospectus containing further updated information if so required by law or by any regulatory authority but assumes no further obligation to publish additional information.

Deutsche Bank and Morgan Stanley are acting for Indivior PLC as joint sponsors and Jefferies as financial adviser in connection with the Demerger and no one else and will not be responsible to anyone other than Indivior PLC for providing the protections afforded to their clients or for providing advice in relation to this Prospectus and the Demerger or for providing advice in connection with the proposed listing or admission to trading of the Indivior Ordinary Shares or any other matters referred to in this Prospectus, other than to the extent required by law or appropriate regulation in the UK. Deutsche Bank is authorised under German Banking Law (competent authority: BaFin—Federal Financial Supervisory Authority) and also

authorised by the PRA, but may only be subject to limited regulation in the UK by the FCA and the PRA. Morgan Stanley is authorised by the PRA and regulated in the UK by the PRA and the FCA. Jefferies is regulated in the UK by the FCA. Apart from the responsibilities and liabilities, if any, which may be imposed on Deutsche Bank, Morgan Stanley or Jefferies by FSMA, or the regulatory regime established thereunder, or under the regulatory regime of any other jurisdiction where exclusion of liability under the relevant regulatory regime would be illegal, void or unenforceable, neither Deutsche Bank, Morgan Stanley, Jefferies nor any person affiliated with any of them accept any responsibility whatsoever and make no representation or warranty, express or implied, in respect of the contents of this Prospectus, including its accuracy, completeness or verification or for any other statement made or purported to be made by any of them, or on behalf of them, in connection with Indivior PLC and/or the Demerger and nothing in this Prospectus is or shall be relied upon as a promise or representation in this respect, whether as to the past or future. Deutsche Bank, Morgan Stanley and Jefferies accordingly disclaim, to the fullest extent permitted by applicable law, all and any responsibility and liability whatsoever, whether arising in tort, contract or otherwise (save as referred to above) which any of them might otherwise have in respect of this Prospectus or any such statement.

#### **OVERSEAS SHAREHOLDERS**

The implications of the Demerger and Admission for, and the distribution of this Prospectus to, RB Overseas Shareholders may be affected by the laws of the relevant jurisdictions in which such RB Overseas Shareholders are located. Such RB Overseas Shareholders should inform themselves about and observe all applicable legal requirements. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. Neither this Prospectus nor any advertisement may be distributed or published in any jurisdiction except under circumstances that will result in compliance with any applicable laws and regulations. This Prospectus does not constitute or form part of an offer to sell or allot, or the solicitation of an offer to buy or subscribe for, Indivior Ordinary Shares to any person in any jurisdiction to whom or in which such offer or solicitation is unlawful.

It is the responsibility of any person into whose possession this Prospectus comes to satisfy themselves as to their full observance of the laws of the relevant jurisdiction in connection with the Demerger, Admission and the distribution of this Prospectus, including the obtaining of any governmental, exchange control or other consents which may be required and/or compliance with other necessary formalities which are required to be observed and the payment of any issue, transfer or other taxes due in such jurisdiction.

RB Overseas Shareholders should consult their own legal and tax advisers with respect to the legal and tax consequences of the Demerger in their particular circumstances.

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005, as amended.

This Prospectus is not a New Zealand prospectus, an investment statement or product disclosure statement and has not been registered, filed with or approved by any New Zealand regulatory authority under or in accordance with the Securities Act 1978 or the Financial Markets Conduct Act 2013 (or any other relevant New Zealand law). This Prospectus may not contain all the information that a prospectus, investment statement or product disclosure statement under New Zealand law is required to contain. The Indivior Ordinary Shares are offered in New Zealand under this Prospectus in reliance on the Securities Act (Indivior PLC) Exemption Notice 2014 (New Zealand) and not otherwise. This Prospectus must not be made available or distributed in New Zealand to any person unless the recipient will be entitled to receive Indivior Ordinary Shares pursuant to this Prospectus and the Securities Act (Indivior PLC) Exemption Notice 2014.

The distribution of the Indivior Ordinary Shares in Canada is being made on a private placement basis only and is exempt from the requirement that RB or Indivior prepare and file a prospectus with the relevant Canadian securities regulatory authorities. Accordingly, any resale of the Indivior Ordinary Shares must be made in accordance with applicable Canadian securities laws which may require resales to be made in accordance with prospectus and dealer registration requirements or exemptions from prospectus and dealer registration requirements. These resale restrictions may in some circumstances apply to resales of the Indivior Ordinary Shares outside Canada. Canadian shareholders are advised to seek legal advice prior to any resale of the Indivior Ordinary Shares.

Neither RB nor Indivior are “reporting issuers”, as such term is defined under applicable Canadian securities laws, in any province or territory of Canada, and neither RB nor Indivior intend to become “reporting issuers” in any province or territory of Canada. Canadian Shareholders are advised that neither RB nor Indivior is required to file a prospectus or similar document with any securities regulatory authority in Canada qualifying the resale of Indivior Ordinary Shares to the public in any province or territory in Canada. Canadian Shareholders are further advised that neither RB nor Indivior intends to file a prospectus or similar document with any securities regulatory authority in Canada qualifying the resale of Indivior Ordinary Shares to the public in any province or territory of Canada in connection with the Demerger.

The Indivior Ordinary Shares have not been and will not be registered under the Securities Act or under the securities laws of any state or other jurisdiction of the US and may not be offered or sold within the US, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and in compliance with any applicable securities laws of any state or other jurisdiction of the US. There will be no public offering of the Indivior Ordinary Shares in the US for the purposes of the Securities Act. At Demerger, the Indivior Ordinary Shares will not be listed on any securities exchange in the US, and Indivior expects to rely on an exemption from registration under the Exchange Act provided by Rule 12g3-2(b) thereunder. The Company expects to establish at the Demerger Effective Time an ADR facility in the US representing underlying Indivior Ordinary Shares. The Indivior ADSs will not be listed on any securities exchange in the US (see paragraph 5.5 of Part XV (*Additional Information*) of this Prospectus for further details).

This document has not been approved or disapproved by the US Securities and Exchange Commission, any state securities commission in the US or any US regulatory authority, nor have any of the foregoing authorities passed upon or endorsed the merits of the offering of the Indivior Ordinary Shares or the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offence in the US.

#### **INTERPRETATION**

Certain terms used in this Prospectus are defined in Part XVII (*Definitions*) of this Prospectus.

References to the singular in this Prospectus shall include the plural and vice versa, where the context so requires. References to paragraphs or Parts are to paragraphs or Parts of this Prospectus. The terms “subsidiary”, “subsidiary undertaking” and “undertaking” have the meanings given to them by the Companies Act. All references to time in this Prospectus are to London time unless otherwise stated.

The date of this Prospectus is 17 November 2014.

## **TABLE OF CONTENTS**

	<i>Page</i>
PART I SUMMARY	5
PART II RISK FACTORS	20
PART III DIRECTORS, SECRETARY, REGISTERED OFFICE AND ADVISERS	49
PART IV EXPECTED TIMETABLE OF PRINCIPAL EVENTS	51
PART V PRESENTATION OF INFORMATION	52
PART VI INFORMATION ON THE INDIVIOR GROUP AND ITS INDUSTRY	57
PART VII REGULATORY OVERVIEW	85
PART VIII DIRECTORS AND CORPORATE GOVERNANCE	98
PART IX SELECTED FINANCIAL INFORMATION	106
PART X OPERATING AND FINANCIAL REVIEW	108
PART XI CAPITALISATION AND INDEBTEDNESS	128
PART XII HISTORICAL FINANCIAL INFORMATION	129
PART XIII UNAUDITED PRO FORMA FINANCIAL INFORMATION	173
PART XIV TAXATION	179
PART XV ADDITIONAL INFORMATION	188
PART XVI GLOSSARY	231
PART XVII DEFINITIONS	234

## PART I

### SUMMARY

Summaries are made up of disclosure requirements known as “Elements”. These Elements are numbered in Sections A-E (A.1 – E.7).

This summary contains all the Elements required to be included in a summary for this type of security and issuer. Because some Elements are not required to be addressed, there may be gaps in the numbering sequence of the Elements.

Even though an Element might be required to be inserted in the summary because of the type of securities and issuer, it is possible that no relevant information can be given regarding the Element. In this case a short description of the Element is included in the summary with the mention of the words “not applicable”.

Section A — Introduction and warnings		
Element		
A.1	<b>Introduction and warnings</b>	<p>This summary should be read as an introduction to this Prospectus.</p> <p>Any decision to invest in the Indivior Ordinary Shares should be based on consideration of this Prospectus as a whole by the investor.</p> <p>Where a claim relating to the information contained in this Prospectus is brought before a court, the plaintiff investor might, under the national legislation of a Member State, have to bear the costs of translating this Prospectus before the legal proceedings are initiated.</p> <p>Civil liability attaches only to those persons who have tabled the summary, including any translation thereof, but only if the summary is misleading, inaccurate or inconsistent when read together with the other parts of this Prospectus or it does not provide, when read together with the other parts of this Prospectus, key information in order to aid investors when considering whether to invest in the Indivior Ordinary Shares.</p>
A.2	<b>Subsequent resale of securities or final placement of securities through financial intermediaries</b>	<p>Not applicable: no consent is given by Indivior for the subsequent resale or final placement of Indivior Ordinary Shares by financial intermediaries.</p>

Section B — Issuer		
Element		
B.1	<b>Legal and commercial name</b>	Indivior PLC

B.2	<b>Domicile/Legal Form/ Legislation/Country of incorporation</b>	The Company is a public limited company, incorporated in England and Wales with registered number 9237894 and its registered office is situated in England and Wales. The Company operates under the Companies Act.
B.3	<b>Current operations/principal activities and markets</b>	<p>The Indivior Group is a global specialty pharmaceutical business and the global leader in the treatment of opioid dependence, with 20 years' experience in that field.</p> <p>The Indivior Group's core products, which are currently sold in up to 44 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. Suboxone Film, initially launched in the US in 2010 as the world's first approved pharmaceutical prescription sublingual film product, currently maintains a share of 60% in the US market for buprenorphine-based opioid dependence treatment (based on volume of prescribed milligrams), despite market entry of generic tablets and branded competitors.</p> <p>The Indivior Group also sells two 'legacy products': Temgesic sublingual tablets and injections outside the US for the treatment of moderate to severe pain, as well as Buprenex injection in the US for the relief of moderate to severe pain.</p> <p>The Indivior Group is committed to delivering innovative, high quality treatments for the chronic relapsing conditions and co-morbidities of addiction, and plans to expand its range of products beyond its core opioid dependence treatment business. In addition to extension candidates for its opioid dependence treatments, the Indivior Group has a pipeline of new drug candidates for the treatment of alcohol dependence, cocaine intoxication, schizophrenia and opioid overdose. The Board believes that the development of these product candidates capitalises on the Indivior Group's expertise in neurological science, clinical development and experience within the highly regulated and technical nature of pharmaceutical industry drug development and commercialisation.</p> <p>The Indivior Group's core geographic market (based on the country where the sale originates) is the US, which accounted for 77% of net revenues in H1 2014 (H1 2013: 78%; 2013: 78%; 2012: 80%; and 2011: 77%).</p>
B.4a	<b>Recent trends</b>	The Indivior Group's net revenues decreased 8% from \$295 million in Q3 2013 to \$270 million in Q3 2014, with low double-digit market growth being more than offset by loss in US market share and pricing pressure associated with branded and generic competitors. Profit before taxation decreased 24%, which was primarily attributable to lower net revenues and higher research and development expenses (due to continued advancement of the pipeline products). There has been no material change in the

		<p>Indivior Group's trading trends between 30 September and 31 October 2014 compared to Q3.</p> <p>The Indivior Group expects the rate of growth in the US opioid addiction treatment market in the short term to be low double-digit. It anticipates that the recent approval of two additional generic competitors (one of which has already entered the US market) and the entry of an additional branded competitor in the US in the last quarter of 2014 will result in a rapid change in the dynamics of its US business and create downward pressure on the Indivior Group's market share and pricing. These competitive pressures are likely to result in the loss of the majority of the Indivior Group's market share in its distribution channels that are the most price-sensitive (such as cash and commercial managed care channels, which together accounted for between 25-30% of Indivior's net revenue by channel during H1 2014). The Board believes, however, that the Indivior Group's value to patients, physicians and payers will help to ensure stronger resilience in less price-sensitive distribution channels. Accordingly, the increased pricing pressure associated with competition is likely to result in downward pressure on the Indivior Group's net revenue in 2015, potentially continuing into 2016, before the market adjusts to the increased competitive landscape and before it begins to benefit from expected pipeline launches. In Europe, the Board expects increased austerity measures associated with price reduction decrees and generic first initiatives to impact net revenue.</p> <p>Going forward, the Board expects increased research and development expenses and a high single-digit percentage increase in selling, distribution and administrative expenses in 2015 as product candidates progress to later stages of development, as well as incremental legal costs associated with litigation.</p> <p>The Indivior Group does not expect a material change in its tax rate in the short term.</p> <p>As is customary with other transactions of this type, the Board expects ongoing incremental expenditure to ensure the capability of a stand-alone UK public listed company and one-off expenditure and capital investment associated with the Demerger. The Board estimates an increase in annual recurring expenses of approximately \$40-50 million (compared to 2013) in connection with the establishment of stand-alone public company functions and services. As the Indivior Group transitions away from the historical services and organisational structure afforded by the RB Group, the Board believes that the Indivior Group may incur a total of \$25-35 million of non-recurring transitional costs over the next 12 months to establish its own stand-alone structure and capability. The Board also anticipates additional capital expenditures of up to \$75 million over the next two to three financial years, primarily relating to information systems and the design</p>
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		and construction of a new research and development facility. The Indivior Group will also incur additional expenses to service its debt.															
B.5	<b>Description of Issuer’s group</b>	The Company will, at the Demerger Effective Time, be the UK holding company of the Indivior Group, a global specialty pharmaceutical business and the global leader in the treatment of opioid dependence, with 20 years’ experience in that field.															
B.6	<b>Shareholders</b>	<p>As at 13 November 2014 (being the last practicable date prior to the publication of this Prospectus), insofar as it is known to the Company, by reference to relevant notifications to RB made in accordance with rule 5.1 of the Disclosure and Transparency Rules, the name of each person who holds voting rights representing 3% or more of the total voting rights in respect of RB Ordinary Shares (excluding treasury shares) and the amount of such person’s holding of the total voting rights in respect of Indivior Ordinary Shares immediately following the Demerger becoming effective and on Admission is expected to be as follows:</p> <table><tr><th><i>Name</i></th><th><i>Number of RB Ordinary Shares</i></th><th><i>Percentage of RB issued share capital (excluding treasury shares)</i></th><th><i>Number of Indivior Ordinary Shares on Admission</i></th><th><i>Percentage of Indivior issued share capital on Admission (excluding treasury shares)</i></th></tr><tr><td>JAB Holdings B.V.</td><td>76,659,342</td><td>10.66%</td><td>76,659,342</td><td>10.66%</td></tr><tr><td>Massachusetts Financial Services Company</td><td>44,281,281</td><td>6.15%</td><td>44,281,281</td><td>6.15%</td></tr></table> <p>Save as disclosed above, and by reference to relevant notifications to RB made in accordance with rule 5.1 of the Disclosure and Transparency Rules, the Company is not aware of any person who, as at 13 November 2014 (being the last practicable date prior to the publication of this Prospectus), directly or indirectly, has a holding which exceeds the threshold of 3% or more of the total voting rights attaching to the issued share capital of RB (excluding treasury shares).</p> <p>The Company is not aware of any persons who, as at 13 November 2014 (being the last practicable date prior to the publication of this Prospectus), directly or indirectly, jointly or severally, will exercise or could exercise immediately following the Demerger and on Admission control over the Company nor is it aware of any arrangements the operation of which may at a subsequent date result in a change in control of the Company.</p> <p>None of the Shareholders referred to above has or will have different voting rights from any other holder of Indivior Ordinary Shares in the Company in respect of any Indivior Ordinary Shares held by them.</p>	<i>Name</i>	<i>Number of RB Ordinary Shares</i>	<i>Percentage of RB issued share capital (excluding treasury shares)</i>	<i>Number of Indivior Ordinary Shares on Admission</i>	<i>Percentage of Indivior issued share capital on Admission (excluding treasury shares)</i>	JAB Holdings B.V.	76,659,342	10.66%	76,659,342	10.66%	Massachusetts Financial Services Company	44,281,281	6.15%	44,281,281	6.15%
<i>Name</i>	<i>Number of RB Ordinary Shares</i>	<i>Percentage of RB issued share capital (excluding treasury shares)</i>	<i>Number of Indivior Ordinary Shares on Admission</i>	<i>Percentage of Indivior issued share capital on Admission (excluding treasury shares)</i>													
JAB Holdings B.V.	76,659,342	10.66%	76,659,342	10.66%													
Massachusetts Financial Services Company	44,281,281	6.15%	44,281,281	6.15%													
B.7	<b>Selected historical key financial information</b>	The selected financial information set out below has been extracted without material adjustment from the historical financial information relating to the Indivior Group															

included in Part XII (*Historical Financial Information*). Prospective investors should review the following selected financial information together with the whole of this document and should not rely on the selected financial information below.

#### Combined Income Statement Data:

	Year ended 31 December			Six-month period ended 30 June <i>Unaudited</i>		Nine-month period ended 30 September <i>Unaudited</i>	
	2011 \$m	2012 \$m	2013 \$m	2013 \$m	2014 \$m	2013 \$m	2014 \$m
Net revenues	1,254	1,339	1,216	618	574	913	844
Cost of sales	(81)	(94)	(104)	(53)	(49)	(78)	(73)
<b>Gross profit</b>	<b>1,173</b>	<b>1,245</b>	<b>1,112</b>	<b>565</b>	<b>525</b>	<b>835</b>	<b>771</b>
Selling, distribution and administrative expenses	(266)	(320)	(341)	(185)	(158)	(266)	(250)
Research and development expenses	(35)	(41)	(76)	(25)	(41)	(40)	(63)
<b>Profit on ordinary activities before taxation</b>	<b>872</b>	<b>884</b>	<b>695</b>	<b>355</b>	<b>326</b>	<b>529</b>	<b>458</b>
Taxation	(258)	(277)	(206)	(105)	(93)	(157)	(132)
<b>Net income</b>	<b>614</b>	<b>607</b>	<b>489</b>	<b>250</b>	<b>233</b>	<b>372</b>	<b>326</b>

#### Combined Balance Sheet data:

	As of 31 December			As of 30 June	As of 30 September
	2011 \$m	2012 \$m	2013 \$m	2014 \$m	2014 \$m <i>Unaudited</i>
Intangible assets	135	117	94	107	98
Total non-current assets	230	208	198	212	203
Cash and cash equivalents	7	25	7	11	32
Total current assets	329	349	228	243	273
<b>Total assets</b>	<b>559</b>	<b>557</b>	<b>426</b>	<b>455</b>	<b>476</b>
Total current liabilities	(305)	(396)	(451)	(467)	(480)
Total non-current liabilities	–	(16)	(41)	(41)	(41)
<b>Total liabilities</b>	<b>(305)</b>	<b>(412)</b>	<b>(492)</b>	<b>(508)</b>	<b>(521)</b>
<b>Net assets/(liabilities)</b>	<b>254</b>	<b>145</b>	<b>(66)</b>	<b>(53)</b>	<b>(45)</b>

#### Combined Cash Flow Data:

	Year ended 31 December			Six-month period ended 30 June <i>Unaudited</i>		Nine-month period ended 30 September <i>Unaudited</i>	
	2011 \$m	2012 \$m	2013 \$m	2013 \$m	2014 \$m	2013 \$m	2014 \$m
Net cash provided by operating activities	715	866	791	483	295	633	414
Net cash used in investing activities	(25)	(3)	(3)	–	(25)	–	(25)
Net cash used in financing activities	(697)	(845)	(806)	(503)	(266)	(647)	(364)
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(7)</b>	<b>18</b>	<b>(18)</b>	<b>(20)</b>	<b>4</b>	<b>(14)</b>	<b>25</b>

		<p>On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. The Company expects to use approximately \$500 million from the proceeds of the term loan financing to pay a dividend to RB.</p> <p>Save as described above, there has been no significant change in the trading or financial position of the Indivior Group since 30 September 2014, the date to which the Indivior Group's last unaudited 2014 interim financial statements were prepared.</p> <p>There has been no significant change in the trading or financial position of the Company since 26 September 2014, being the date of its incorporation.</p> <p>The Indivior Group's net revenues decreased from \$1,339 million in 2012 to \$1,216 million in 2013, and from \$618 million in H1 2013 to \$574 million in H1 2014. These decreases reflect double-digit US market growth being more than offset by loss of market share in the US (by volume (mg)) and pricing pressure associated with competitors' branded and generic products, the Indivior Group's voluntary discontinuation of Suboxone Tablet in the US in March 2013 and negative product mix. Net revenues increased from \$1,254 million in 2011 to \$1,339 million in 2012. The increase was attributable to double-digit US market growth and price increases on Suboxone Film and Suboxone Tablet, and was partially offset by loss of market share (by volume (mg)) in the US to monotherapy, negative product mix (reflecting a higher proportion of sales of Suboxone Film), and the impact of increased accruals due to negative channel mix.</p> <p>Selling, distribution and administrative expenses decreased 15% from \$185 million in H1 2013 to \$158 million in H1 2014 which was primarily due to the recognition of a legal provision of \$23 million in H1 2013. These expenses increased 7% from \$320 million in 2012 to \$341 million in 2013 primarily due to legal costs associated with the Indivior Group's patent infringement lawsuits and increased investment in compliance. Selling, distribution and administrative expenses increased 20% from \$266 million in 2011 to \$320 million in 2012 primarily due to the recognition of a \$16 million legal provision in 2012, the full year impact of the licensing rights that were repurchased by RB from Merck in March 2010, and increased marketing and investment in clinical trials to support claims.</p>
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		<p>Net revenues decreased 8% from \$295 million in Q3 2013 to \$270 million in Q3 2014, with low double-digit US market growth being more than offset by loss in market share and pricing pressure associated with branded and generic competitors. Profit before taxation decreased 24%, which was primarily attributable to lower net revenues and higher research and developments expenses (due to continued advancement of the pipeline products).</p> <p>Net cash provided by operating activities was \$295 million in H1 2014 (H1 2013: \$483 million), which reflected the impact of a \$29 million decrease in profit before taxation, \$98 million arising due to fluctuations in net working capital and \$91 million arising due to fluctuations in provisions for liabilities and charges. Net cash provided by operating activities decreased from \$866 million in 2012 to \$791 million in 2013 reflecting a \$189 million decrease in profit before taxation and \$72 million arising due to fluctuations in provisions for liabilities and charges, offset by a \$171 million fluctuation in net working capital. Net cash provided by operating activities in 2012 was \$866 million (2011: \$715 million), reflecting improved working capital management and a favourable movement of provisions for liabilities and charges.</p> <p>Net cash used in financing activities was \$266 million in H1 2014 (H1 2013: \$503 million) in line with declining cash generated by operating activities. Net cash transferred to owners was \$806 million in 2013 (2012: \$845 million).</p>
B.8	<b>Selected key pro forma financial information</b>	<p>The unaudited combined pro forma statement of net assets set out below has been prepared to illustrate the effect of the Demerger on the net assets of the Indivior Group as if the Demerger had taken place on 30 September 2014 and the effect on the combined income statement of the Indivior Group for the year ended 31 December 2013 and the nine months ended 30 September 2014 as if the Demerger had taken place at 1 January 2013. The information, which has been produced for illustrative purposes only, by its nature addresses a hypothetical situation and, therefore, does not represent the Indivior Group's actual financial position or results.</p>

# **Unaudited pro forma statement of net assets at 30 September 2014**

	Adjustments			
	Indivior Group As at 30 September 2014 (Note 1) \$m	New Financing (Note 2) \$m	Cash retained by the Indivior Group (Note 3) \$m	Unaudited Pro Forma Total (Note 4) \$m
<b>ASSETS</b>				
<b>Non-current assets</b>				
Intangible assets	98	–	–	98
Property, plant and equipment	12	–	–	12
Deferred tax assets	89	–	–	89
Other receivables	4	–	–	4
	203	–	–	203
<b>Current assets</b>				
Inventories	45	–	–	45
Trade and other receivables	196	–	–	196
Cash and cash equivalents	32	228	42	302
	273	228	42	543
<b>Total assets</b>	<b>476</b>	<b>228</b>	<b>42</b>	<b>746</b>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Provisions for liabilities and charges	(308)	–	–	(308)
Trade & other payables	(126)	–	–	(126)
Current tax liabilities	(46)	–	–	(46)
	(480)	–	–	(480)
<b>Non-current liabilities</b>				
Borrowings	–	(728)	–	(728)
Provisions for liabilities and charges	(41)	–	–	(41)
	(41)	(728)	–	(769)
<b>Total Liabilities</b>	<b>(521)</b>	<b>(728)</b>	<b>–</b>	<b>(1,249)</b>
<b>Net (liabilities)/assets</b>	<b>(45)</b>	<b>(500)</b>	<b>42</b>	<b>(503)</b>

## **Notes:**

- (1) The financial information has been extracted without material adjustment from the combined financial information of the Indivior Group as set out in Part XII (*Historical Financial Information*) of this Prospectus. Indivior was incorporated on 26 September 2014 with subscriber share capital of \$4, being 2 ordinary shares of \$2. The insertion of a new holding company constitutes a group reconstruction and will be accounted for using merger accounting principles. The group reconstruction will not become effective until the Demerger Effective Time and the combined financial statements will be presented as if the Indivior Business and Indivior had always been part of the same group.
- (2) On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. An adjustment of \$728 million has been made to the pro forma statement of net assets to reflect the drawdown of the term loan presented net of issue costs of \$22 million. The proceeds of the financing will be used to pay a dividend to RB and for general corporate purposes. The issue costs will be paid by the Indivior Group from cash to be retained by the business as detailed in note 3.

- (3) At the Demerger Effective Time, it is expected that a cash balance of approximately \$302 million will be retained by the Indivior Group. This amount will consist of \$750 million gross proceeds raised from the new term loan financing, less a dividend payment to RB expected to be approximately \$500 million, and cash retained for general corporate purposes. No adjustment has been made for the estimated demerger and related costs, which will be borne by RB.
- (4) No adjustment has been made to reflect the trading results of the Indivior Group since 30 September 2014.

**Unaudited pro forma income statement for the year ended 31 December 2013**

	<i>Indivior Group for the year ended 31 December 2013 (Note 1) \$m</i>	<i>New Financing (Note 2) \$m</i>	<i>Unaudited Pro Forma Total (Notes 3 and 4) \$m</i>
Net Revenues	1,216	–	1,216
Cost of Sales	(104)	–	(104)
<b>Gross Profit</b>	<b>1,112</b>	<b>–</b>	<b>1,112</b>
Selling, distribution and administrative expenses	(341)	–	(341)
Research & Development expenses	(76)	–	(76)
<b>Operating Profit</b>	<b>695</b>	<b>–</b>	<b>695</b>
Interest Expense	–	(44)	(44)
<b>Profit before Taxation</b>	<b>695</b>	<b>(44)</b>	<b>651</b>
Taxation	(206)	13	(193)
<b>Net Income</b>	<b>489</b>	<b>(31)</b>	<b>458</b>

**Notes:**

- (1) The financial information has been extracted without material adjustment from the combined financial information of the Indivior Group as set out in Part XII (*Historical Financial Information*) of this Prospectus. Indivior was incorporated on 26 September 2014. Indivior has not traded since incorporation other than the gift of £50,000 and therefore the income statement of the Indivior Group for the year ended 31 December 2013 is equivalent to the aggregated income statements of the Indivior Group and Indivior for the same period.
- (2) On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. Interest expense of \$44 million comprises interest payable on the term loan and amortisation of the capitalised issue costs. Pro forma interest expense of \$41 million is calculated based on a 1% minimum LIBOR rate plus 4.5%. The pro forma interest expense only takes into account committed repayments under the term loan during the year ended 31 December 2013. Pro forma amortisation of \$3 million of issue costs in relation to the term loan and revolving credit facility is calculated based upon the 7-year term of the term loan, and the 5-year term of the revolving credit facility. The proceeds of the financing will be used to pay a dividend to RB and for general corporate purposes. Tax has been reflected at the effective tax rate of the Indivior Group for the period presented.
- (3) No adjustment has been made for the estimated demerger costs which will be borne by RB.

- (4) No adjustment has been made to reflect the trading results of the Indivior Group since 31 December 2013.

**Unaudited pro forma income statement for the nine-month period ended 30 September 2014**

	<i>Indivior Group for the nine-month period ended 30 September 2014</i>		<i>Unaudited Pro Forma Total</i>
	<i>\$m (Note 1)</i>	<i>New Financing \$m (Note 2)</i>	<i>\$m (Notes 3 and 4)</i>
Net Revenues	844	–	844
Cost of Sales	(73)	–	(73)
<b>Gross Profit</b>	<b>771</b>	<b>–</b>	<b>771</b>
Selling, distribution and administrative expenses	(250)	–	(250)
Research & Development expenses	(63)	–	(63)
<b>Operating Profit</b>	<b>458</b>	<b>–</b>	<b>458</b>
Interest Expense	–	(33)	(33)
<b>Profit before Taxation</b>	<b>458</b>	<b>(33)</b>	<b>425</b>
Taxation	(132)	10	(122)
<b>Net Income</b>	<b>326</b>	<b>(23)</b>	<b>303</b>

**Notes:**

- (1) The financial information has been extracted without material adjustment from the combined financial information of the Indivior Group as set out in Part XII (*Historical Financial Information*) of this Prospectus. Indivior was incorporated on 26 September 2014. Indivior has not traded since incorporation other than the gift of £50,000 and therefore the income statement of the Indivior Group for the nine-month period ended 30 September 2014 is equivalent to the aggregated income statements of the Indivior Group and Indivior for the same period.
- (2) On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. Interest expense of \$33 million comprises interest payable on the term loan and amortisation of the capitalised issue costs. Pro forma interest expense of \$31 million is calculated based on a 1% minimum LIBOR rate plus 4.5%. The pro forma interest expense only takes into account committed repayments under the term loan during the nine-month period ended 30 September 2014. Pro forma amortisation of \$2 million of issue costs in relation to the term loan and revolving credit facility is calculated based upon the 7-year term of the term loan, and the 5-year term of the revolving credit facility. The proceeds of the financing will be used to pay a dividend to RB and for general corporate purposes. Tax has been reflected at the effective tax rate of the Indivior Group for the period presented.
- (3) No adjustment has been made for the estimated demerger costs which will be borne by RB.
- (4) No adjustment has been made to reflect the trading results of the Indivior Group since 30 September 2014.

B.9	<b>Profit forecast/estimate</b>	Not applicable: no profit forecasts or estimates have been made.
B.10	<b>Audit report – qualifications</b>	Not applicable: there are no qualifications in the accountant's report on the historical financial information.
B.11	<b>Insufficient working capital</b>	Not applicable: the Company is of the opinion that the Indivior Group has sufficient working capital for its present requirements, that is, for at least the next 12 months from the date of this Prospectus.

<b>Section C Securities</b>		
<b>Element</b>		
C.1	<b>Type and class of securities</b>	<p>This Prospectus has been prepared in connection with the proposed admission of up to 736,535,179 Indivior Ordinary Shares (based on the number of RB Ordinary Shares (including treasury shares) in issue as at 13 November 2014 (the last practicable date prior to the publication of this Prospectus)) to the premium listing segment of the Official List and to trading on the London Stock Exchange's main market for listed securities following the demerger of the Indivior Business from the RB Group.</p> <p>When admitted to trading, the Indivior Ordinary Shares will be registered with ISIN GB00BRS65X63 and the SEDOL number will be BRS65X6.</p>
C.2	<b>Currency of issue</b>	The Indivior Ordinary Shares are denominated in US dollars.
C.3	<b>Number of Indivior Ordinary Shares issued and par value</b>	<p>As at the date of this Prospectus, the issued share capital of the Company is \$4.00 comprising 2 Indivior Ordinary Shares. At the Demerger Effective Time, based on the number of RB Ordinary Shares (including treasury shares, in issue as at 13 November 2014 (the last practicable date prior to the publication of this Prospectus), up to 736,535,179 Indivior Ordinary Shares will be issued fully paid to RB Shareholders in connection with the Demerger. Each Indivior Ordinary Share has a par value of \$2.00.</p>
C.4	<b>Rights attaching to the Indivior Ordinary Shares</b>	<p>The Indivior Ordinary Shares rank equally for voting purposes. On a show of hands each Shareholder has one vote, and on a poll each Shareholder as one vote per Indivior Ordinary Share held.</p> <p>Each Indivior Ordinary Share ranks equally for any dividend declared. Each Indivior Ordinary Share ranks equally for any distributions made on a winding up of the Company.</p> <p>Each Indivior Ordinary Share ranks equally in the right to receive a relative proportion of shares in case of a capitalisation of reserves.</p>

C.5	<b>Restrictions on transfer</b>	The Indivior Ordinary Shares are freely transferable and there are no restrictions on transfer in the UK.
C.6	<b>Admission to trading</b>	<p>Application will be made for the entire issued ordinary share capital of the Company to be admitted to the premium listing segment of the Official List of the UK Listing Authority and to trading on the London Stock Exchange's main market for listed securities.</p> <p>No application has been made or is currently intended to be made for the Indivior Ordinary Shares to be admitted to listing or trading on any other exchange.</p>
C.7	<b>Dividend policy</b>	<p>The Board intends to recommend a dividend for the 2015 financial year equivalent to 40% of net income after tax. The dividend will be split, in proportions to be determined, between an interim dividend, payable in October 2015, and the balance, to be paid (subject to approval at the Company's first annual general meeting) in June 2016. The intention of this dividend policy is to limit possible dilution of dividend income received by Shareholders in the short term as a result of the Demerger. The Board will review its dividend policy for the financial years after 2015 having regard to the Company's capital allocation strategy, financial position and future growth potential, including the strong product pipeline.</p>

Section D Risks		
Element		
D.1	<b>Key information on key risks that are specific to the Issuer or its industry</b>	<p>Substantially all the Indivior Group's revenues derive from sales of Suboxone Film, Suboxone Tablet and Subutex Tablet, any decrease in which would significantly affect the Indivior Group's results of operations and prospects.</p> <p>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 the Indivior Group's business, prospects, results of operations and financial condition.</p> <p>The success of the Indivior Group depends, in part, on its ability to obtain and maintain patent and other intellectual property protection, particularly for its drug delivery and formulation technologies and associated manufacturing processes. The process of obtaining patents can be lengthy and expensive. Failure to obtain and maintain patents and protect other proprietary rights, including in-licences of such rights from third parties, or an inability to enforce intellectual property rights, may mean that the Indivior Group is unable to protect its rights to or commercialise its products. The Indivior Group may also incur substantial costs as a result of intellectual property litigation to protect its intellectual property. Given the importance of intellectual property to the its business, the Indivior Group also faces a risk of disruption to its business through potential allegations of</p>

		<p>infringement of third-party intellectual property, which could lead to the Indivior Group being liable for substantial costs and damages.</p> <p>The Indivior Group's revenues are partly dependent on the availability and level of coverage provided to the Indivior Group by private insurance companies and governmental reimbursement schemes for pharmaceutical products, such as Medicare and Medicaid in the US. The failure to obtain and maintain coverage, or an adequate level of reimbursement, by governmental or third-party payers for the Indivior Group's products may impact the Indivior Group's business, prospects, results of operations and financial condition.</p> <p>The manufacture of the Indivior Group's products is highly exacting and complex, due in part to strict regulatory and manufacturing requirements. Manufacturing or supply problems encountered by the Indivior Group or its suppliers could have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition.</p> <p>Active pharmaceutical ingredients in many of the Indivior Group's products and product candidates are controlled substances that are subject to extensive regulation in all the countries in which the Indivior Group markets its products. Insufficient importation assessments for necessary active pharmaceutical ingredients or the failure to obtain or maintain necessary import and export licences may adversely impact the Indivior Group's ability to meet commercial demand or complete clinical trials, which could have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition.</p> <p>The testing, manufacturing, marketing and sales of pharmaceutical products entail a risk of product liability claims, product recalls, litigation and associated adverse publicity, each of which could have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition.</p> <p>Clinical trials for the development of products may be unsuccessful and the Indivior Group's product candidates may not receive authorisation for manufacture and sale.</p> <p>The regulatory approval process is expensive, time-consuming and uncertain and may prevent the Indivior Group or its partners from obtaining approvals for the commercialisation of some or all of their product candidates. Even if such product candidates are approved, there is no guarantee that they will be able to achieve expected market acceptance, which could materially adversely affect the Indivior Group's business, prospects, results of operations and financial condition.</p>
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		<p>The Indivior Group operates in a highly competitive industry, which includes companies with greater resources, including larger sales organisations and more experience working with large and diverse product portfolios, than the Indivior Group.</p> <p>The Indivior Group is currently subject to investigations, including through subpoenas and other information requests, by various governmental authorities. If as a result of any ongoing investigations the Indivior Group is found or suspected to have violated any applicable laws and regulations, it may be subject to a variety of fines, penalties, related administrative sanctions, potential exclusion from government healthcare programme reimbursement or civil and/or criminal prosecution, any of which could have a material adverse effect on its reputation, business, financial condition and results of operations.</p> <p>The Indivior Group is dependent on a relatively small number of significant customers for a substantial proportion of its 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 the Indivior Group's business, prospects, results of operations and financial condition.</p> <p>The Indivior Group's success depends substantially on the abilities of its key personnel. The Indivior Group may be unable to retain such key personnel or attract highly skilled individuals to its business in the future.</p>
D.3	<b>Key information on key risks relating to the Indivior Ordinary Shares</b>	<p>Since the Indivior Ordinary Shares have not previously traded, their market value is uncertain. Following Admission, the market price of the Indivior Ordinary Shares may be volatile and may go down as well as up.</p> <p>The Company may decide to offer additional Indivior Ordinary Shares in the future, diluting the interests of existing Shareholders and potentially adversely affecting the market price of the Indivior Ordinary Shares.</p> <p>The Company may determine not to pay dividends. If it determines that it will pay dividends, there can be no assurance that it will be able to pay dividends in the future.</p> <p>Shareholders may not be able to exercise pre-emption rights or participate in future issues of Indivior Ordinary Shares and Shareholders outside the UK may not be able to participate in future issues of Indivior Ordinary Shares.</p> <p>The ability of Overseas Shareholders to bring actions or enforce judgments against the Company or the Directors may be limited.</p>

Section E Demerger		
Element		
E.1	<b>Net proceeds/expenses</b>	Not applicable: this Prospectus does not constitute an offer or invitation to any person to subscribe for or purchase any shares in the Company. It is intended solely for holders of RB Ordinary Shares. It has been prepared solely in connection with the application to listing on the premium listing segment of the Official List and trading on the London Stock Exchange's main market for listed securities of up to 736,535,179 Indivior Ordinary Shares (based on the number of RB Ordinary Shares (including treasury shares) in issue as at 13 November 2014 (the last practicable date prior to the publication of this Prospectus)) to be issued in connection with the Demerger. Neither the Company nor RB will receive any proceeds as a result of Admission or the Demerger.
E.2a	<b>Reasons for the Offer/Use of proceeds</b>	Not applicable: this document does not constitute an offer or invitation to any person to subscribe for or purchase any shares in the Company.  The Company will not receive any proceeds as a result of Admission or the Demerger.
E.3	<b>Terms and conditions of the Offer</b>	Not applicable: this Prospectus does not constitute an offer or invitation to any person to subscribe for or purchase any shares in the Company.
E.4	<b>Material interests</b>	So far as the Board is aware, no person involved in the Demerger has any interest, including any conflicting interest, that is material to the Demerger.
E.5	<b>Selling shareholders/ Lock-up arrangements</b>	Not applicable: there are no selling shareholders or lock-up arrangements in connection with Admission or the Demerger.
E.6	<b>Dilution</b>	Not applicable.
E.7	<b>Estimated expenses charged to investor</b>	Not applicable: there are no commissions, fees or expenses to be charged to Shareholders or RB Shareholders by the Company in connection with Admission or the Demerger.

## PART II

### RISK FACTORS

*Any investment in or holding of Indivior Ordinary Shares is subject to a number of risks. RB Shareholders and prospective investors in Indivior Ordinary Shares should consider the factors and risks associated with the Indivior Group's business and the industry in which it operates, together with all other information contained in this Prospectus including, in particular, the risk factors described below. The risks relating to the Indivior Group and its industry summarised in Part I (Summary) are the risks that the Directors believe to be the most essential to an assessment of whether to consider investing in or otherwise holding the Indivior Ordinary Shares. However, as the risks which the Indivior Group faces relate to events and depend on circumstances that may or may not occur in the future, RB Shareholders and prospective investors in Indivior Ordinary Shares should consider not only the information on the key risks summarised in Part I (Summary) but also, among other things, the risks and uncertainties described below.*

*The following is not an exhaustive list or explanation all of the risks that holding an investment in the Indivior Ordinary Shares may entail and should be used as guidance only. The order in which risks are presented is not necessarily an indication of the likelihood of the risks actually materialising, of the potential significance of the risks or of the scope of any potential harm to the Indivior Group's business, prospects, results of operations and financial position. Additional risks and uncertainties relating to the Indivior Group that are not currently known to the Indivior Group, or that the Indivior Group currently deems immaterial, may individually or cumulatively also have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition and, if any such risk should occur, the price of the Indivior Ordinary Shares may decline and shareholders could lose all or part of their investment. RB Shareholders and prospective investors in Indivior Ordinary Shares should consider whether holding or investing in Indivior Ordinary Shares is suitable for them in the light of the information in this Prospectus and their personal circumstances.*

#### **RISKS RELATING TO THE INDIVIOR GROUP'S BUSINESS**

***The Indivior Group is 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 the Indivior Group's results of operations and prospects***

Substantially all the Indivior Group's revenues derive from sales of Suboxone Film (a buprenorphine and naloxone-based sublingual film), currently marketed in the US, Australia and Malaysia, Suboxone Tablet (a buprenorphine and naloxone-based sublingual tablet), currently marketed in 41 countries, and Subutex Tablet (a buprenorphine-based sublingual tablet), currently marketed in 24 countries, all of which are treatments for opioid dependence. Any factors that decrease the sales of Suboxone Film (which accounted for 70% of net revenues in 2013 and H1 2014) or, to a lesser degree, Suboxone Tablet or Subutex Tablet, would significantly decrease the Indivior Group's net revenues. The Indivior Group's ability to maintain or increase sales of Suboxone Film, Suboxone Tablet and Subutex Tablet is subject to the following risks and uncertainties:

- (A) 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;
- (B) loss of patent protection or ability of competitors to challenge or circumvent the Indivior Group's patents;

- (C) 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 DEA or an import or export licence from the UK Home Office and other similar regulatory authorities in other countries;
- (D) technological advances, including the approval of new competing products for the treatment of opioid dependence;
- (E) increase in the level of market acceptance of existing alternative treatments for opioid dependence, such as, for example, Vivitrol®;
- (F) changes in reimbursement policies of third-party payers;
- (G) exclusion or suspension from US federal and state healthcare programmes as a result of the outcome of ongoing government investigations;
- (H) legislation allowing or requiring the dispensation of generic products rather than branded products where a generic version of a drug is available;
- (I) government action/intervention, including the imposition of restrictions on medication and treatment to control diversion and misuse;
- (J) intervention by the WHO or by individual governments to reschedule buprenorphine as a substance with a higher potential for abuse than currently accepted;
- (K) marketing or pricing actions by competitors;
- (L) current payers requiring a reduction in pricing;
- (M) public opinion towards treatments for opioid dependence;
- (N) third-party allegations of intellectual property infringement;
- (O) any enforced change in labelling, or other such regulatory intervention;
- (P) product liability claims; and
- (Q) physicians' willingness to prescribe Suboxone Film, Suboxone Tablet and Subutex Tablet.

The Board believes the Indivior Group has sufficient working capital for its present requirements, that is, for at least the next 12 months from the date of this Prospectus. If sales of Suboxone Film or, to a lesser degree, Suboxone Tablet or Subutex Tablet, were to decrease significantly, the Indivior Group might need to increase rebates, discounts and chargebacks (which reduce net revenues) to remain competitive. Additionally, Indivior may need to reduce its operating expenses or seek to raise additional funds. The Indivior Group considers that any such significant decreases would take time to materialise and, as such, considers that the risk applies to the medium to long-term but not short-term (i.e. the next 12 months). 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 the Indivior Group's business, prospects, results of operations and financial condition. The risks of product concentration are also affected by geographic concentration (with the US accounting for 77% of net revenues in H1 2014).

***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 the Indivior Group's 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 US 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 US, the exclusivity afforded to Suboxone Tablet by its orphan drug status under FDA regulations ended in October 2009, and similar exclusivity in the European Union, Norway and Iceland expires in 2016. The Indivior Group's patents (assuming those at application stage are granted) relating to Suboxone Film will expire on various dates up to 2030.

In the US, 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. The Indivior Group ceased sale and distribution of its branded Subutex Tablet in the US in 2011.

In the US, two manufacturers launched generic versions of Suboxone Tablet in March 2013 and a third in August 2014. These generic formulations have gained a 17% market share (by mg volume) of the buprenorphine market in the US. A fourth manufacturer received approval from the FDA for a generic version of Suboxone Tablet in September 2014. The Group expects this fourth generic product, and additional generic products competing with Suboxone Tablet, to enter the US market, which could in future further impact the Indivior Group's share and pricing in the US buprenorphine market, thereby resulting in a material impact on its net revenues and operating profit. The Indivior Group is 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, the Indivior Group was informed of ANDA filings by Par, Watson, Alvogen and Teva for generic versions of Suboxone Film in the US. The Indivior Group has filed patent infringement lawsuits against Par, Watson and Alvogen, which means that the FDA cannot approve their generic entrants until the earlier of 30 months after notice to the Indivior Group of their ANDA filings or the disposition of the patent infringement proceedings. The litigation against Alvogen was dismissed without prejudice on the basis that Alvogen prematurely served the Indivior Group with a Paragraph IV Notice. The Indivior Group can re-file the case if and when Alvogen receives notice from the FDA that its ANDA has been accepted for filing and resubmits a Paragraph IV Notice to the Indivior Group. In addition, the Indivior Group is currently assessing Teva's Paragraph IV Notice received on 20 October 2014. The litigation against Watson and Par is proceeding and may not be resolved in the Indivior Group's favour, or the Indivior Group may choose to withdraw the lawsuits due to the unpredictable nature and significant costs of patent litigation.

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 the Indivior Group's Suboxone Film, which could have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition.

#### *Branded products*

The introduction of branded products that compete with the Indivior Group's products may lead to a loss of sales of the Indivior Group's products and/or a decrease in the price at which its products can be sold. Orexo Inc. introduced a branded buprenorphine and naloxone sublingual tablet, Zubsolv®, in September 2013 which has gained a 3% share (by mg volume) of the buprenorphine market in the US, and BDSI launched its branded buccal film product, Bunavail™, in November 2014. The Indivior Group filed a patent infringement lawsuit against BDSI on 22 September 2014 asserting an MSRX-licensed patent that is not related to Suboxone Film.

Although Suboxone Film has a market share (by mg volume) of 60% of the US 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 the Indivior Group's 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 US 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.

***Failure to obtain and maintain patents and protect other proprietary rights, including in-licences of such rights from third parties, may adversely affect the Indivior Group***

The success of the Indivior Group depends, in part, on its ability to obtain and maintain patent and other intellectual property protection, particularly for its drug delivery and formulation technologies and associated manufacturing processes. The process of obtaining patents can be lengthy and expensive.

The Indivior Group owns, or licenses in, a number of patent rights in the US and other countries covering certain products and has also developed brand names and trade marks for other products. The Indivior Group's business is materially dependent upon a group of owned as well as in-licensed patents relating to Suboxone Film. The Indivior Group owns the formulation patent that is specifically directed to Suboxone Film, which expires in the US in March 2030.

The Indivior Group will be able to protect its proprietary rights from unauthorised use by third parties only to the extent that its 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. The Indivior Group's existing patents, and any future patents it obtains, may not be sufficiently broad to prevent others from using its technologies or from developing competing products and technologies. If third parties disclose or misappropriate the Indivior Group's proprietary rights, it may materially and adversely impact its business, prospects, results of operations and financial condition.

Moreover, the patent positions of many pharmaceutical and life sciences companies are highly uncertain and involve complex legal and factual questions for which some important legal principles remain unresolved. As a result, the validity and enforceability of the Indivior Group's patents cannot be predicted with certainty. In addition, the Indivior Group cannot guarantee that:

- (A) the Indivior Group was the first to make the inventions covered by each of its issued patents and pending patent applications;
- (B) the Indivior Group was the first to file patent applications for these inventions;
- (C) patents will be granted in connection with any of the currently pending or future applications of the Indivior Group;
- (D) other companies will not independently develop similar or alternative technologies or duplicate any of the Indivior Group's technologies by inventing around its claims;
- (E) a third party will not challenge the Indivior Group's proprietary rights, and if challenged that a court will hold that the Indivior Group's patents are valid and enforceable;
- (F) any patents issued to the Indivior Group or its collaboration partners will cover its products as ultimately developed, or provide it with any competitive advantages, or will not be challenged by third parties;

- (G) the Indivior Group will develop additional proprietary technologies that are patentable; or
- (H) the patents of others will not have an adverse effect on the business of the Indivior Group.

The Indivior Group also relies on trade secrets and other unpatented confidential information in its activities. To the extent that the Indivior Group relies on trade secrets and unpatented confidential information to maintain its competitive position, 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. The Indivior Group has sought to protect trade secrets and confidential information, in some cases through the provisions of confidentiality and non-use agreements with its employees, consultants, advisers and partners. Nevertheless, it may not always be possible to prevent disclosure of the Indivior Group's trade secrets and other confidential information and for the Indivior Group to obtain an adequate remedy in the event of unauthorised disclosure or use of such information.

The Indivior Group has entered into a number of collaborative arrangements for the development and commercialisation of products. In connection therewith, the Indivior Group shares certain of its proprietary knowledge with such collaborative partners. Although enforcement of the Indivior Group's patents and other proprietary rights is intended to protect the Indivior Group from misuse by such partners or other third parties, it may not be possible or practical to prevent its partners from developing similar or functionally equivalent products. In addition, the Indivior Group's arrangements with its partners frequently contain representations, warranties and other assurances given by the Indivior Group regarding the scope of its own intellectual property and the non-infringement by the Indivior Group of intellectual property owned by third parties. If the Indivior Group were found to be in breach of any of these provisions, its partners could sue the Indivior Group for damages, which could have a material adverse effect on the Indivior Group's business, results of operations and financial condition.

The Indivior Group has entered into and relies 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 its products. If the Indivior Group does not continue to comply with the terms of such licences, the Indivior Group may not be able to maintain them. The termination of such licences could have a material adverse effect on the Indivior Group's business, results of operations and financial condition.

In addition, patent laws in the jurisdictions in which the Indivior Group has operations and/or their interpretation may also change over time. The Indivior Group cannot predict the effect that any such changes would have on the operations of the Indivior Group and its ability to protect its current and future products and technologies.

If the Indivior Group fails to obtain and maintain sufficient intellectual property protection for its current and future products and technologies, its ability to successfully and fully exploit these products and technologies could be adversely affected, which in turn would adversely affect the Indivior Group's business, prospects, results of operation and financial condition.

***The Indivior Group may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and it may be unable to protect its rights to, or commercialise, its products***

Litigation and other similar proceedings, such as inter partes reviews in the US (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. The Indivior Group may receive notifications of challenges to the validity of its patents or alleged infringement of patents owned by third parties.

If the Indivior Group chooses to go to court to prevent a third party from infringing its patents, its licensed patents or its partners' patents (where it has 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. These lawsuits are expensive and time-consuming, even if the Indivior Group is 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 the Indivior Group does not have the right to prevent the other party from using the patented subject matter. There is also the risk that, even if the validity of these patents is upheld and infringement of these patents found, the court will refuse to stop the other party on the grounds that it is in the public interest to permit the infringing activity.

The Indivior Group is currently conducting patent-related US litigation against Watson, Par and BDSI. In addition, BDSI is currently bringing proceedings against the Indivior Group before the USPTO seeking inter partes review of a key patent relating to Suboxone Film and has filed a lawsuit against the Indivior Group and MSRX seeking a declaratory judgment of non-infringement and invalidity of three patents relating to Suboxone Film, one of which is the subject of the inter partes review before the USPTO and two of which are related to the process of manufacturing Suboxone Film. There can be no assurance that these, or other litigation that the Indivior Group may file in the future, will be successful in preventing the infringement of its patents, that the Indivior Group will be able to successfully defend the validity of its patents, that any such litigation will be cost-effective, or that the litigation will have a satisfactory result for the Indivior Group. In addition, such litigation diverts the attention of management and development personnel. Failure to stop infringement of the Indivior Group's patents or an unsatisfactory result in litigation would adversely affect the Indivior Group's business and results of operations.

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

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 the Indivior Group is sued for patent infringement, it would need to demonstrate that its products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, which it may not be able to do, and which could in turn result in it being required to pay substantial sums. These sums potentially include damages, legal fees, and increased damages if the Indivior Group is found to have infringed such rights willfully. These damages potentially include increased damages and legal fees if the Indivior Group is found to have infringed such rights wilfully. Further, if a patent infringement suit is brought against the Indivior Group, its 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 the Indivior Group.

The Indivior Group cannot be certain that others have not filed patent applications for inventions covered by its licensors' or the Indivior Group's issued patents or pending applications, or that the Indivior Group or its licensors were the first inventors. The Indivior Group's 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 the Indivior Group's or its licensors' patents or applications and could further require the Indivior Group to obtain rights to issued patents covering such subject matter. In the US, if another party has filed a patent application on inventions similar to those of the Indivior Group, the Indivior Group may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the US. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of the Indivior Group's US patent position with respect to such inventions. Patent interferences are limited or unavailable for applications filed after 16 March 2013.

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

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

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

***The Indivior Group may not be able to protect its 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 the Indivior Group's product candidates and technologies throughout the world would be prohibitively expensive. Competitors may use the Indivior Group's technologies in jurisdictions where it has not obtained patent protection to develop their own products, and further, may export otherwise infringing products to territories where the Indivior Group has patent protection but where enforcement is more difficult. These products may compete with the Indivior Group's future products in jurisdictions where it does not have any issued patents and its 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 favour the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for the Indivior Group to stop infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce the Indivior Group's patent rights in foreign jurisdictions could result in substantial cost and divert efforts and attention from other aspects of its business, which could adversely affect its operations and financial condition. Moreover, the patent rights can be challenged in post-grant or inter partes review.

***The Indivior Group may not be able to assert proprietary rights over intellectual property developed by employees, consultants or partners of the Indivior Group, or under sponsored research agreements***

If the employees, consultants or partners of the Indivior Group develop inventions or processes independently that may be applicable to the Indivior Group's 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 the property of the Indivior Group, 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 the proprietary rights of the Indivior Group.

The Indivior Group has 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 the Indivior Group has 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 the Indivior Group's business, prospects, results of operations and financial condition.

***If the Indivior Group is unable to secure new products or compounds for development, its business, prospects, results of operations and financial condition could be materially adversely affected***

The Indivior Group intends to grow its business over the long term by acquiring or in-licensing and developing additional products and product candidates that it believes have significant commercial potential. For example, on 14 May 2014, the Indivior Group entered into an exclusive worldwide licensing agreement with XenoPort, Inc. for the development and commercialisation 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, the Indivior Group may not be able to successfully identify them, or may not have the financial, marketing and sales resources relative to its competitors that are necessary to pursue them.

In addition, any growth through development will depend upon the Indivior Group identifying and obtaining product candidates, its ability to develop those product candidates and the availability of funding to complete the development of, obtain regulatory approval for and commercialise these product candidates.

The Indivior Group 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 realise 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 the Indivior Group cannot predict whether its 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 the Indivior Group's business, prospects, results of operations and financial condition.

***The failure to obtain and maintain coverage, or an adequate level of reimbursement, by governmental or third-party payers for the Indivior Group's products may impact the Indivior Group's business, prospects, results of operations and financial condition***

The Indivior Group's revenues are partly dependent on the coverage and level of reimbursement provided to the Indivior Group by private insurance companies and governmental reimbursement schemes for pharmaceutical products, such as Medicare and Medicaid in the US. The cost of treatment established by healthcare providers, private health insurers and other organisations, such as health maintenance organisations and managed care organisations, are under downward pressure and this, in turn, could result in lower prices for the Indivior Group's products and/or in reduced demand for the Indivior Group's products.

In addition, changes to governmental policy or practices could adversely affect the level of reimbursement through governmental schemes. In the US, there continue to be proposals by legislators at both federal and state levels, regulators and third-party payers to keep healthcare costs down while expanding individual healthcare benefits. 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 the Indivior Group will be able to charge for its 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 ongoing 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 the Indivior Group's revenues and profitability. Moreover, in order to obtain reimbursement of products in some countries, including some EU member states, the Indivior Group may be required to conduct clinical trials that compare the cost-effectiveness of its products to other available therapies.

The prices for certain of the Indivior Group's products, when commercialised, may be high compared to other pharmaceutical products. The Indivior Group 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 the Indivior Group's results of operations and prospects.

There can be no assurance that the Indivior Group's products will obtain favourable reimbursement status in any country. The failure to obtain and maintain reimbursement, or an adequate level of reimbursement, for the Indivior Group's products may have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition.

***Manufacturing or supply problems encountered by the Indivior Group or its suppliers could have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition***

The manufacture of the Indivior Group's 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.

All facilities and manufacturing techniques used for the manufacture of the Indivior Group's products must be operated in conformity with the mandatory manufacturing standards (often

referred to as cGMP) of the FDA, the 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 the Indivior Group's manufacturing facilities or its third-party suppliers to possible legal or regulatory action, including shutdown, which may adversely affect the Indivior Group's ability to manufacture, or its third-party suppliers' ability to supply, finished products.

The Indivior Group relies on a single source in the US for the production of Suboxone Film and on a single source in the UK for the production of Suboxone Tablet and Subutex Tablet. Any delay in supplying, or any failure or refusal to supply, products to, or delays in manufacturing by, the Indivior Group's manufacturing facilities, or any catastrophe or natural disaster affecting such manufacturing facilities or suppliers, could result in the Indivior Group's inability to meet the commercial demand for its products or its needs for use in clinical trials, and could adversely affect the Indivior Group's business, prospects, results of operations and financial condition.

In addition, the loss of one of these suppliers could require the Indivior Group 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 or manufacturing process. Indivior believes it could take up to two years or longer in certain cases to qualify a new supplier or manufacturer, and if the Indivior Group is not able to obtain the ingredients or finished products from suppliers or manufacturers on acceptable terms and at reasonable prices, or at all, the Indivior Group's business, prospects, results of operations and financial condition could be adversely affected.

***Insufficient importation assessments for necessary active pharmaceutical ingredients or the failure to obtain or maintain necessary import and export licences may adversely impact the Indivior Group's ability to meet commercial demand or complete clinical trials***

Suboxone Film, Suboxone Tablet, Subutex Tablet and certain of the Indivior Group's product candidates contain controlled substances. In the US, controlled substances that are pharmaceutical products are subject to extensive regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, import, export and other requirements administered by the DEA. All countries in which the Indivior Group markets its products are subject to similar controls supervised by the relevant regulatory authorities, for example the Home Office in the UK.

An annual importation assessment value for buprenorphine is set by each importing country through the INCB. In the US, the DEA limits the availability of buprenorphine, and may limit the availability of active ingredients in other product candidates. As a result, the Indivior Group's importation assessment for buprenorphine in the countries in which the Indivior Group markets its products may not be sufficient to meet commercial demand or to complete clinical trials for buprenorphine-based and other product candidates. In the US, the DEA may not establish an importation assessment following FDA approval of a 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 the Indivior Group or the elimination of an assessment entirely.

Any delay or refusal by the DEA or a similar non-US authority in establishing the Indivior Group's importation assessment for controlled substances, any importation assessment that is established but which is insufficient for the Indivior Group's purposes, or any failure to obtain or maintain the necessary import and export licences 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 the Indivior Group's business, financial condition and results of operations.

***Product liability and product recalls could have a material adverse effect on the Indivior Group***

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, the Indivior Group's 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 the Indivior Group's 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 payers, 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 the Indivior Group is subject to regulatory action by the FDA, EMA or other competent authorities, or following a product recall. The Indivior Group cannot predict the frequency, outcome or cost of defending any such claims.

The cost of defending such claims is expensive even when the claims are not merited. A successful product liability claim against the Indivior Group could require the Indivior Group 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 the Indivior Group's products and business and inhibit or prevent commercialisation of other products.

Although the Indivior Group carries 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 the Indivior Group's discretion or at the discretion of its suppliers, government agencies and other entities that have regulatory authority over pharmaceutical sales. Any recall of the Indivior Group's products could materially adversely affect its business by rendering the Indivior Group unable to sell that product for some time and by adversely affecting its reputation. In addition, product liability claims or product complaints could result in an investigation (conducted by the FDA, the EMA, or the competent authorities of EU member states) into the safety or efficacy of the Indivior Group's products, its manufacturing processes and facilities, or its marketing programmes. An FDA investigation could potentially lead to a recall of the Indivior Group's 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.

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

***Clinical trials for the development of products may be unsuccessful and the Indivior Group's product candidates may not receive authorisation for manufacture and sale***

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

- (A) delays or failures in obtaining regulatory authorisation to commence a trial because of safety concerns of regulators relating to the Indivior Group's product candidates or similar product candidates of the Indivior Group's competitors or failure to follow regulatory guidelines;

- (B) delays or failures in obtaining clinical materials and sufficient quantities of the product candidate for use in trials;
- (C) delays or failures in reaching agreement on acceptable terms with prospective study sites;
- (D) delays or failures in obtaining approval of the Indivior Group's clinical trial protocol from an institutional review board to conduct a clinical trial at a prospective study site;
- (E) delays in recruiting patients to participate in a clinical trial;
- (F) failure of clinical trials and clinical investigators to comply with FDA and other regulatory agencies' GCP requirements;
- (G) unforeseen safety issues, including negative results from ongoing pre-clinical studies and adverse events associated with product candidates;
- (H) inability to monitor patients adequately during or after treatment;
- (I) difficulty monitoring multiple study sites;
- (J) failure of the Indivior Group's third-party clinical trial managers to satisfactorily perform their contractual duties, comply with regulations or meet expected deadlines;
- (K) disagreements with collaborative partners on the planning and execution of product development; or
- (L) insufficient funds to complete the trials.

The results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. In that case, the FDA or the equivalent in jurisdictions outside the US may determine the Indivior Group's data are not sufficiently compelling to warrant marketing approval and may require the Indivior Group to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. Many companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials, after showing positive results in earlier clinical trials.

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. Failure to demonstrate adequately the quality, safety and efficacy of a therapeutic drug under development would delay or prevent regulatory approval of the product. In addition, regulatory authorities in Europe, the US 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.

Ultimately, the Indivior Group cannot be certain that, if clinical trials are completed, either it or its collaborative partners would file for, or receive, required authorisations to manufacture and/or market potential products (including a marketing authorisation application or NDA) or that such application will be reviewed and approved by the regulatory authorities in a timely manner, if at all.

***The Indivior Group relies on third parties to conduct its clinical trials, and if they do not properly and successfully perform their legal and regulatory obligations, as well as their contractual obligations to the Indivior Group, it may not be able to obtain regulatory approvals for its product candidates***

The Indivior Group relies on contract research organisations and other third parties to assist in designing, managing, monitoring and otherwise carrying out its clinical trials, including with

respect to site selection, contract negotiation and data management. The Indivior Group does not control these third parties and, as a result, they may not treat the Indivior Group's clinical studies as a high priority, or in the manner in which the Indivior Group would prefer, which could result in delays. If the Indivior Group, contract research organisations, other third parties assisting the Indivior Group or its 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-US counterparts may require the Indivior Group to perform additional clinical trials before approving its marketing applications.

In addition, clinical trials must be conducted with products produced under the FDA's and non-US regulatory agencies' cGMP regulations. The Indivior Group's failure, or the failure of its product manufacturers, to comply with these regulations may require the Indivior Group to repeat or redesign clinical trials, which would delay the regulatory approval process.

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

***The regulatory approval process is expensive, time-consuming and uncertain and may prevent the Indivior Group or its partners from obtaining approvals for the commercialisation of some or all of their product candidates***

The research, testing, manufacturing, labelling, advertising and promotion, distribution 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 the Indivior Group may be unable to obtain approval for its product candidates. For example, the Indivior Group is not permitted to market its product candidates in the US 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 BLA or a marketing authorisation 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 authorisation does not assure approval for marketing in any jurisdiction, and the Indivior Group may encounter significant difficulties or costs in its efforts to obtain approval to market products. If the Indivior Group is unable to obtain regulatory approval for its product candidates, it will not be able to commercialise them and recoup its research and development expenses. If the Indivior Group fails to obtain approval, or approval is delayed or received for narrower conditions of use than sought, the Indivior Group's prospects, financial condition and results of operations could be adversely affected.

The Indivior Group may also be required to include a proposed REMS as part of an NDA 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. The Indivior Group 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 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. Any new REMS requirements applicable to any of the Indivior Group's products may adversely affect its business, results of operations or financial condition.

***Failure to comply with post-marketing obligations imposed by regulatory authorities could result in suspension of marketing authorisations for the Indivior Group's products, which could have an adverse effect on the Indivior Group's business, prospects, financial condition and results of operations***

Within the pharmaceutical industry, authorities such as the FDA, the European Commission or the competent authorities of the EU member states make determinations relative to the risk/benefit profile of pharmaceutical products. 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 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 authorisation for the product. Suspension of the marketing authorisation for any of the Indivior Group's products could have an adverse impact on its business, prospects, results of operations and financial condition.

***If the Indivior Group's product candidates that are approved are unable to achieve expected market acceptance, its business, prospects, results of operations and financial condition may be materially adversely affected***

The Indivior Group's ability to generate significant revenue from its products depends on their acceptance by physicians, patients, third-party payers and the medical community. The market acceptance of any product depends on a number of factors, including the following:

- (A) indication statement and warnings approved by regulatory authorities on the product label;
- (B) continued demonstration of efficacy and safety in commercial use;
- (C) the prevalence of the disease or condition for which the product is approved and the severity of side effects;
- (D) legislation and regulation controlling the conditions of treatment and the distribution of the product;
- (E) physicians' willingness to prescribe the product;
- (F) reimbursement from third-party payers such as government healthcare programmes and insurance companies;
- (G) the price of the product relative to alternative treatments, including generic products;
- (H) perceived advantages over alternative treatments;
- (I) relative convenience and ease of administration;
- (J) the extent to which the product is approved for inclusion on formularies of hospitals and managed care organisations;
- (K) the nature of any post-approval risk management plans mandated by regulatory authorities; and
- (L) marketing and distribution support.

Any factors preventing or limiting the market acceptance of the Indivior Group's products could have a material adverse effect on its sales and hence its business, results of operations and financial condition.

***The Indivior Group operates in a highly competitive industry, which includes companies with greater resources, including larger sales organisations and more experience working with large and diverse product portfolios, than the Indivior Group***

The manufacture and sale of pharmaceuticals is highly competitive. Many of the Indivior Group's competitors are large, prominent pharmaceutical, biotechnology, chemical and healthcare companies that have substantially greater financial, operational and human resources than the Indivior Group does. 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. 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 the Indivior Group in acquiring or licensing new products for development and commercialisation. 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 the Indivior Group's products or product candidates is approved, the Indivior Group's sales of that product could decrease, the effect of which would be heightened by the Indivior Group's product and geographic concentration, which could have an adverse impact on its 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 the Indivior Group. The Indivior Group currently has a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of the Indivior Group's sales representatives is responsible for a territory of significant size. The continued growth of the Indivior Group's current products and the launch of any future products may require expansion of the Indivior Group's sales force and sales support organisation internationally and the Indivior Group may need to commit significant additional funds, management and other resources to the growth of its sales organisation. The Indivior Group may not be able to achieve any such necessary growth in a timely or cost-effective manner or realise a positive return on its investment and it may not have the financial resources to achieve the necessary growth in a timely manner or at all. The Indivior Group also has to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel and turnover in the Indivior Group's sales force and marketing personnel could negatively affect sales of the Indivior Group's products. If the Indivior Group's sales force and sales organisation are not appropriately sized to promote any current or potential future products adequately, the commercial potential of the Indivior Group's current products and any future products may be diminished, which could materially adversely affect the Indivior Group's business, prospects, results of operations and financial condition.

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

Among other things, competition could continue to require the Indivior Group to increase further the level of rebates and other offsets to gross sales, particularly in its US operations, and could impact potential volume growth of any particular product, which could reduce the Group's net revenues and therefore its results of operations in future periods. Any of the

foregoing could have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition.

***The Indivior Group is dependent on a relatively small number of significant customers for a substantial proportion of its 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 the Indivior Group's business, prospects, results of operations and financial condition***

A limited number of significant customers have historically accounted for a substantial portion of the Indivior Group's net revenues. The Indivior Group's three largest customers are wholesalers that accounted for 70% of its net revenues in H1 2014 and 2013 (2012: 71%; 2011: 68%). The Indivior Group expects that a significant portion of its net revenues will continue to be derived from a small number of customers.

There can be no assurance that these customers will continue their relationship with the Indivior Group. Demand for the Indivior Group's products is largely derived from acceptance of the products by physicians, patients and third-party payers. Accordingly, if physicians were no longer willing to prescribe, patients no longer accepted or third-party payers were no longer willing to reimburse for the Indivior Group's products, these significant customers could reduce their purchasing levels or cease buying products from the Indivior Group at any time.

If the Indivior Group ceases to do business with a significant customer or if sales of its products to a significant customer materially decrease, due to physician and/or patient demand or payers' lack of willingness to reimburse, the Indivior Group's business, prospects, results of operations and financial condition may be materially adversely affected.

In addition, the Indivior Group 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, the Indivior Group could be prevented from collecting its receivables, which would adversely affect the Indivior Group's results of operations and financial condition.

***The absence of shipment licences for, or delayed shipments of, products and active pharmaceutical ingredients could have a material adverse effect on the Indivior Group's business, results of operations and financial condition***

The shipment of pharmaceutical products that contain controlled substances, such as Suboxone Film, Suboxone Tablet, Subutex Tablet and certain of the Indivior Group's product candidates requires import and export licences from the relevant authorities. The Indivior Group may not be granted or, if granted, may not maintain, such licences. Even if the Indivior Group maintains such licences, 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 Suboxone Film, Suboxone Tablet, Subutex Tablet, certain of the Indivior Group's product candidates and necessary active pharmaceutical ingredients. A partial or total loss of revenue from one or more such shipments could have a material adverse effect on the Indivior Group's business, results of operations and financial condition.

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

The Indivior Group relies upon a number of key executives and employees (including its sales force with high quality access to physicians) who have an in-depth and long-term understanding of the industry and the Indivior Group's technologies, products, programmes, collaborative relationships and strategic goals. Competition for such personnel in the biotechnology and pharmaceutical industries is intense, and there can be no assurance that the

Indivior Group will be able to continue to attract and retain such personnel, particularly as competitors may attempt to recruit them.

The Group does not carry “key person” insurance. The loss of the services of any of the Indivior Group’s key executives or employees could delay or prevent the successful completion of some of the Indivior Group’s 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 the Indivior Group’s operations and future growth.

***The Indivior Group is subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and potential liability***

The Indivior Group is subject to significant ongoing regulatory obligations, 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 ongoing regulatory requirements.

If the Indivior Group becomes aware of previously unknown problems or potential safety risks associated with any of its products, a regulatory agency may impose restrictions on its products, its contract manufacturers or on the Indivior Group. If the Indivior Group, its products and product candidates, or the manufacturing facilities for its products and product candidates, fail to comply with applicable regulatory requirements, a regulatory agency may send enforcement letters, mandate labelling changes, suspend or withdraw regulatory approval, suspend any ongoing clinical trials, require new clinical trials, impose a REMS, refuse to approve pending applications or supplements filed by the Indivior Group, suspend or impose restrictions on manufacturing operations, request a recall of, seize or detain a product, seek criminal prosecution or an injunction, or impose civil or criminal penalties or monetary fines. In such instances, the Indivior Group could experience a significant drop in the sales of the affected products, the Indivior Group’s 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 its business, prospects, results of operations and financial condition.

The Indivior Group is also subject to various US 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 programmes. Moreover, there are some laws and regulations that apply even in the absence of a government payer, and there are laws and regulations that require manufacturers to implement compliance programmes 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 programmes such as Medicare and Medicaid and debarment from contracting with the US 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.

Because of the breadth of these laws and regulations and the lack of definitive legal guidance in certain areas, it is possible that some of the Indivior Group’s 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 the Indivior Group’s business, prospects, reputation, results of operations and financial condition.

***The Indivior Group is subject to ongoing investigations and information requests which could have a significant effect on its financial condition and results of operations***

The Indivior Group is currently subject to investigations, including through subpoenas and other information requests, by various governmental authorities.

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 and the Attorney General of the State of New York commenced non-public investigations of RB, RBP and various other entities in the RB Group focusing on business practices relating to Suboxone Film, Suboxone Tablet and Subutex Tablet, including alleged involvement in a scheme to delay FDA approval of generic versions of Suboxone Tablet. RBP has responded to both the FTC and to the Attorney General of the State of New York by producing documents and other information. The investigations are ongoing, and as yet no decision has been made by either agency on whether to pursue any legal action for enforcement.

In December 2013, the USAO-VAW executed a search warrant on RBP's headquarters in Richmond and conducted searches of the homes of four field-based employees. The USAO-VAW has since served a number of subpoenas relating to Suboxone Film, Suboxone Tablet, Subutex Tablet, buprenorphine and any real or potential competitor, among other issues. The investigation is ongoing and RBP is in the process of responding to the USAO-VAW by producing documents and other information.

Given the limited information available to the Indivior Group regarding the foregoing civil and criminal investigations, it is not possible at this time to predict with any certainty or to quantify the potential impact on the Indivior Group, but it is cooperating fully with the relevant agencies and prosecutors and will continue to do so.

If as a result of the foregoing investigations the Indivior Group is found or suspected to have violated any applicable laws and regulations, it may be subject to a variety of fines, penalties, related administrative sanctions, potential exclusion from government healthcare programme reimbursement or civil and/or criminal prosecution, any of which could have a material adverse effect on its reputation, business, financial condition and results of operations.

***Changes in healthcare law in the US and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact the Indivior Group's business in ways that it cannot currently predict and these changes could have a material adverse effect on its business and financial condition***

The US Affordable Care Act 2010 contains a number of provisions that are expected to impact the Indivior Group's business and operations, in some cases in ways it cannot currently predict. Changes that may affect the Indivior Group's business include those governing enrolment in federal healthcare programmes, the imposition of an annual fee on branded prescription pharmaceutical manufacturers and increased rebates in the Medicaid Fee-For-Service Programme and Medicaid Managed Care plans, rules regarding prescription drug benefits under the health insurance exchanges, changes in the Medicare Part D coverage gap (whereby the Indivior Group is required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this coverage gap), expansion of the 340B Programme, and fraud and abuse and enforcement. There are a number of other provisions in the legislation that are collectively expected to have a small impact, including originator average manufacturers' price for new formulations. These changes will impact existing government healthcare programmes and will result in the development of new programmes, including improvements to the physician quality reporting system and feedback programme.

The US Supreme Court has struck down a provision of the Affordable Care Act that penalised states that choose not to expand their Medicaid programmes. As a result, some states have elected not to expand their Medicaid programmes. For each state that does not choose to expand its Medicaid programme, there may be fewer insured patients overall, which could impact the Indivior Group's sales, business and financial condition. Where patients receive insurance coverage under any of the new options made available by the Affordable Care Act, the possibility exists that pharmaceutical companies may be required to pay Medicaid rebates on drugs used for these patients, a decision that could impact revenues.

Moreover, legislative changes to the Affordable Care Act remain possible. The Indivior Group expects 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 the Indivior Group's industry generally and on the Indivior Group's ability to maintain or increase its product sales or successfully commercialise its product candidates, which could adversely affect the Indivior Group's business, prospects, results of operations and financial condition.

***If the Indivior Group fails to comply with payment and reporting obligations under the Medicaid Drug Rebate programme or other governmental pricing programmes in the US, it could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could adversely affect the Indivior Group's business, prospects, results of operations and financial condition***

In the US, the Indivior Group participates in the Medicaid Drug Rebate and Medicare Part D programmes and, by virtue of such participation, is also required by federal law to participate in the 340B and FSS pricing programmes. These programmes require the Indivior Group to pay certain rebates based on pricing data, such as (among others) average manufacturer price and average sales price, reported by the Indivior Group to the various federal agencies administering the programmes.

Pricing and rebate calculations vary among products and programmes. The calculations are complex and are often subject to interpretation by the Indivior Group, governmental or regulatory agencies and the courts. If the Indivior Group becomes aware that its reporting for a prior period was incorrect, or has changed as a result of recalculation of the pricing data, it is obliged to resubmit the corrected data. Such restatements and recalculations increase the Indivior Group's costs for complying with the laws and regulations governing the various programmes. Any corrections to the Indivior Group's 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 the Indivior Group is required to offer its products to certain covered healthcare entities, such as safety-net providers, under the 340B Programme.

The Indivior Group is liable for errors associated with its submission of pricing data. In addition to retroactive rebates and the potential for 340B Programme refunds, if the Indivior Group is found to have knowingly submitted false average manufacturer price, average sales price, or best price information to the government, it may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Any failure to submit data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the information is late beyond the due date. In the case of the Medicaid Drug Rebate programme, such failure could also be grounds for CMS to terminate the Indivior Group's Medicaid drug rebate agreement, pursuant to which the Indivior Group participates in the Medicaid programme. In the event that CMS terminates the Indivior Group's rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for its covered outpatient drugs.

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 programme interpretations, requirements or conditions of participation, some of which may have implications for amounts

previously estimated or paid. There can be no assurance that the Indivior Group's 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 the Indivior Group's business, prospects, results of operations and financial condition.

***Controlled substance legislation differs between countries and legislation in certain countries may restrict or limit the Indivior Group's ability to sell its products and product candidates***

Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including buprenorphine. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to the Indivior Group's obtaining marketing approval for Suboxone Film, Suboxone Tablet, Subutex Tablet and its product candidates in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit Suboxone Film, Suboxone Tablet, Subutex Tablet or the Indivior Group's product candidates to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time, which could have a material adverse effect on the Indivior Group's business and prospects.

***If buprenorphine is in the future considered to have a higher potential for abuse, the Indivior Group's products may not be prescribed and dispensed in the manner permitted by DATA 2000***

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 dispense 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, it may be reclassified as a Schedule II substance, in which case the Indivior Group's products 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. In addition, increased incidence of abuse 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 the Indivior Group's business, results of operations and financial condition.

***Business interruptions could disrupt the Indivior Group's product sales and delay the development of its product candidates***

Loss of manufacturing facilities, stored inventory or laboratory facilities through any natural disaster or man-made catastrophe, or loss of necessary raw materials, could have an adverse effect on the Indivior Group's ability to meet demand for its products, to continue product development activities and to conduct its business. The Indivior Group currently has insurance coverage against such business interruptions; however, such coverage may prove insufficient to compensate the Indivior Group fully for damage to its business resulting from any significant property or casualty loss to inventory or facilities, which could have an adverse impact on its business, prospects, results of operations and financial condition.

***Significant disruptions of information technology systems or breaches of data security could adversely affect the Indivior Group's business***

The Indivior Group is increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate its business. In the ordinary course of

its business, the Indivior Group collects, stores and transmits large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that the Indivior Group does so in a secure manner to maintain the confidentiality and integrity of such confidential information. The Indivior Group has also outsourced elements of its information technology infrastructure and as a result manages a number of third-party vendors who have or could have access to its confidential information. The size and complexity of the Indivior Group's information technology systems, and those of third-party vendors with whom it contracts, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber attacks. 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 the Indivior Group has implemented security measures to protect its data security and information technology systems, such measures may not prevent the adverse effect of such events.

Significant disruptions of the Indivior Group's information technology systems or breaches of data security could adversely affect the Indivior Group's business and results of operations.

***The Indivior Group's insurance cover may not be adequate***

The Indivior Group's business exposes it to potential product liability and professional indemnity and other risks which are inherent in the research, pre-clinical and clinical evaluation, manufacturing, sales and marketing and use of pharmaceutical products. The Indivior Group has taken out public and products liability insurance covering customary insurable risks in respect of such matters. Additional insurances taken out by the Indivior Group include property damage and business interruption, directors, and officers' liability, employers' liability and personal accident and travel.

While the Indivior Group believes that the cover in place is appropriate for a business of its 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 the Indivior Group in the conduct of its 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 the Indivior Group in excess of or outside the ambit of its insurance coverage may have a material adverse effect on its business, prospects, results of operations and financial condition.

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

The Indivior Group is 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 Indivior Group believes that it is in compliance in all material respects with all such laws, rules, regulations and policies applicable to the Indivior Group. However, there can be no assurance that the Indivior Group will not be required to incur significant costs to comply with such environmental and health and safety laws and regulations in the future. In particular, an environmental study is currently being carried out on the land occupied by the FCP, with the results due on or around 1 December 2014. If that study recommends that remediation works are required, the Indivior Group will be liable to meet the costs of those works. While the outcome of the study and potential costs of the remediation works are unknown, any costs could be significant and may have an adverse impact on the Indivior Group's business, prospects, results of operations and financial condition.

***The Indivior Group 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. The Indivior Group produces synthetic narcotics which can cause death if used improperly and its products are inherently prone to the health and safety risks arising from their misuse and diversion. Negative publicity about the Indivior Group or its products, or any other part of the industry, may adversely affect the Indivior Group's public image, which could impact its operations, impair its ability to gain market acceptance for its products or lead to government intervention, which in turn could have an adverse impact on the Indivior Group's business, prospects, results of operations and financial condition.

***The Indivior Group may be unable to identify, acquire, close or integrate acquisition targets successfully***

Part of the Indivior Group's business strategy includes evaluating potential acquisitions and other business combinations to create shareholder value. Acquisitions or similar arrangements may be complex, time-consuming and expensive. The Indivior Group may not succeed in some negotiations for acquisitions or other arrangements, which could result in significant diversion of management and other employee time, as well as substantial costs. In addition, there are a number of risks and uncertainties relating to closing transactions.

If an acquisition or other potential business combination is completed, the integration of the acquired business, product or other assets into the Indivior Group may be complex and time-consuming and, if such businesses, products or assets are not successfully integrated, the Indivior Group may not achieve the anticipated benefits.

Furthermore, these acquisitions and other arrangements, even if successfully integrated, may fail to further the Indivior Group's business strategy as anticipated or expose it to additional liabilities associated with an acquired business, product, technology or other asset or arrangement.

Any of these challenges or risks could impair the Indivior Group's ability to realise any benefit from an acquisition or arrangement after it has expended resources on them, which could have an adverse impact on the Indivior Group's business, prospects, results of operations and financial condition.

***The Indivior Group is exposed to risks related to currency exchange rates***

The Company is incorporated in England and Wales but the Indivior Group conducts the majority of its operations outside the UK and presents its financial statements in US dollars. Changes in currency exchange rates could have a significant effect on the Indivior Group's operating results and financial condition. Exchange rate fluctuations between local currencies and the US dollar create risk in several ways, including but not limited to: (i) increasing the US dollar cost of non-US research and development expenses and the cost of sourced product components outside the US (in the case of a weakening of the US dollar); (ii) decreasing the value of the Indivior Group's revenues denominated in other currencies (in the case of a strengthening of the US dollar); (iii) distorting the value of non-US dollar transactions and cash deposits; and (iv) affecting commercial pricing and profit margins of the Indivior Group's products. These effects can have an adverse impact on the Indivior Group's results of operations and financial condition and may also make it more difficult for investors to understand the relative strengths or weaknesses of the Indivior Group's underlying business on a period-over-period comparative basis.

***In preparing its financial statements, the Indivior Group uses estimates and assumptions that may differ from actual results, and new accounting pronouncements or guidance may require the Indivior Group to change the way in which it accounts for its operations and activities***

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and contingent liabilities as at the date of the financial statements and the reported amounts of revenues and expenses during a reporting period. Management evaluates critical estimates and judgements, including, among others, those related to revenue recognition, including rebates, discounts, chargebacks and return accruals, inventories, research and development costs, investments, property and equipment, patents and other intangible assets, income taxes and accounting for share-based compensation. Critical estimates and assumptions are based on historical experience, management's view of trends in the marketplace, and various other factors believed to be reasonable under the circumstances. If actual results differ from these estimates as a result of unexpected conditions or events occurring that cause management to re-evaluate assumptions, there could be a material adverse effect on the Indivior Group's reported results.

Standard-setting bodies that have jurisdiction over the form and content of the Indivior Group's financial statements regularly evaluate accounting standards and from time to time issue pronouncements and interpretations of pronouncements that impact the preparation of financial statements. These pronouncements and interpretations of pronouncements may have the effect of requiring the Indivior Group to change its accounting policies, including how it accounts for revenues and/or expenses, which could have a material adverse effect on reported results.

***If Indivior loses its foreign private issuer status in the future, it may incur significant additional expenses which could have a material adverse effect on the Indivior Group's business, prospects, results of operations and financial condition***

Immediately after the Demerger, the Company expects that in the range of not more than 25% of its ordinary shares will be held by Shareholders resident in the US. The Company therefore expects to qualify as a "foreign private issuer" (within the meaning of Rule 405 of the Securities Act and Rule 3b-4 of the Exchange Act) and to rely on the exemption from registration under the Exchange Act provided by Rule 12g3-2(b) thereunder.

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, the Company will next make a determination with respect to its foreign private issuer status on 30 June 2015. There is a risk that the Company could lose its foreign private issuer status if, for example, more than 50% of its issued ordinary share capital is held by US residents. If the Company loses its foreign private issuer status, it would not be able to rely on Rule 12g3-2(b) of the Exchange Act, and would be required to register its ordinary shares with the US SEC as a "domestic issuer. As a result, the Company would become subject to the extensive periodic and ongoing disclosure and reporting requirements under the US securities laws that apply to domestic issuers, including preparing consolidated financial statements in accordance with US GAAP (in addition to those prepared in accordance with IFRS as required by the Listing Rules), and preparing quarterly (rather than half-yearly) financial statements. Moreover, the Company would become subject to the Sarbanes-Oxley Act 2002, which requires, among others things, management to certify to, and report on, the effectiveness of the Company's internal control over financial reporting with respect to its operations as at the end of such financial year. The Company would also be subject to the proxy statement requirements under Section 14 of the Exchange Act, and its 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 the Company is required to register with the US SEC as a domestic issuer, it may incur significant additional expenses which could have a material adverse effect on the Indivior Group's results of operations.

#### **RISKS RELATING TO THE DEMERGER**

##### ***For a period following the Demerger, the Indivior Group will be reliant on the RB Group for the provision of certain services***

For a period of up to three years following the Demerger, the Indivior Group will be reliant 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 will vary depending on a number of factors relating to the Indivior Group, such as independent procurement of appropriate information systems, software and processes and the ability of the Indivior Group to enter into such contracts with third parties as are necessary for the Indivior Group to operate in certain jurisdictions.

If the RB Group fails to provide the expected 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, the Indivior Group 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 the Indivior Group's business, prospects, results of operations and financial condition.

##### ***After the Demerger, the Indivior Group could fail to meet the challenges involved in operating successfully as a stand-alone business***

Although the Board expects that the Demerger will result in benefits to the Indivior Group, it may not realise those benefits because of the challenges of operating successfully as a stand-alone business. These challenges include (i) demonstrating to interested parties that the Demerger will not result in adverse changes in standards of business and impairment of relationships with customers or employees; (ii) retaining key personnel; (iii) distraction of management; (iv) difficulty in marketing and communicating effectively the capabilities of the Indivior Group as a stand-alone business; and (v) successfully negotiating the rebranding exercise such that patients, physicians and regulators accept the new branding under the Indivior name (in particular, transferring existing regulatory approvals currently held by the RB Group on behalf of the Indivior Group or obtaining new regulatory approvals to enable the Indivior Group to operate under the Indivior name may be time-consuming).

Any failure of the Indivior Group to meet the challenges involved in operating as a successful stand-alone business could have a material adverse effect on the Indivior Group's business, reputation, financial condition and/or operating results.

##### ***Indivior has indemnification obligations in favour of RB***

Indivior and RB have entered into the Demerger Agreement, the Demerger Tax Deed and the US Tax Matters Agreement that govern the allocation of the assets and liabilities of the businesses between the Indivior Group and the RB Group, their post-Demerger obligations to each other in respect of, among other things, taxes and their respective indemnity obligations. Subject to certain conditions contained in such agreements, Indivior has agreed to indemnify 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 the Indivior Business prior to the Demerger (whether or not in the ordinary course of business) and in respect of certain tax liabilities that may arise after, or as part of, the Demerger. RB has also provided similar indemnities to Indivior. Some of these indemnities are unlimited in terms of amount and duration and the amounts payable by the Indivior Group pursuant to such indemnity obligations could be significant and could have a material adverse effect on the Indivior Group's business, financial condition and/or operating results.

***The Demerger may fail to realise anticipated benefits***

There can be no guarantee that Indivior will realise any or all the anticipated benefits of the Demerger, in either a timely manner or at all. If Indivior fails to realise some or all the anticipated Demerger benefits, it could have a material adverse effect on Indivior's business, reputation, financial condition and/or operating results.

***The Demerger may give rise to unanticipated tax consequences***

RB has undertaken tax due diligence to identify the likely tax treatment of the Demerger and has structured the Demerger so as to reduce any adverse tax consequences. However, tax law and practice can be subject to differing interpretations and, in some jurisdictions, the tax authorities are entitled to exercise discretion in how the tax law should be applied in certain cases. Consequently, Indivior is not able to guarantee that the tax authorities in each jurisdiction in which Indivior companies have a taxable presence will interpret or apply the relevant tax law and practice in the manner in which Indivior anticipates, which may adversely affect the Indivior Group's results of operations and financial condition. Details of the UK and US tax treatment of shareholders who will hold Indivior Ordinary Shares following the Demerger are set out in Part XIV (Taxation) of this Prospectus. The RB Shareholder Circular contains an explanation of certain UK and US tax consequences of the Demerger.

***The Demerger could result in significant tax liability to the RB Group and the Indivior Group, and the Indivior Group could be required to indemnify RB for such liability under the US Tax Matters Agreement***

If the Demerger were determined not to qualify as a tax-free transaction for US federal income tax purposes, each US Holder generally would be treated as receiving a distribution taxable as a dividend in an amount equal to the fair market value of the Indivior Ordinary Shares received by the US Holder with the consequences described in "United States Taxation Considerations – Demerger". In addition, RB generally would recognise a gain with respect to the Demerger for US federal income tax purposes. Because RB is not a US taxpayer, RB would not be subject to US federal income taxation with respect to such gain. However, the failure of the Demerger to qualify as a tax-free transaction for US federal income tax purposes could affect the tax-free status of the internal restructuring, which, in turn, would result in adverse US federal income tax consequences to the RB Group, and Indivior could be required to indemnify RB for any resulting taxes and related expenses, which could be material.

The Demerger could fail to qualify as a tax-free transaction for US federal income tax purposes if the Indivior Group or its shareholders were to engage in certain transactions after the Demerger. In such cases, RB and/or its shareholders could incur significant US federal income tax liabilities, and Indivior could be required to indemnify RB for any resulting taxes and related expenses, which could be material.

In addition, the failure of the Demerger to qualify as a tax-free transaction could result in significant tax liabilities to the Indivior Group if it results in the failure of the internal restructuring to qualify as a tax-free transaction for US federal income tax purposes.

***Indivior is agreeing to certain restrictions to preserve the treatment of the Demerger as tax-free to RB and its shareholders, which will reduce the strategic and operating flexibility of the Indivior Group***

If the Demerger fails to qualify for tax-free treatment as discussed above, it will be treated as a taxable dividend to shareholders of RB in an amount equal to the fair market value of Indivior Ordinary Shares issued to shareholders of RB. In that event, RB generally would recognise a gain with respect to the Demerger for US federal income tax purposes. As discussed above, RB would not be subject to US federal income taxation with respect to such gain, but the failure of the Demerger to qualify as a tax-free transaction for US federal income tax purposes may result in

adverse US federal income tax consequences to the RB Group or the Indivior Group with respect to the internal restructuring.

In addition, current tax law generally creates a presumption that the Demerger would be taxable to RB (but not to its shareholders), if the Indivior Group or shareholders of Indivior were to engage in a transaction that would result in a 50% or greater change by vote or by value in the ownership of shares in Indivior during the two-year period beginning on the date of the Demerger, unless it is established that the Demerger and the transaction are not part of a plan or series of related transactions to effect such a change in ownership.

Under the US Tax Matters Agreement, which Indivior will enter into with RB, the Indivior Group will generally be prohibited, except in specified circumstances, for specified periods of up to 24 months following the Demerger, from:

- (A) issuing, redeeming or being involved in other significant acquisitions of equity securities of the Indivior Group;
- (B) transferring significant amounts of the assets of the Indivior Group;
- (C) failing to engage in the active conduct of a trade or business; or
- (D) engaging in certain other actions or transactions that could jeopardise the tax-free status of the Demerger.

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

Under the US Tax Matters Agreement that Indivior will enter into with RB, Indivior will agree 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:

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

The indemnity provided by Indivior under the US Tax Matters Agreement will cover both corporate level taxes and related losses imposed on the RB Group in the event of a 50% or greater change in the share ownership of Indivior described in the preceding risk factor, as well as taxes and related losses imposed on RB if, due to Indivior's representations or undertakings being incorrect or violated, the Demerger or the internal restructuring is determined to be taxable for other reasons.

Indemnities that Indivior may be required to provide RB may be significant and could have a material adverse effect on the business, results of operations and financial condition of the Indivior Group, 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 will be sufficient to protect Indivior against the full

amount of such liabilities, or that RB will be able to fully satisfy its indemnification obligations. Moreover, even if Indivior ultimately succeeds in recovering from RB any amounts for which Indivior is held liable, Indivior may be temporarily required to bear these losses itself. Each of these risks could have a material adverse effect on the business, results of operations and financial condition of the Indivior Group.

## **RISKS RELATING TO THE INDIVIOR ORDINARY SHARES**

### ***There is no prior trading record for Indivior Ordinary Shares***

Since the Indivior Ordinary Shares have not previously traded, their market value is uncertain. Following Admission, the market price of the Indivior Ordinary Shares may be volatile and may go down as well as up. The Indivior Group's operating results and prospects from time to time may be below the expectations of market analysts and investors.

At the same time, equity market conditions may affect the Indivior Ordinary Shares regardless of the Indivior Group's operating performance. Stock market conditions are affected by many factors, such as general economic and political conditions, terrorist activity, movements in, or outlook on, interest rates and inflation rates, currency fluctuations, commodity prices, changes in investor sentiment towards the pharmaceutical sector and the supply of and demand for capital. In addition, the price of Indivior Ordinary Shares could be negatively affected by the occurrence of any of the risks described in this Prospectus.

Accordingly, the market price of Indivior Ordinary Shares may not reflect the underlying value of the Indivior Group's assets, and the price at which investors may dispose of their Indivior Ordinary Shares at any point in time may be influenced by a number of factors, only some of which may pertain to the Indivior Group while others may be outside its control.

### ***Significant trading volumes of Indivior Ordinary Shares in the public market in the period post-Demerger and subsequently could impact the share price***

Following Admission of the Indivior Ordinary Shares there may be a period of relatively high volume trading in the Indivior Ordinary Shares as the shareholder register of the Company finds its natural composition. The Directors are unable to predict whether substantial amounts of the Indivior Ordinary Shares will be sold in the open market following Admission. Sales of a substantial number of the Indivior Ordinary Shares in the public market after Admission, or the perception that these sales might occur, could depress the market price of the Indivior Ordinary Shares.

### ***The Company may decide to offer additional Indivior Ordinary Shares in the future, diluting the interests of existing Shareholders and potentially adversely affecting the market price of the Indivior Ordinary Shares***

If the Company decides to offer additional Indivior Ordinary Shares or other securities convertible into Indivior Ordinary Shares in the future, this could dilute the interests of existing Shareholders and/or have an adverse impact on the market price of Indivior Ordinary Shares. An additional offering by the Company, or the public perception that an offering may occur, could have an adverse impact on the market price of the Indivior Ordinary Shares.

### ***There is no guarantee that dividends will be paid on the Indivior Ordinary Shares***

The Company may determine not to pay dividends. If it determines that it will pay dividends, there can be no assurance that it will be able to pay dividends in the future. Under UK company law, a company can only pay cash dividends to the extent that it has distributable reserves and cash available for this purpose. As a holding company, the Company's ability to pay dividends in the future will be affected by a number of factors, including having sufficient distributable reserves and its ability to receive sufficient dividends from subsidiaries.

The ability of companies within the Indivior Group to pay dividends and the Company'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 and cash and covenants in the Indivior Group's facilities. Any of the foregoing could have an adverse impact on the market price of the Indivior Ordinary Shares.

***Any dividend payments will be in US dollars and any Shareholder whose principal currency is not US dollars will be subject to exchange rate fluctuations***

The Indivior Ordinary Shares are, and any dividends to be paid in respect of them will be, denominated in US dollars. An investment in Indivior Ordinary Shares by a Shareholder whose principal currency is not US dollars exposes such a Shareholder to foreign currency exchange risk. Any depreciation of the US dollar in relation to such foreign currency will reduce the value of the investment in Indivior Ordinary Shares or any dividends in foreign currency terms and any appreciation of the US dollar will increase such value in foreign currency terms.

***Shareholders may not be able to exercise pre-emption rights or participate in future issues of Indivior Ordinary Shares and Shareholders outside the UK may not be able to participate in future issues of Indivior Ordinary Shares***

Securities laws of certain jurisdictions outside the UK (including the US) may restrict the participation, or the Company's ability to allow participation, by certain Shareholders in such jurisdictions in any future issue of Indivior Ordinary Shares or of other securities carried out by the Company.

In the case of a future allotment of new Indivior Ordinary Shares for cash, existing Shareholders have certain statutory pre-emption rights unless those rights are disapplied by a special resolution of the Shareholders at a general meeting. An issue of new Indivior Ordinary Shares not for cash or when pre-emption rights have been disapplied could dilute the interests of the then-existing Shareholders. Even where pre-emption rights do apply, holders of Indivior Ordinary Shares who are located in the US, or holders of Indivior ADSs representing Indivior Ordinary Shares, may not be able to exercise pre-emption rights unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements is available thereunder. Unless the Company is otherwise required by reason of its US shareholder base to register under the Exchange Act, there can be no assurance that the Company will file any such registration statements, or that an exemption to the registration requirements of the Securities Act will be available, which would result in certain Shareholders in the US (and holders of Indivior ADSs representing Indivior Ordinary Shares) being unable to exercise pre-emption rights. Securities laws of certain other jurisdictions may restrict the Company's ability to allow participation by Shareholders in such jurisdictions in any future issue of Indivior Ordinary Shares or of other securities carried out by the Company.

This could have an adverse impact on the market price of the Indivior Ordinary Shares and the ability of the Company to raise funds to meet its business requirements.

***The ability of Overseas Shareholders to bring actions or enforce judgments against the Company or the Directors may be limited***

The ability of an Overseas Shareholder to bring an action against the Company may be limited under law. The Company is a public limited company incorporated in England and Wales. The rights of holders of the Indivior Ordinary Shares are governed by English law and by the Articles of Association. These rights differ from the rights of shareholders in typical US corporations and some other non-UK corporations.

An Overseas Shareholder may not be able to enforce a judgment against some or all the Directors and executive officers. All the Directors and executive officers are residents of the UK or the US. Consequently, it may not be possible for an Overseas Shareholder to effect service of process upon the Directors and executive officers within the Overseas Shareholder's

country of residence or to enforce against the Directors and executive officers judgments of courts of the Overseas Shareholder's country of residence based on civil liabilities under that country's securities laws. There can be no assurance that an Overseas Shareholder will be able to enforce any judgments in civil and commercial matters or any judgments under the securities laws of countries other than the UK against the Directors or executive officers who are residents of countries other than those in which judgment is made. In addition, English or other courts may not impose civil liability on the Directors or executive officers in any original action based solely on foreign securities laws brought against the Company or the Directors in a court of competent jurisdiction in England or other countries. This could have an adverse impact on the market price of the Indivior Ordinary Shares.

## PART III

### DIRECTORS, SECRETARY, REGISTERED OFFICE AND ADVISERS

<b>Directors</b>	Howard Pien ( <i>Chairman</i> ) Shaun Thaxter ( <i>Chief Executive Officer</i> ) Cary Claiborne ( <i>Chief Financial Officer</i> ) Rupert Bondy ( <i>Senior Independent Director</i> ) Yvonne Greenstreet ( <i>Independent Non-Executive Director</i> ) Adrian Hennah ( <i>Non-Executive Director</i> ) A. Thomas McLellan ( <i>Independent Non-Executive Director</i> ) Lorna Parker ( <i>Independent Non-Executive Director</i> ) Daniel J. Phelan ( <i>Independent Non-Executive Director</i> ) Christian S. Schade ( <i>Independent Non-Executive Director</i> ) Daniel Tassé ( <i>Independent Non-Executive Director</i> )
<b>Company secretary</b>	Lola Emetulu
<b>Registered office</b>	103-105 Bath Road Slough Berkshire SL1 3UH
<b>ADVISERS:</b>	
<b>Joint Sponsors</b>	Deutsche Bank AG, London Branch Winchester House 1 Great Winchester Street London EC2N 2DB  Morgan Stanley & Co. International PLC 25 Cabot Square London E14 4QA
<b>Financial adviser</b>	Jefferies International Limited Vintners Place 68 Upper Thames Street London EC4V 3BJ
<b>Legal advisers to the Company</b>	
<i>As to English law:</i>	Slaughter and May One Bunhill Row London EC1Y 8YY
<i>As to US law:</i>	Paul Weiss, Rifkind, Wharton & Garrison LLP Alder Castle 10 Noble Street London EC2V 7JU
<i>As to English and US law:</i>	Covington & Burling LLP 265 Strand London WC2R 1BH

## **Legal advisers to the Joint Sponsors**

*As to English and US law:*

Freshfields Bruckhaus Deringer LLP  
65 Fleet Street  
London EC4Y 1HS

## **Auditor and Reporting Accountants**

PricewaterhouseCoopers LLP  
1 Embankment Place  
London WC2N 6RH

## **Registrar**

Computershare Investor Services PLC  
The Pavilions  
Bridgwater Road  
Bristol BS99 6ZZ

## PART IV

### EXPECTED TIMETABLE OF PRINCIPAL EVENTS

	<i>Time and Date<sup>(1)(2)</sup></i>
Publication of the RB Shareholder Circular and Indivior Prospectus	17 November 2014
RB General Meeting	3.00 p.m. on 11 December 2014
Latest time and date for transfers of RB Ordinary Shares to be registered in order for the transferee to be registered at the Demerger Record Time	6.00 p.m. on 22 December 2014
Demerger Record Time	6.00 p.m. on 22 December 2014
Demerger Effective Time	8.00 a.m. on 23 December 2014
Admission of Indivior Ordinary Shares to the premium listing segment of the Official List, and commencement of trading on the main market of the London Stock Exchange	8.00 a.m. on 23 December 2014
CREST accounts credited in respect of Indivior Ordinary Shares in uncertificated form	8.00 a.m. on 23 December 2014
Latest date for despatch of definitive share certificates for Indivior Ordinary Shares in certificated form	30 January 2015

**Notes:**

- (1) Times and dates set out in the timetable above and mentioned throughout this document that fall after the date of publication of this Prospectus are indicative only and may be subject to change without further notice.
- (2) All references to time in this timetable are to London time.

## PART V

### PRESENTATION OF INFORMATION

#### 1. General

**No person has been authorised to give any information or to make any representations in connection with the Demerger or Admission other than those contained in this Prospectus and, if given or made, such information or representations must not be relied upon as having been authorised by or on behalf of the Company, the Directors, Deutsche Bank, Morgan Stanley or Jefferies. No representation or warranty, express or implied, is made by Deutsche Bank, Morgan Stanley or Jefferies or any person affiliated with any of them as to the accuracy or completeness of such information, and nothing contained in this Prospectus is, or shall be relied upon as, a promise or representation by Deutsche Bank, Morgan Stanley, Jefferies or any person affiliated with either of them as to the past, present or future. Without prejudice to any obligation of the Company to publish a supplementary prospectus pursuant to section 87G of FSMA and PR 3.4.1 of the Prospectus Rules, neither the delivery of this Prospectus nor any sale made under this Prospectus shall, under any circumstances, create any implication that there has been no change in the business or affairs of the Company or of the Indivior Group taken as a whole since the date hereof or that the information contained herein is correct as at any time subsequent to the earlier of the date hereof and any earlier specified date with respect to such information.**

The Company will update the information provided in this Prospectus by means of a supplement hereto if a significant new factor that may affect the evaluation of Indivior Ordinary Shares occurs prior to Admission or if this Prospectus contains any mistake or substantial inaccuracy. Any supplement to this Prospectus will be subject to approval by the FCA and will be made public in accordance with the Prospectus Rules.

The contents of this Prospectus are not to be construed as legal, business or tax advice. RB Shareholders and prospective investors in Indivior Ordinary Shares should consult their own lawyers, financial advisers or tax advisers for legal, financial or tax advice in relation to the Demerger, including in order to determine whether they are legally permitted to hold shares under applicable legal investment or similar laws or regulations. RB Shareholders and prospective investors in Indivior Ordinary Shares should be aware that they may be required to bear the financial risks of this investment for an indefinite period of time.

RB Shareholders and prospective investors in Indivior Ordinary Shares should read this Prospectus in its entirety and, in particular, Part II (*Risk Factors*). Any decision to hold Indivior Ordinary Shares should be based solely on this Prospectus.

RB Shareholders and prospective investors in Indivior Ordinary Shares will be deemed to have acknowledged that: (i) they have not relied on Deutsche Bank, Morgan Stanley or any person affiliated with either of them in connection with any investigation of the accuracy of any information contained in this Prospectus for their investment decision; (ii) they have relied solely on the information contained in this Prospectus; and (iii) no person has been authorised to give any information or to make any representation concerning the Indivior Group or the Indivior Ordinary Shares (other than as contained in this Prospectus) and, if given or made, any such other information or representation should not be relied upon as having been authorised by the Company, the Directors, Deutsche Bank or Morgan Stanley.

Deutsche Bank, Morgan Stanley and any of their respective affiliates may have engaged in transactions with, and provided various investment banking, financial advisory and other services to the Company and RB, for which they would have received customary fees. Deutsche Bank, Morgan Stanley and any of their respective affiliates may provide such services to the Company, RB and any of their respective affiliates in future.

## **2. Presentation of financial information**

The Indivior Group's combined historical financial information included in Part XII (*Historical Financial Information*) of this Prospectus has been prepared in accordance with the requirements of the PD Regulation and the Listing Rules and in accordance with IFRS as adopted by the EU. The basis of preparation and significant accounting policies are set out within notes 2 and 3 of the Indivior Group's combined historical financial information in Part XII (*Historical Financial information*). The Indivior Group presents unaudited financial information for the six-month period ended 30 June 2013 for comparative purposes.

The Indivior Group's combined unaudited interim financial information as of and for the nine months ended 30 September 2014 included in Part XII (*Historical Financial Information*) of this Prospectus has been prepared in accordance with IAS 34 "Interim Financial Reporting".

## **3. Non-IFRS measures**

In this Prospectus, the Company presents certain financial information and measures and certain operational data which are not calculated in accordance with IFRS, such as information relating to gross sales and the contribution of products to net revenue, market shares of the Indivior Group's products and free cash flow (calculated as cash flows from operating activities less net cash flows from the purchase and disposal of property, plant and equipment, and intangible assets).

## **4. Rounding**

Percentages and certain amounts included in this Prospectus have been rounded for ease of presentation. Accordingly, figures shown as totals in certain tables may not be the precise sum of the figures that precede them.

## **5. Currencies**

The Indivior Group's financial information is presented in US dollars. The abbreviations "\$m" or "\$ million" represent millions of US dollars, and reference to "cents" represents cents in US dollars.

## **6. Forward-looking statements**

Certain statements contained in this Prospectus, including those in Part II (*Risk Factors*), Part VI (*Information on the Indivior Group and its Industry*) and Part X (*Operating and Financial Review*) 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. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results, performance or achievements of the Indivior Group 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 the Directors' expectations and beliefs concerning future events impacting the Indivior Group and therefore involve a number of known and unknown risks and uncertainties. Such forward-looking statements are based on numerous assumptions regarding the Indivior Group's present and future business strategies and the environment in which it will operate, which may prove to be inaccurate. The Company cautions that these forward-looking statements are not guarantees and that actual results could differ materially from those expressed or implied in these forward-looking statements.

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

- (A) any factors affecting sales of Suboxone Tablet, Suboxone Film, Subutex Tablet and any future products;
- (B) 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, and launch dates for product candidates, as well as the possibility of unfavourable clinical trial results, including unfavourable new clinical data and additional analyses of existing clinical data;
- (C) decisions by regulatory authorities regarding whether and when to approve the Indivior Group's drug applications, as well as their decisions regarding labelling, ingredients and other matters that could affect the availability or commercial potential of the Indivior Group's products;
- (D) the speed with which regulatory authorisations, pricing approvals and product launches may be achieved;
- (E) 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;
- (F) competitive developments, including the impact on the Indivior Group's competitive position 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 the Indivior Group's products and product candidates, and the ability to meet generic and branded competition after the loss of patent protection for the Indivior Group's products or competitor products;
- (G) difficulties or delays in manufacturing;
- (H) the impact of existing and future legislation and regulatory provisions on product exclusivity;
- (I) trends toward managed care and healthcare cost containment;
- (J) legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access;
- (K) claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates;
- (L) legal defence costs, insurance expenses, settlement costs, the risk of an adverse decision or settlement and the adequacy of reserves related to product liability, patent protection, government investigations, consumer, commercial, securities, antitrust, environmental and tax issues, and other legal proceedings;
- (M) the Indivior Group's ability to protect its patents and other intellectual property;
- (N) the outcome of the Suboxone Film patent litigation relating to the two ongoing ANDA lawsuits;
- (O) governmental laws and regulations, including those affecting pharmaceutical product pricing, reimbursement or access, as well as the Group's US and foreign operations, including, without limitation, tax obligations and changes affecting the tax treatment by the US of income earned outside the US that may result from pending and possible future proposals;

- (P) 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;
- (Q) uncertainties related to general economic, political, business, industry, regulatory and market conditions including, without limitation, uncertainties related to the impact on the Indivior Group, its customers, suppliers and other counterparties of challenging global economic conditions and recent and possible future changes in the global financial markets; and
- (R) the impact of acquisitions, divestitures, restructurings, internal reorganisations, product recalls and withdrawals and other unusual items.

In light of these risks, uncertainties and assumptions, the forward-looking events described in this Prospectus may not occur. The forward-looking statements referred to above speak only as at the date of this Prospectus. Subject to any obligations under applicable law, including the Prospectus Rules, the Listing Rules and the Disclosure and Transparency Rules, the Company undertakes no obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this Prospectus. All subsequent written and oral forward-looking statements attributable to the Indivior Group or individuals acting on behalf of the Indivior Group are expressly qualified in their entirety by this paragraph.

It is strongly recommended that RB Shareholders and prospective investors in Indivior Ordinary Shares read the risk factors set out in Part II (*Risk Factors*) of this Prospectus for a more complete discussion of the factors that could affect the Indivior Group's future performance and the industry in which it operates.

## **7. Market, economic and industry data**

This Prospectus contains information regarding the Indivior Business and the industry in which it operates and competes, which the Company has obtained from various third-party sources. Where information has been sourced from a third party it has been accurately reproduced and, so far as the Company is aware and is able to ascertain from information published by that third party, no facts have been omitted which would render the reproduced information inaccurate or misleading. The Company has generally obtained the market and competitive position data in this Prospectus from industry publications and from surveys, studies conducted or data collected by third-party sources. Information relating to the market share in the US of the Indivior Group's and its competitors' products is taken from Source Healthcare Analytics Retail Pharmaceutical Audit Suite Weekly Data and, unless otherwise stated, is taken for the week ending 3 October 2014.

## **8. Intellectual property**

The Indivior Group owns, or has a right to use, in the most important jurisdictions in which the Indivior Group operates, the key trade marks, service marks, copyrights and trade names that it uses in conjunction with the operation of its business, namely Suboxone® Film, Suboxone® Tablet and Subutex® Tablet.

This Prospectus also includes trade marks, service marks and trade names of other companies. Each trade mark, service mark or trade name of any other company appearing in this Prospectus belongs to its holder. Use or display in this Prospectus of other parties' trade marks, service marks or trade names is not intended to and does not imply a relationship with, or endorsement or sponsorship by the Indivior Group of, the trade mark, service mark or trade name owner.

**9. No incorporation of website information**

The contents of neither the Indivior Group's nor the RB Group's websites form any part of this Prospectus.

## PART VI

### INFORMATION ON THE INDIVIOR GROUP AND ITS INDUSTRY

#### 1. Introduction

The board of directors of RB announced on 28 July 2014 its intention to separate the Indivior Business from the RB Group.

It is proposed that this separation will be effected by way of a demerger of the Indivior Business to the Company. The Demerger is conditional on the following matters:

- (A) the approval of the Demerger at the RB General Meeting by RB Shareholders holding a majority of the RB Ordinary Shares;
- (B) the Sponsors' Agreement not having terminated in accordance with its terms;
- (C) the Demerger Agreement having become unconditional and not having terminated in accordance with its terms;
- (D) the UKLA having acknowledged to Indivior or its agent (and such acknowledgement not having been withdrawn) that the application for the admission of the Indivior Ordinary Shares to the premium listing segment of the Official List has been approved and (after satisfaction of any conditions to which such approval is expressed to be subject ("**listing conditions**")) will become effective as soon as a dealing notice has been issued by the FCA and any listing conditions having been satisfied; and
- (E) the London Stock Exchange having acknowledged to Indivior or its agent (and such acknowledgement not having been withdrawn) that the Indivior Ordinary Shares will be admitted to trading.

It should be noted that, although it is currently RB's intention that the Demerger should be concluded, RB is entitled to decide not to proceed with the Demerger at any time prior to the Demerger Effective Time if it determines that it would not be in the interests of RB Shareholders. The Demerger is not conditional on Admission.

If the Demerger proceeds, each RB Shareholder will receive one ordinary share in Indivior for each ordinary share in RB that they hold at the Demerger Record Time, save that the number of Indivior Ordinary Shares to be allotted and issued to each of the two initial Shareholders will be reduced by the number of Indivior Ordinary Shares already held by them so that, upon the Demerger becoming effective, all RB Shareholders (including the two initial Shareholders) will hold one Indivior Ordinary Share for each RB Ordinary Share held at the Demerger Record Time. RB Shareholders will continue to own their existing RB Ordinary Shares.

The Demerger is to be effected by RB declaring a dividend in specie on the RB Ordinary Shares equal to the book value of RB's shareholding in RBP Global Holdings Ltd, the current holding company of the Indivior Group, which will immediately prior to the Demerger Effective Time be a wholly owned subsidiary of RB in accordance with the terms of the Demerger Agreement. This dividend in specie will be satisfied by the transfer by RB to Indivior of the shares in RBP Global Holdings Ltd. In return for this transfer, Indivior will then allot and issue Indivior Ordinary Shares to each RB Shareholder who is registered on the RB share register at the Demerger Record Time on the basis of one Indivior Ordinary Share for each RB Ordinary Share then held, save that the number of Indivior Ordinary Shares to be allotted and issued to each of the two initial Shareholders will be reduced by the number of Indivior Ordinary Shares already held by them so that, upon the Demerger becoming effective, all RB Shareholders (including the two initial Shareholders) will hold one Indivior Ordinary Share for each RB Ordinary Share held at the Demerger Record Time.

Following the Demerger, it is expected that the Indivior Ordinary Shares will be admitted to the premium listing segment of the Official List and be admitted to trading on the main market of the London Stock Exchange. The Demerger is expected to become effective on 23 December 2014. It is expected that Admission of, and dealings on the London Stock Exchange in, the Indivior Ordinary Shares will commence at 8.00 a.m. on 23 December 2014. Following the Demerger, Indivior will be the holding company of the Indivior Group.

Further details in relation to the Demerger are set out in the RB Shareholder Circular published today.

## **2. Background to and reasons for the Demerger**

The Indivior Business is a specialty pharmaceutical business that has been developed and managed as a separate division of the RB Group. Owing to the distinct nature of the business, and its significantly different characteristics compared to the RB Group's core operations in the fast-moving consumer goods segment, the RB Group has always regarded and operated the Indivior Business as a non-core business and, since 2007, reported the results of the Indivior Business as a separate operating segment.

In October 2013, RB commenced a strategic review of the Indivior Business. The timing of the strategic review was influenced by multiple factors, including the following:

- (A) the significant share of the US buprenorphine-based opioid dependence treatment market captured by Suboxone Film since the expiry of orphan drug exclusivity for Suboxone Tablet in October 2009. The RB Group and the Indivior Group consider the sublingual film business to be significantly more sustainable than the tablet business as sublingual film dissolves faster and it cannot currently be substituted for generic tablets by pharmacists when filling patients' prescriptions; and moreover, surveys conducted by the Indivior Group show that over 90% of patients and physicians surveyed were satisfied with Suboxone Film and prefer it to tablets;
- (B) potential volatility of Suboxone Film market share following the launch of generic Suboxone tablets. Two manufacturers launched generic Suboxone tablets in the US in March 2013 and a third in August 2014 (although the impact on Suboxone Film market share to date has proved to be limited). A fourth manufacturer received approval from the FDA for a generic Suboxone tablet in September 2014. These, and additional generic Suboxone tablets, are expected to enter the US market; and
- (C) investment in the development pipeline (for both existing and new products), and in the Indivior Business in jurisdictions outside the US, having reached a point where good, long-term prospects for a global, independent, specialty pharmaceutical business with a strong pipeline were becoming evident.

On 28 July 2014, RB announced the outcome of the strategic review, which concluded that the Indivior Business should be separated from the RB Group by way of the Demerger. RB believes that the Demerger will provide the RB Group and the Indivior Group with a number of opportunities and benefits, including the following:

- (A) The Demerger will create two distinct entities with different strategic, operational and economic characteristics, and with separate management teams. Managed as an independent global specialty pharmaceutical business rather than as a non-core subsidiary of a fast-moving consumer goods group, the boards of both RB and Indivior believe that the Indivior Group's management team will be better placed and incentivised to pursue avenues for growth and to create value by building on Indivior's strong market position in the treatment of opioid dependence and developing and commercialising further products in the area of addiction and its immediate adjacencies. The separation will also allow the RB Group to focus on its core businesses in the health, hygiene and home sectors.

- (B) The Demerger will allow the Indivior Group to allocate resources and deploy capital in a manner consistent with the priorities of the Indivior Business, and will enable the Indivior Group's management team to implement a capital structure, dividend policy and growth strategy tailored to the Indivior Business. Indivior is expected to have direct access to the debt and equity capital markets to fund its growth strategy.

### **3. 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, but that is manageable and responsive to treatment. As a consequence, coherent action to deal with sufferers and the disease is generally lacking.

The number of opioid-dependent individuals in the US has seen dramatic growth over the last few years, reaching an estimated 2.4 million people in 2013. This trend has been driven partially by the relatively liberal prescription of opioid analgesics.

The enactment of DATA 2000 was a significant development in the history of addiction treatment in the US. Previously, treatment options for opioid dependence were limited: abstinence-based programmes 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 medicalising 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 stigmatised owing to societal attitudes towards the disease, low awareness of treatment options and limited access to treatment in several areas of the US.

The European market is smaller than the US with an estimated 1.3 million problem opioid users, the majority of whom are heroin users. The 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,<sup>1</sup> but there is also an emerging patient population of opioid analgesic-dependent patients who are currently under-diagnosed. Initial conservative estimates suggest that there are potentially over 300,000 individuals dependent on prescription opioid analgesics in the UK, France, Germany, Spain, Italy and the Nordic countries.<sup>2</sup>

Treatment methods in the EU differ from the US. While US 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

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1 <http://www.emcdda.europa.eu/topics/pods/preventing-overdose-deaths>.

2 Alho H et al, Nov 2013, International Society Addiction Medicine, Malaysia.

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 recognise 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 20 million opioid-dependent individuals, the majority of whom are in Asia and Australia. 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 there are an estimated 110,000 heroin users in Australia and approximately 47,000 patients are treated annually for opioid dependence.<sup>3</sup> There is increasing awareness among healthcare providers of the misuse of opioid analgesics and the need for treatment. Recent policy changes to address this concern in Australia include rescheduling products containing codeine so that they must be dispensed by a pharmacist rather than over the counter.

The Board believes that there is an opportunity for the Indivior Group 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. There are 1.2 million registered opioid-dependent individuals in China (although the total number is estimated at approximately five million<sup>4</sup>) of which approximately only 450,000 have received treatment.<sup>5</sup>

### ***Alcohol dependence***

Alcohol abuse and dependence are associated with more than 60 disease types and injuries that contribute to approximately 2.5 million deaths annually.<sup>6</sup> An estimated 4% of the global burden of disease and injury is attributed to alcohol. 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 underutilised.<sup>7</sup>

### ***Opioid overdose***

Opioid overdose is the second leading cause of accidental death in the US, claiming 16,000 lives in 2012. There were over four times as many opioid overdose deaths in the US in 2010 than there were in 1999. Accidental death caused by opioid overdose is a problem that also affects the EU, with opioid overdose estimated to have claimed 70,000 lives during the first decade of the 21st century and an estimated 6,100 lives in 2012. Standard medical protocol for treating opioid overdose is to administer naloxone, an injectable opioid receptor antagonist approved in 1971 that rapidly and effectively reverses the effects of natural and synthetic opioids including propoxyphene, methadone and certain mixed agonist-antagonist analgesics such as nalbuphine, pentazocine, butorphanol and cyclazocine. Despite naloxone's proven clinical efficacy, the injectable format limits the drug's availability where and when it is needed most - on the front line at the time of overdose.

### ***Cocaine intoxication***

Cocaine abuse and its complications represent significant public health issues in the US. Cocaine is the second most commonly used illicit drug in the US with a rate of 88 per 100,000

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3 NOPSAD DATA 2013.

4 Market research projects conducted separately by IMS (5.1m) and LEK (4.8m).

5 China Anti-drug Abuse Agency 2011.

6 World Health Organization, Global status report on alcohol and health 2011, Geneva, Switzerland.

7 Friedmann PD Clinical practice, Alcohol Use in Adults, N Engl J Med, 2013; 368:365-373.

population for Disability Adjusted Life Years due to cocaine dependence.<sup>8</sup> Cocaine is also the most common illicit drug involved in emergency room (ER) visits. In 2011 there were approximately 505,000 visits involving cocaine.<sup>9</sup> It is estimated that between 66,000 and 116,000 of cocaine-related ER visits may represent severe cocaine intoxication.<sup>10</sup> Approximately 33% of the cocaine-related visits also involved alcohol, and 33% involved other drugs but not alcohol. Nearly a quarter of all patients with cocaine-related visits are admitted to hospital, including 3% who are admitted to a critical care unit.<sup>11</sup> Cost estimates from US private payers and New Jersey Medicaid suggest emergency room costs of approximately \$800-\$1000 per visit and an additional \$4200-\$8600 per admission. The number of poisoning deaths involving cocaine in the US rose steadily from under 4,000 in 1999 to approximately 7,500 in 2006, more than from any other illicit drug.<sup>12</sup> The number decreased to approximately 2,000 in 2010, but continued to surpass the number involving heroin.<sup>13</sup>

#### **4. Business overview**

The Indivior Group is a global specialty pharmaceutical business and the global leader in the treatment of opioid dependence, with 20 years' experience in that field.

The Indivior Group's core products, which are currently sold in up to 44 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. Suboxone Film, initially launched in the US in 2010 as the world's first approved pharmaceutical prescription sublingual film product, currently maintains a share of 60% in the US market for buprenorphine-based opioid dependence treatment (based on volume of prescribed milligrams), despite market entry of generic tablets and branded competitors.

The Indivior Group also sells two 'legacy products': Temgesic sublingual tablets and injections outside the US for the treatment of moderate to severe pain, as well as Buprenex injection in the US for the relief of moderate to severe pain. There is no current or planned marketing activity to support Temgesic or Buprenex. Temgesic and Buprenex comprise less than 4% of total Indivior Group net revenues.

The Indivior Group also supplies 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".

The Indivior Group is committed to delivering innovative, high quality treatments for the chronic relapsing conditions and co-morbidities of addiction, and plans to expand its range of products beyond its core opioid dependence treatment business. In addition to extension candidates for its opioid dependence treatments, the Indivior Group has a pipeline of new drug candidates for the treatment of alcohol dependence, cocaine intoxication, schizophrenia and opioid overdose. The Board believes that the development of these product candidates capitalises on the Indivior Group's expertise in neurological science, clinical development and experience within the highly regulated and technical nature of pharmaceutical industry drug development and commercialisation.

8 Degenhardt L, Baxter AJ, Lee YY, Hall W, et al. (2014) The global epidemiology and burden of psychostimulant dependence: Findings from the Global Burden of Disease Study 2010. *Drug Alcohol Depend.*, 137: 36-47. <http://dx.doi.org/10.1016/j.drugalcdep.2013.12.025>

9 Drug Abuse Warning Network (DAWN) 2011. <http://www.samhsa.gov/data/dawn.aspx>

10 National Hospital Ambulatory Medical Care Survey, 2007-2010

11 National Hospital Ambulatory Medical Care Survey, 2007-2010

12 National Center for Health Statistics (NCHS) Data Brief 22: September 2009

13 CESAR FAX April 22, 2013; 22:16. <http://www.cesar.umd.edu/cesar/cesarfax/vol22/22-16.pdf>

The Indivior Group generated net revenues of \$574 million in H1 2014 (H1 2013: \$618 million; 2013: \$1,216 million; 2012: \$1,339 million; 2011: \$1,254 million). Its core geographic market (based on the country where the sale originates) is the US which accounted for 77% of net revenues in H1 2014 (H1 2013: 78%; 2013: 78%; 2012: 80%; 2011: 77%).

## **5. Key strengths**

The Board believes that the Indivior Group's key strengths include the following:

### ***Suboxone is the leading opioid dependence treatment franchise***

WHO indicates that buprenorphine is an essential medication for the treatment of opioid dependence. In the US, 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 US. Following the successful introduction of Suboxone Tablet, the Indivior Group developed a film formulation which the Board believes provides a significant benefit for patients, physicians, payers and regulators. Suboxone Film dissolves faster than Suboxone Tablet and each individual Suboxone Film is packaged in a unit-dose child-resistant pouch. Surveys conducted by the Indivior Group show 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. Between 2010 and 2013, over 14,000 waived physicians (physicians that receive waivers under DATA 2000 to treat opioid dependence with Schedule III, IV and V narcotic medications approved by the FDA) have prescribed Suboxone Film in the US, and since its launch in 2010 over 19 million prescriptions have been written for Suboxone Film in the US.<sup>14</sup>

The Indivior Group has also created a tailored managed care strategy to drive payer 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. The Board believes the strength of the Suboxone franchise is demonstrated by its favourable formulary position, as well as by Suboxone Film's market share of 60% of the US buprenorphine-based opioid dependence treatment market, despite the entry of both generic and branded tablet competition.

The Board believes that the Indivior Group's intellectual property protection is robust. With respect to Suboxone Film, the Indivior Group has a patent portfolio consisting of formulation patents, process patents and pending patent applications relating to the product. In the US, the Indivior Group has 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. In the EU, where the launch of Suboxone Film is expected in 2016, the Indivior Group has patent protection for the product until October 2022.

### ***The Indivior Group operates in attractive high growth markets for the treatment of opioid dependence***

The opioid dependence treatment market in the US, the Indivior Group's key market representing over 70% of its total net revenues in 2013 and H1 2014, has experienced consistent low double-digit growth over the past two years. The Board believes that the market continues to remain under-penetrated: there are approximately 2.4 million opioid-dependent individuals in the US, but fewer than 800,000 receive medication-assisted treatment. There are also a further 11.1 million individuals misusing prescription opioids in the US.

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<sup>14</sup> Source Healthcare Analytics Retail Sales Data; NTIS DEA Certification List and internal modelling.

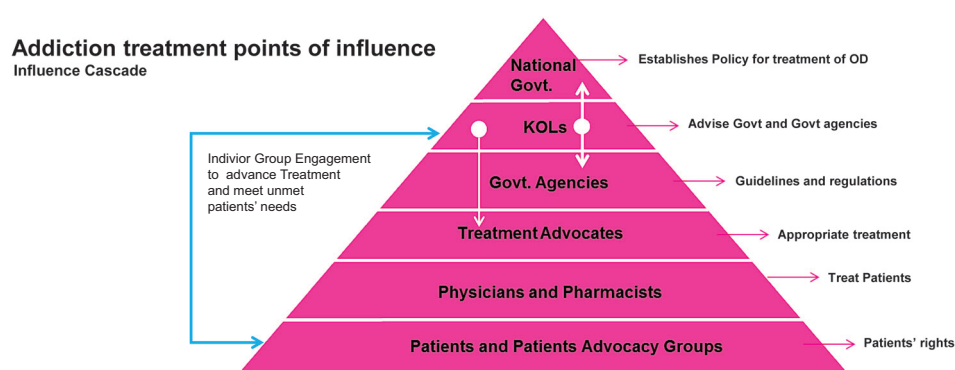
The Board believes there are no signs that the incidence of opioid dependence is slowing. While strict regulations have been implemented aimed at limiting the availability of opioid prescription analgesics to reduce abuse and diversion, those struggling with addiction continue to find alternative opioid options. Progress continues to be made towards medicalising 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 the Board believes will likely serve to drive market growth. Importantly, an increasing number of payers have begun to recognise 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.<sup>15</sup> For the reasons outlined above, the US opioid dependence market is expected to grow.<sup>16</sup>

In addition, considering the high number of opioid-dependent individuals in several other jurisdictions around the world, as described in paragraph 3 of this Part VI (*Information on the Indivior Group and its Industry*), the Board further believes that there is also a significant opportunity to grow the Indivior Group's business outside the US.

***Cultivation of strong relationships with key stakeholders, including through a committed sales force with high quality physician access***

The Indivior Group has a strong commitment to its patient-focused business. It approaches this disease space with a public health mindset and seeks to partner with relevant stakeholders in the opioid dependence community to ensure access to high quality treatment services for patients suffering from the chronic relapsing diseases of addiction.

The Indivior Group engages at all levels across the addiction treatment spectrum, interacting with governments, key opinion leaders, physicians, payers, patients and patient advocacy groups in order to expand access to treatment and improve patient outcomes. The Board believes that the Indivior Group's leadership in this market segment is demonstrated by its 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 involved in addiction treatment and the Indivior Group's points of influence.



OD: Opioid dependence

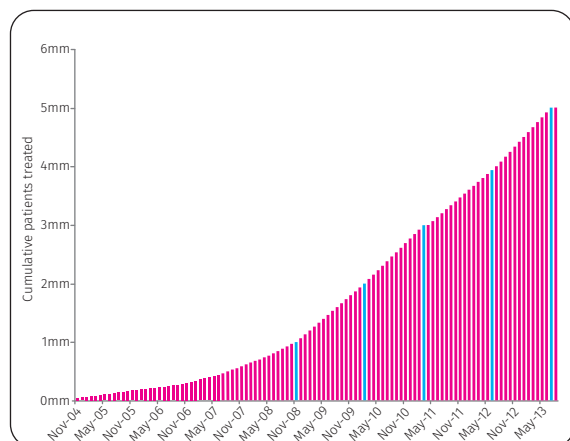
KOL: Key opinion leader

<sup>15</sup> American Society of Addiction Medicine

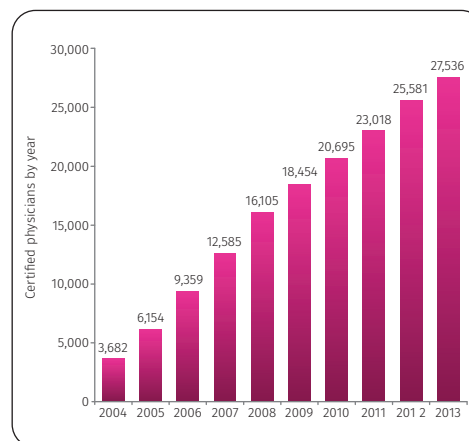
<sup>16</sup> 2012 National Survey on Drug Use and Health – SAMSHA.

The Indivior Group's US sales force consists of over 200 trained professionals who are dedicated to educating key stakeholders in the opioid dependence community about the treatment of opioid dependence and the science of Suboxone Film. The Indivior Group works closely with physicians and professional medical societies to educate them about DATA 2000 certification and to expand access to treatment. In the US over 27,000 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. This has enabled the treatment of over five million patients with Suboxone Tablet and Suboxone Film, as shown in the charts below.

#### Growth in number of Patients



#### Growth in number of certified physicians



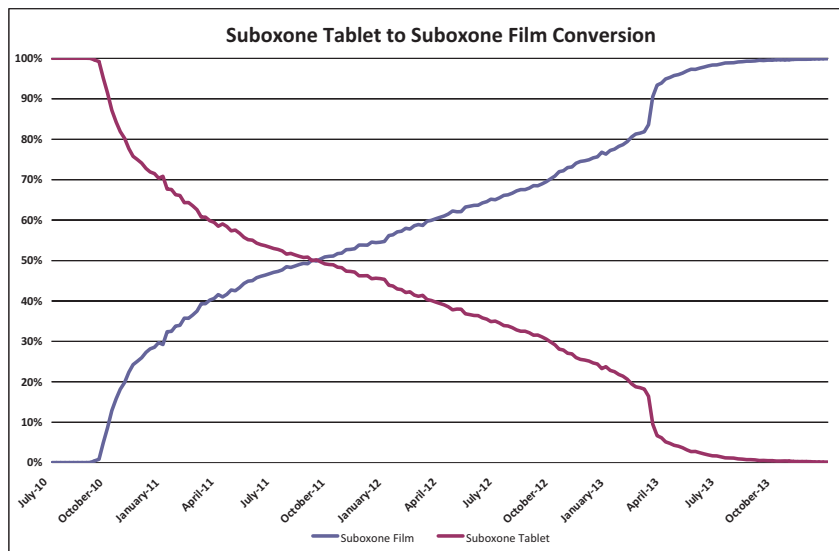
Source: Source Healthcare Analytics Retail Pharmaceutical Audit Suite Weekly Data, 2004-2013; internal modelling; NTIS DEA Certification List

In the EU and other countries outside the US, the Indivior Group has built a specialised commercial team across 31 countries that is committed to expanding access to treatment for patients, and forges strong relationships with physicians.

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

The Board believes that the Indivior Group's leading position in the treatment of opioid dependence and its effective engagement with stakeholders improves its ability to anticipate and identify market and public health trends that can reveal unmet treatment needs. The Board believes that the Indivior Group's global research and development function, clinical development capability and regulatory expertise means it is well positioned to innovate and to develop products designed to address unmet needs, to extend its franchises, strengthen its intellectual property estate and to evolve treatment.

The introduction of Suboxone Film in the US is an example of the Indivior Group's 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 recognised by payers. As shown in the chart below, the innovative and differentiated aspects of Suboxone Film have resulted in a high level of patient conversion from Suboxone Tablet.



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

The Indivior Group has a robust pipeline of life-cycle products which are fully supported by line-extension strategies and development programmes designed to optimise the opioid dependence treatment franchise. These programmes include developing (i) a monthly depot buprenorphine product that releases buprenorphine over a minimum of 28 days by diffusion, (ii) a swallowable capsule with abuse deterrent potential, and (iii) a higher dose Suboxone Tablet for distribution in the EU. For more information on these product candidates, please refer to paragraph 9 of this Part VI (*Information on the Indivior Group and its Industry*).

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

The Indivior Group launched the first buprenorphine-based product for the opioid dependence treatment market in 1996 and continues to lead that market after 18 years. The Board believes that this leadership derives from the Indivior Group's strong global research and development team which capitalises on significant and specialised scientific expertise and knowledge of the brain disease model of behavioural disorders to deliver treatments for the chronic relapsing conditions and co-morbidities of addiction. The Indivior Group's research and development team consists of 141 personnel led by the Chief Scientific Officer, Christian Heidebreder, a leading authority on the development of addiction treatments.

The Indivior Group's development of the Suboxone Tablet and Suboxone Film formulations are examples of its 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 US in 2010, successfully completed 21 clinical studies in 18 months. The Board believes that the Indivior Group has a promising pipeline of product candidates in various stages of development for the treatment of alcohol dependence, opioid overdose, cocaine intoxication and schizophrenia, as well as extensions to its core opioid dependence treatments, and the Board has confidence in the Indivior Group's ability to capitalise on and commercialise these opportunities given its track record with the Suboxone franchise.

***Market growth balanced with responsible management***

Because of the recognised risks of buprenorphine, the Indivior Group conducts active risk management programmes to ensure patient safety. In the US, under an FDA-approved REMS, the Indivior Group disseminates information for patients, pharmacists and prescribers about the safe use of Suboxone Film designed to (i) mitigate against the risks of accidental overdose, misuse and abuse, and (ii) inform prescribers, pharmacists, and patients of the serious risks associated with Suboxone Film.

The elements to assure safe use include multiple conditions, such as documenting specified safe use conditions prior to dispensing Suboxone Film to patients, and monitoring each patient using Suboxone Film. The REMS also incorporates multiple documents, including the Suboxone Medication Guide, Appropriate Use Checklist, Dear Prescriber Letter, Dear Pharmacist Letter, the Suboxone Film REMS website, “Office-Based buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers” and “Office-Based buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists”. Among other requirements of the REMS implementation system, the Indivior Group surveys physicians and patients periodically to formally assess how well safety messages are received and understood. The survey reports must be submitted to the FDA annually and inform regulatory decisions regarding potential changes to the REMS materials.

In addition, the 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 the Indivior Group’s 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, the Indivior Group monitors for specific events agreed with the EMA as part of its risk management plan for Suboxone Tablet.

The Board believes that drug safety is a function that can add value and support rather than being only a function of necessity and the Indivior Group continually looks at system improvements to provide flexibility in the face of legislative change and business growth in terms of new products and geographies.

#### ***Attractive returns profile with strong free cash flow generation***

The Indivior Business has a strong financial profile, having increased its net revenues at a compound annual growth rate of 30% from 2007 (the year in which the results of the Indivior Business began to be reported as a separate operating segment of the RB Group) to 2009, and at a compound annual growth rate of 5% between 2009 and 2013. While the Indivior Group’s revenues and operating profit continue to be affected in the short term by competition from both branded and generic Suboxone tablets, the Board believes that future long term revenue growth will be achieved by a combination of market growth, the differentiated product proposition of Suboxone Film (supported by its robust intellectual property estate and the Indivior Group’s strong stakeholder relationships), the incremental commercialisation of the Indivior Group’s product candidates and entry into new geographic markets. The board also believes that future revenue growth could be enhanced through targeted business development opportunities.

The Indivior Group also has a strong cash flow profile, with free cash flow (calculated as cash flows from operating activities less net cash flows from the purchase and disposal of property, plant and equipment, and intangible assets) of \$788 million, \$863 million and \$690 million, respectively, in 2013, 2012 and 2011. This provides flexibility to allocate capital towards new research projects, for business development activities such as in-licensing and acquisitions and to return capital to Shareholders. The Indivior Group’s current intention is to recommend a dividend for the 2015 financial year equivalent to 40% of net income after tax, having regard to Indivior’s liquidity needs and resources required for growth and potential acquisitions in line with its growth strategy. Please refer to paragraph 16 of this Part VI (*Information on the Indivior Group and its Industry*) for further details.

### ***Highly experienced management team***

The Indivior Group's management team has over 60 years' cumulative experience in leading the Indivior Group's business:

- (A) Shaun Thaxter, Chief Executive Officer, has over 15 years' experience in the pharmaceutical sector and has led the development of a bespoke, patient-focused model and inclusive culture within the Indivior Group;
- (B) Christian Heidebreder, Chief Scientific Officer, is a leading authority on the development of addiction treatments;
- (C) Chris Chapleo, Clinical and Scientific Affairs Director, has been involved in buprenorphine research since the 1980s and was the Indivior Group's Principal Investigator for the Cooperative Research and Development Agreement with NIDA to develop buprenorphine products for the treatment of opioid dependence; and
- (D) Rolley E. Johnson, Vice President, Treatment and Health Policy, was the lead or collaborative investigator for numerous clinical studies during his 17-year tenure at NIDA's Intramural Research programme and his 12 years at The Johns Hopkins School of Medicine, including the first pivotal clinical trial and supporting studies leading to FDA approval of buprenorphine for the treatment of opioid dependence.

The management team has built a global organisation of nearly 700 individuals, and the Board believes that the culture of the Indivior Group contributes to its ability to retain, develop and recruit high-performing talent while serving as the foundation for current and future growth.

In addition, Howard H. Pien, Chairman of the Board, has extensive experience as a senior executive in the pharmaceutical industry, including as chairman and CEO of Medarex and president and CEO of Chiron Corporation. He also serves on the boards of Sage Therapeutics, Juno Therapeutics, Vanda Pharmaceuticals, Ikaria and Immunogen.

### ***Unique company culture which helps to inspire outstanding performance***

The Board believes that the Indivior Group's culture is a powerful driver of success and that it displays many of the strengths associated with the RB Group's culture, such as entrepreneurship, team spirit and commitment, each executed with a high level of energy within a business mindset of strong financial discipline.

The Indivior Group's purpose is to pioneer life-transforming treatments for patients suffering from addiction and its co-morbidities. To enable this, the Indivior Group has a set of "Guiding Principles" which the Board believes has successfully guided decision making and set the blueprint for the Indivior Group's operations since the launch of the US business in 2003. These Guiding Principles are:

- (A) Focus on patient needs to drive decisions;
- (B) Believe that people's actions are well-intended;
- (C) Seek the wisdom of the team;
- (D) See it, own it, make it happen;
- (E) Care enough to coach; and
- (F) Demonstrate honesty and integrity at all times.

The Indivior Group has successfully created a disease space development capability which leverages its patient-focused model, which has resulted in the expansion of the number of patients in treatment in most of the countries in which it operates. Market development, driven

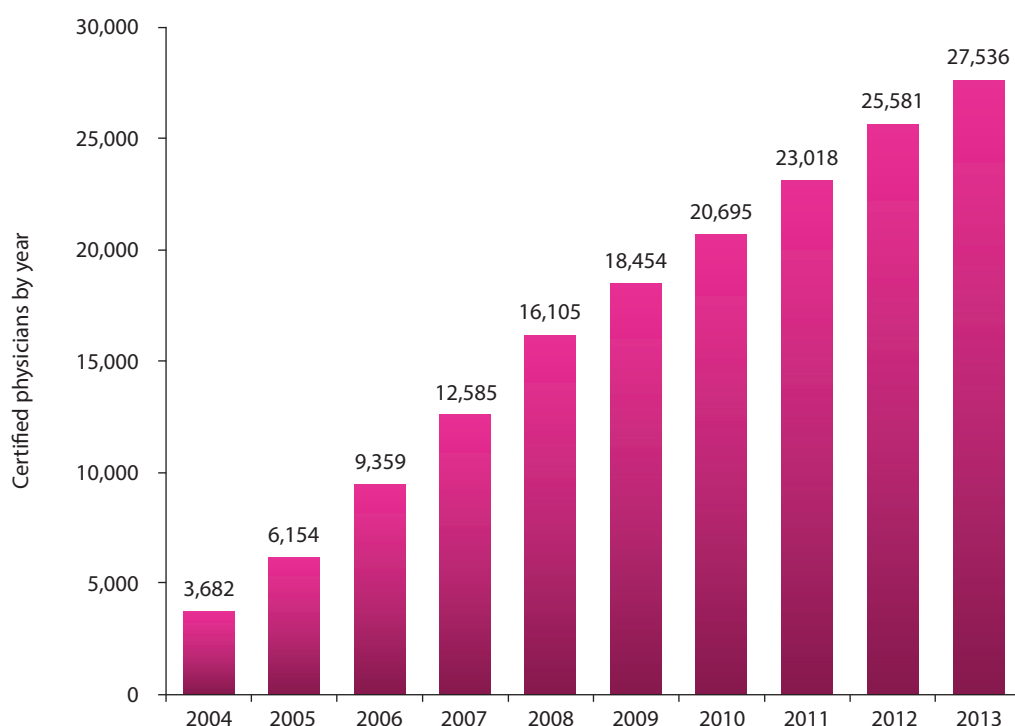
by the Indivior Group's bespoke culture, is considered by the Board to be a core strength of the Indivior Group.

## 6. Strategy

The key elements of the Indivior Group's strategy are as follows:

### ***Continue to grow the opioid dependence market and maintain a leadership position***

The Indivior Group has a track record of pioneering and expanding access to treatment for opioid-dependence. By driving increased awareness of the disease space, the Indivior Group has encouraged an expansion in the number of physicians certified under DATA 2000 to treat opioid dependence from just over 3,600 in 2004 to over 27,000 at the end of 2013, driving the delivery of treatment to millions of patients and contributing to double-digit market growth over the past 10 years.



Source: NTIS DEA Certification List

The Indivior Group will seek to further build on this approach to increase market penetration in the US beyond the estimated 20% of the US opioid-dependent population being treated with buprenorphine, in order to reduce the estimated \$55 billion societal cost associated with opioid misuse.<sup>17</sup>

The Indivior Group will strive to maintain its market-leading position in developing physician- and patient-preferred formulations that improve the treatment of opioid dependence. For example, the Indivior Group is in the process of developing (i) a monthly subcutaneous buprenorphine depot product that releases buprenorphine over a minimum of 28 days by diffusion, (ii) a swallowable capsule with abuse deterrent potential, and (iii) a higher dose Suboxone Tablet for distribution in the EU. For more information on these product candidates, please refer to paragraph 9 of this Part VI (*Information on the Indivior Group and its Industry*).

### ***Expand into adjacencies aligned with the Indivior Group's core competencies***

The Indivior Group will seek to capitalise on its existing expertise in neuroscience to realise its mission of ensuring that all patients in its target markets have unrestricted access to high-quality treatments for the chronic relapsing conditions and co-morbidities of addiction. The

<sup>17</sup> American Society of Addiction Medicine

Indivior Group seeks to do so by extending its business to new indications in addiction and immediately adjacent central nervous system therapeutic areas. In addition to extension candidates for its opioid dependence treatments, the Indivior Group's current pipeline includes expansion into the treatment of alcohol addiction, opioid overdose, cocaine intoxication and the co-morbidity of schizophrenia. For more information on these product candidates, please refer to paragraph 9 of this Part VI (*Information on the Indivior Group and its Industry*). These adjacencies represent a significant global growth opportunity which the Board believes the Indivior Group is well placed to capitalise on, based on management's significant experience in identifying areas of unmet medical needs and expertise in developing appropriate therapies.

### ***Capitalise on international growth opportunities***

There are an estimated 10 million opioid-dependent individuals in the countries in which the Indivior Group has a commercial presence, only 30% of whom are currently receiving treatment. Geographic expansion of the Indivior Group's footprint to countries currently underserved by existing therapies and treatment options brings a further 10 million opioid-dependent individuals within the Indivior Group's commercial reach. Expansion of the Indivior Group's business to the treatment of alcohol and psychostimulant (e.g. cocaine) addiction in all markets offers an opportunity to access an estimated total of 136 million potential patients, illustrating significant international growth opportunities for the Indivior Group.

### ***Growth through targeted and disciplined acquisitions***

The Indivior Group will seek to leverage its cash flow and balance sheet flexibility for the acquisition of assets that enable the fulfilment of its vision. Its focus will be on capitalising on existing commercialisation capability and scientific expertise. Specifically, the Indivior Group will seek to target underserved disease spaces that require long-held experience of the regulatory framework, the ability to create public awareness and to define a market, and a sales force with an ability to achieve physician access. The Indivior Group will seek to focus on the areas of addiction and on specialised disease areas which complement the Indivior Group's existing expertise in neuroscience. The Indivior Group's two most recent transactions illustrate this strategy:

On 10 February 2014, the Indivior Group entered into an agreement with AntiOp, Inc. to co-develop a naloxone nasal spray to aid in the reversal of opioid overdose with the option to acquire all rights to the product upon receipt of regulatory and marketing approval. The product has the potential to be the first of its kind to treat overdose from opioid prescription analgesics and heroin – a growing epidemic across the globe.

On 14 May 2014, the Indivior Group entered into an exclusive worldwide licensing agreement with XenoPort, Inc. for the development and commercialisation of a clinical-stage oral product candidate called arbaclofen placarbil. Arbaclofen placarbil is a new patent-protected chemical entity that the Indivior Group intends to advance into a Phase IIB proof-of-concept study for the treatment of alcohol use disorder – a condition estimated to affect approximately 122 million people worldwide.

## **7. History and development of the Indivior Group**

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 US 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 1964, RB (previously known as Reckitt & Colman until 1999) assumed full control from former partners over a research programme to produce OTC analgesics and made, in 1966, the breakthrough discovery of buprenorphine. It was assumed that buprenorphine would have a therapeutic application as an analgesic of low abuse potential. RB launched injectable

buprenorphine for severe pain relief in the UK 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.

In 1994, RB established the buprenorphine Business Group, to which the Indivior Group can trace its history. The buprenorphine Business Group, in partnership with NIDA, a US government agency which jointly funded the programme, focused on developing buprenorphine for the treatment of opioid dependence. Subutex Tablet, the Indivior Group's first product for the treatment of opioid dependence, was developed as a result and, in 1995, France became the first country to approve Subutex Tablet for the treatment of opioid dependence in general medical practice.

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. By the end of that year, Subutex Tablet was prescribed to an estimated 25,000 patients in France. Shortly thereafter, Subutex Tablet was approved in further EU countries. Suboxone Tablet was approved across the EU by the EMA in September 2006. In the EU, Suboxone Tablet is protected by data exclusivity until September 2016.

The enactment of DATA 2000 was a significant development in the history of addiction treatment in the US. Under the provisions of that Act, 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 their 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.

The Indivior Group launched Subutex Tablet and Suboxone Tablet in the US in 2003, following FDA approval in October 2002. In August 2010, the FDA approved Suboxone Film, which succeeded in capturing 69% of the US market for buprenorphine-based opioid dependence treatment by May 2013, based on volume of prescribed milligrams.

In the US, between October 2009 and July 2011, four 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 US in September 2011.

In addition two market participants launched generic Suboxone tablets in the US in March 2013 and one launched a branded Suboxone Tablet in September 2013. Despite the launch of these generic formulations and branded competition, Suboxone Film has been able to maintain a share of 60% of the buprenorphine-based opioid dependence treatment market (by mg volume) over time. A third generic version of Suboxone Tablet launched in August 2014 and a fourth was approved by the FDA in September 2014 (but has yet to launch), and in November 2014, a branded buprenorphine and naloxone film entered the market.

The Indivior Group announced that it was discontinuing distribution of Suboxone Tablet in the US market in September 2012 owing to paediatric 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 the only buprenorphine and naloxone-based product approved for use in this phase of treatment.

In the EU, generic versions of Subutex Tablet have been available for more than six years; but the Indivior Group's branded Subutex Tablet currently maintains a market share above 55% (by mg volume) of the mono-buprenorphine market, giving the Indivior Group a total market share (mono-buprenorphine and buprenorphine/naloxone) of above 70%.

## **8. Products of the Indivior Group**

The Indivior Group currently markets and promotes Suboxone Film, Suboxone Tablet and Subutex Tablet, each buprenorphine-based treatments for opioid dependence recognised by several health authorities around the world as vital treatment options to address the growing public health concern for a traditionally stigmatised population of opioid-dependent patients. The Indivior Group also sells two legacy products: Temgesic sublingual tablets and injections outside the US for the treatment of moderate to severe pain, as well as Buprenex injection in the US for the relief of moderate to severe pain; although these products account for less than 4% of Indivior Group total net revenues.

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 UK and subsequently around the world both as an injection and as a sublingual tablet, although it was marketed in the US 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 US and launched in April 2003, but were discontinued from sale in the US market in September 2011 due to market share erosion and their potential for abuse in comparison with buprenorphine-naloxone formulations. The Indivior Group currently markets Subutex Tablet in 24 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 administered parenterally. When administered sublingually, naloxone is poorly absorbed and has no clinically significant effect.

Suboxone Tablet has been designed to discourage intravenous abuse of the tablet formulation in patients dependent on full opioid agonists. 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 US by the FDA in October 2002 as an orphan drug for maintenance treatment of opioid dependence. In the US, Suboxone Tablet lost orphan drug exclusivity in October 2009.

Suboxone Tablet is approved in 48 countries worldwide and marketed in 41 countries, with marketing approval pending in additional countries. The Indivior Group currently expects to receive approval for Suboxone Tablet in China in 2018.

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

Suboxone Film initially launched in the US in 2010 and is currently marketed in the US, Australia and Malaysia. It is the only product currently approved by the FDA for the treatment of opioid dependence pursuant to DATA 2000 in both the Induction and the Maintenance Phases of

treatment. 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, utilising 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 US 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 US in August 2012 and in Australia in May 2014. Suboxone Film was also approved in the US in April 2014 for use in the Induction Phase of buprenorphine-based treatment of opioid dependence.

The Indivior Group currently expects to receive approval for Suboxone Film in Canada and the EU in 2016 and in China in 2018.

### ***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. The Indivior Group distributes Temgesic in Algeria, Australia, Austria, Belgium, Denmark, Finland, France, Germany, Hong Kong, Italy, Luxembourg, Morocco, the Netherlands, New Zealand, Norway, South Africa, Spain, Sweden, Switzerland, Taiwan and the UK. The Indivior Group has appointed MSD Latin America Services S. de R.L. as its exclusive distributor of Temgesic in Ecuador and Mexico.

### ***Buprenex***

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 US.

## **9. Research and development**

Chronic addictive behaviours are characterised 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 behaviours, 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 behaviours 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).

The Indivior Group invests 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 minimise 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.

The Indivior Group's research and development activities are focused on four clusters of projects 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.

## 9.1 ***Expanding the range of treatment options for opioid dependence***

### **Suboxone Film for the EU**

The Indivior Group is developing Suboxone Film for the EU. The US formulation of Suboxone Film was developed with a product quality reference target that met US FDA shelf-life specifications. The shelf-life specifications in the EU are more restrictive with respect to buprenorphine assay, naloxone assay and naloxone-related impurities. The Indivior Group has 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 and obtaining regulatory approval in the EU within the next 3 years.

### **Higher dose Suboxone Tablet for the EU**

The Indivior Group is developing Suboxone Tablet in higher dosages of buprenorphine using existing technology in order to extend the available dosage range in the EU. The new tablets, which will be packaged in child-resistant packaging, will use existing ingredients but will contain higher dosages to provide additional forms for therapeutic dosing. The Indivior Group is currently engaged in two randomised, single-dose, two-way crossover open label bio-equivalence studies that are comparing, under fasted conditions, tablets containing 12mg buprenorphine and 3mg naloxone, and 16mg buprenorphine and 4mg naloxone. These doses are being evaluated in order to offer improved convenience of targeted therapeutic dosing to patients.

### **RBP-6000 – monthly depot buprenorphine**

RBP-6000 is a buprenorphine depot using the Atrigel® delivery system, which consists of a polymeric solution of a biodegradable poly (DL-lactide-co-glycolide) co-polymer, dissolved in N-methyl pyrrolidone (“NMP”), a water-miscible biocompatible solvent. Upon subcutaneous injection, NMP interacts with body fluids, which replace the NMP as it diffuses out of the polymer matrix. This precipitates the polymer, trapping the drug inside and forming an amorphous solid implant in situ. The solid implant releases buprenorphine over a minimum of 28 days by diffusion from the polymer as the polymer biodegrades. RBP-6000 is filled into a syringe and terminally sterilised.

Clinical studies with other active ingredients have demonstrated that the Atrigel® delivery system 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.

Two Phase II clinical trials with RBP-6000 have now 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, which are expected to begin in the first quarter of 2015. 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 paediatric exposure.

The Indivior Group currently plans to launch the product in the US in 2017 and in the EU in 2018, if approved.

### **RBP-6300 – swallowable capsule with abuse deterrent potential**

Sublingual delivery of Suboxone was originally utilised to bypass the extensive first pass metabolism of buprenorphine in the stomach and liver. The Indivior Group is developing buprenorphine hemiadipate HCl, an ester of buprenorphine and adipic acid, as a pro-

drug to improve the oral bio-availability of buprenorphine for the treatment of opioid dependence. This new oral capsule also provides a naloxone-free formulation that acts as a physical barrier (cutting or pulverising) to avoid dose-dumping and dissolution. RBP-Capsugel® aims to achieve physical abuse deterrence by using a gel-like formulation that prevents extraction of the drug for abuse. RBP-Capsugel® is currently at the technical proof-of-concept stage and the Indivior Group currently expects US and EU approval in 2018 (assuming successful completion of trials).

## 9.2 ***Opening access to rescue medications***

### **Intranasal naloxone formulation treating opioid overdose**

The Indivior Group entered into an agreement on 10 February 2014 with AntiOp, Inc., a US-based private company that has developed a novel formulation of naloxone as a nasal spray with a data and regulatory package to support the filing of an NDA in 2015. This nasal formulation would be delivered through a low-cost pre-filled drug and nasal device combination that is inserted into the nose of an overdose victim by a layperson and that would deliver a clinically effective dose of naloxone.

The development programme to achieve FDA approval will require two additional studies that have been agreed upon with the FDA. The Indivior Group is currently assessing study needs to support a launch in Europe, which it currently expects to achieve in 2016 or 2017 (assuming FDA approval by the end of 2015).

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

RBP-8000 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.<sup>18</sup> RBP-8000 is a biological product derived from characterised 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. The Board believes that RBP-8000 has the potential to transform the management of cocaine intoxication in emergency departments, including faster symptom resolution (eliminating cocaine in five to ten minutes) and shorter emergency department visit times, fewer hospitalisations, possibly fewer deaths and overall reduced cost to the medical care system. The Board believes these changes would not only translate into a major public health benefit, but to an improvement in the medical care system as a whole.

The Indivior Group was granted a Breakthrough Therapy Designation by the FDA in the last quarter of 2014 and currently expects to launch the product in the US in 2019.

## 9.3 ***Addressing unmet needs in the treatment of AUD***

Since the approval of disulfiram by the FDA 1951, three additional treatments have been approved for the treatment of alcohol dependence: oral naltrexone (1994), acamprostate (2004) and intramuscular naltrexone (2006)<sup>19</sup>. Recently, nalmefene has also been approved in the EU by the EMA (2013) under an “on demand” treatment schedule.

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

18 Brim RL, Nance MR, Youngstrom DW, et al. A thermally stable form of bacterial cocaine esterase: A potential therapeutic agent for treatment of cocaine abuse. *Mol Pharmacol*. 2010;77:593-600.

19 Muzyk AJ, Rivelli SK, Gagliardi JP. Defining the role of baclofen for the treatment of alcohol dependence. *CNS Drugs*. 2012;26(1):69-78.

spinal cord lesions. Baclofen is an agonist at the B sub-unit of the gaba-aminobutyric acid receptor. Gaba-aminobutyric acid receptors are highly expressed in the limbic system, suggesting a major role in regulating emotional behaviour. 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 available evidence also suggests a potentially unique impact of baclofen for the treatment of alcohol dependence since it has been safely used in patients with co-morbid cirrhosis of the liver, a disease that is not uncommon in alcohol-dependent patients.

The originality of the observational evidence gathered in France over the past few years is that patients with alcohol dependence resistant to usual treatments were treated, for the first time, with escalating doses of baclofen and no superior dose limit. Alcohol consumption (in grams) and craving for alcohol were assessed before treatment and at 3, 6, 12 and 24 months. The outcome measure was the consumption of alcohol, rated according to WHO criteria for risk of chronic harm. While all patients were rated “at high risk” at baseline, approximately half were rated “at low risk” at 3, 6, 12 and 24 months. The average maximal dose of baclofen taken was 150mg per day, and significant relationships were found between the amount in grams of alcohol taken before treatment and the maximal dose of baclofen required. Based on these data, the French regulatory agency (ANSM) granted a temporary use recommendation (“**RTU**”) to baclofen for the treatment of AUD in March 2014. The RTU was granted pending the results of two ongoing clinical trials that are aiming to secure access to baclofen for the treatment of AUD in France. Under the RTU, baclofen is now the subject of a monitoring protocol to collect efficacy and safety data. These are collected via an electronic portal by doctors who prescribe baclofen under the RTU. According to data from the portal, as at April 2014, 1,362 patients had been prescribed baclofen under the RTU for the treatment of AUD, and only five had to stop treatment because of intolerance. In the meantime a decree establishing the reimbursement of baclofen in the treatment of AUD was published in the Journal Officiel in June 2014.

#### **Arbaclofen placarbil – a novel transported prodrug of R-baclofen**

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. The short plasma half-life of baclofen following oral administration contributes to the fact that the drug must be administered three or four times per day to maintain therapeutic levels, resulting in fluctuations of circulating plasma drug levels. Frequent dosing is inconvenient and can lead to significant non-compliance. Eliminating high peaks while maintaining a greater average blood baclofen concentration might minimise side effects. The optimal exposure to R-baclofen for the treatment of alcohol dependence would be a stable therapeutic plasma concentration. This is difficult to achieve with oral racemic baclofen, since absorption of the drug is limited to the upper small intestine. Attempts to develop a sustained release formulation of the drug have not been successful, due to the lack of an absorption pathway in the large intestine.

On 14 May 2014, the Indivior Group entered into a licence agreement pursuant to which it has been granted exclusive worldwide rights (including patent rights relating to compositions, dosage and process for manufacturing) for the development and commercialisation 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. The prodrug is absorbed throughout the intestine by active nutrient transporter monocarboxylate transporter 1 (MCT-1) and also by passive diffusion. Following oral administration, arbaclofen placarbil is efficiently converted to R-baclofen by non-specific carboxylesterases, primarily human carboxylesterase-2 (hCE-2) in gastrointestinal tissues. 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.

A detailed clinical development plan is currently being drafted to assess the clinical efficacy and safety of arbaclofen placarbil for the treatment of alcohol use disorders and the Indivior Group is currently targeting US and EU approval in 2020.

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

Epidemiological and clinical studies<sup>20</sup> 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 recognise a multidisciplinary and holistic approach to the treatment of patients suffering from substance use disorders.

Schizophrenia is a chronic disorder characterised 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, disorganised speech and behaviour); 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)<sup>21</sup>. 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.

#### **RBP-7000 – monthly risperidone depot**

RBP-7000 is a novel sustained-release product using the Atrigel® delivery system for the subcutaneous administration of risperidone once every 28 days for the long-term treatment of schizophrenia.<sup>22 23</sup> 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 pivotal Phase III study to assess its efficacy, safety and tolerability as a treatment for subjects with acute schizophrenia and the Indivior Group currently expects US approval in 2017.

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20 Kessler RC, Chiu WT, Demler O, Merikangas KR, Walters EE. Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry*. 2005; 62(6):617–627.

21 Diagnostic and Statistical Manual of Mental Disorders, fourth edition.

22 Gomeni R., Heidbreder C, Fudala PJ, Nasser AF (2013) A model-based approach to characterise the population pharmacokinetics and the relationship between the pharmacokinetic and safety profiles of RBP-7000, a new, long-acting, sustained-release formulation of risperidone. *J. Clin. Pharmacol.*, 53(10):1010-1019.

23 Laffont CM, Gomeni R, Heidbreder C, Fudala PJ, Nasser AF (2014) Population pharmacokinetics and prediction of dopamine D2 receptor occupancy after multiple doses of RBP-7000, a new sustained-release formulation of risperidone, in schizophrenia patients on stable oral risperidone treatment. *Clin. Pharmacokinetics*, Electronic Publication ahead of print.

## 9.5 **Summary of clinical trials in support of new products under development**

For details regarding the process for obtaining regulatory approval for drug products, including clinical trials, please refer to Part VII (*Regulatory Overview*) of this Prospectus.

<u>Study #</u>	<u>Description</u>	<u>Status</u>
<b>RBP-6000</b>		
RB-US-10-0011	A single-dose, open-label study of depot buprenorphine in opioid-dependent individuals	Phase I
RB-US-11-0020	A multi-centre, open-label, single ascending-dose study to evaluate the safety, tolerability, and pharmacokinetics of depot buprenorphine in opioid-dependent individuals	Phase I
RB-US-12-0005	An open-label, multi-centre, multiple dose study of the safety, tolerability, pharmacokinetics, efficacy markers and opioid receptor availability of subcutaneous injections of depot buprenorphine in treatment seeking opioid-dependent subjects	Phase II
RB-US-13-0002	A multiple-dose study of blockade of subjective opioid effects, plasma levels and safety of subcutaneous injections of depot buprenorphine in subjects with opioid use disorder	Phase II
<b>RBP-6300</b>		
RB-UK-10-0014	An open-label, randomised, parallel group, multiple dose, steady-state pharmacokinetic/safety comparison study between oral RBP-6300 tablets compared to sublingual Suboxone Tablet in healthy male volunteers under a naltrexone block	Phase I
RB-UK-11-0017	A randomised, double-blind, double-dummy, active-drug-controlled, parallel-group, multicentre acceptability and safety study of the transfer from Subutex/Suboxone to RBP-6300 in opioid-dependent subjects	Phase II
RB-UK-11-0018	A randomised, double-blind, placebo-controlled, cross-over study of the effects of buprenorphine hemiadipate hydrochloride/naloxone hydrochloride dihydrate intravenous challenges in opioid dependent subjects stabilised on sublingual buprenorphine hydrochloride/naloxone hydrochloride dihydrate (Suboxone)	Phase II
RB-UK-12-0004	An open-label, three-way, randomised, cross-over study of the pharmacokinetics, safety and tolerability of two formulations of RBP-6300 10mg in healthy volunteers under a naltrexone block in the presence and absence of food	Phase II
<b>RBP-8000</b>		
RB-US-09-0004	A double-blind, randomised, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending doses of RBP-8000 in healthy male subjects	Phase I

<u>Study #</u>	<u>Description</u>	<u>Status</u>
RB-US-13-0004	A randomised, double-blind, placebo-controlled, dose of RBP-8000 following IV cocaine to evaluate the pharmacokinetics parameters of RBP-8000 and cocaine and to assess the effects of drug on cocaine-induced physiologic and behavioural effects in cocaine abusing subjects	Phase II
<b>RBP-7000</b>		
RB-US-09-0007	An open-label, single centre, single dose, first in man study of the safety, tolerability and pharmacokinetic profile of RBP-7000	Phase I
RB-US-09-0008	An open-label, single centre, single ascending dose study of the safety, tolerability and pharmacokinetic profile of RBP-7000 60mg, 90mg and 120mg	Phase I
RB-US-09-0009	An open-label, multiple ascending dose with randomised subjects to receive a single dose of one of three dose levels	Phase II
RB-US-09-0010	A randomised, double-blind, placebo-controlled, multi-centre study to evaluate the efficacy, safety and tolerability of RBP-7000 (90mg and 120mg) as a treatment in subjects with acute schizophrenia over 8 weeks (2 subcutaneous doses)	Phase III

#### 9.6 **Research and development function**

The Indivior Group's research and development function, headed by Christian Heidbreder, has 141 personnel, and comprises the following sub-functions:

- (A) **Chemistry, Manufacturing and Controls**, including personnel based at the FCP responsible for overseeing the tablet formulation and individuals at the former QLT facility in Fort Collins, Colorado working on the Atrigel® delivery platform;
- (B) **Clinical**, responsible for ensuring that the clinical trials outsourced to third parties are implemented accurately and for performing data analysis on the results of studies;
- (C) **Regulatory**, tasked with ensuring all activity is within country-specific guidelines;
- (D) **Global Project Management**, which operates across all locations to ensure projects meet deadlines and deliver according to budget; and
- (E) **Health Economics**, which considers the cost-effectiveness and positioning of a new product and seeks to facilitate seamless launches shortly after approval.

The Indivior Group's research and development function endeavours to conduct all Phase I clinical trials internally. During Phase II and Phase III of clinical trials, because the formulation of the product must be finalised and the scalability of production proven, the Indivior Group engages contractors with the relevant capabilities. During these Phases, therefore, the number of participants in, and consequently the expenses related to, the project increases significantly. The increase in the Indivior Group's research and development expenses from \$35 million in 2011 to \$76 million in 2013 is attributable to a number of projects reaching Phases II and III of clinical trials. Please refer to paragraph 3.2 of Part X (*Operating and Financial Review*) of this Prospectus for further details of research and development expenses.

## **10. Intellectual property**

The Indivior Group owns or licenses a number of patents and patent rights in the US and other countries covering or relating to certain of the products and pipeline products mentioned above, and has created brand names and also registered trade marks where appropriate for its products. Generally, and where possible, the Indivior Group relies upon patent protection to ensure market exclusivity for the life of the patent. The Indivior Group considers the overall protection of its patents, trade marks and licence rights to be of material value and acts to protect these rights from infringement or misuse where appropriate.

The Indivior Group's business is materially dependent upon a group of owned and in-licensed US and non-US patents relating to Suboxone Film. The Indivior Group owns the formulation patent that is specifically directed to Suboxone Film, which expires in the US in March 2030.

The majority of an innovative product's commercial value is usually realised 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 US 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 trade mark 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 US, 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 paediatric 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.

The Indivior Group estimates the likely market exclusivity period for each of its branded products on a case-by-case basis. It is not possible to predict with certainty the length of market exclusivity for any of the Indivior Group's 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 the Indivior Group currently estimates or that the exclusivity will be limited to the estimate.

On 14 May 2014, the Indivior Group entered into a licence agreement with XenoPort, Inc. pursuant to which it has been granted exclusive worldwide rights (including certain patent rights) for the development and commercialisation of XenoPort's clinical-stage oral product candidate arbaclofen placarbil for all indications. Arbaclofen placarbil is a patent-protected new chemical entity that the Indivior Group intends to advance into a Phase IIB proof-of-concept study for the treatment of alcohol use disorders.

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

The Indivior Group has access to the following key patent protection in respect of Suboxone Film:

<i>Number</i>	<i>Held by</i>	<i>Granted geographic scope</i>	<i>Expiry</i>	<i>Description</i>
US 8,017,150 (and foreign equivalents)	MSRX and used by the Indivior Group under exclusive licence	US, Australia, Canada, 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 licence	US, Australia, Canada, China, India, Japan	2024	A drug delivery composition having a uniform content of the drug
US 8,475,832 (and foreign equivalents)	Indivior Group	US, Mexico, South Africa	2030	A film product which comprises a combination of buprenorphine and naloxone

In addition, the Indivior Group also owns, or is licensed, patent rights (i.e. granted patents or pending applications) in certain key jurisdictions in respect of certain other products and pipeline products of the Indivior Group:

- (A) Suboxone Film for the EU with enhanced shelf life (patent applications exclusively licensed to RBP);
- (B) RBP-6000 – monthly depot buprenorphine (patent applications owned by RBP; applications pending with expiry, where granted, up to 2031);
- (C) RBP-6300 – swallowable capsule with abuse deterrent potential (patent coverage up to 2028 in the US (and 2027 outside the US));
- (D) Naloxone intranasal spray (patent applications pending with expiry up to 2034);
- (E) RBP-7000 – monthly risperidone depot (patent applications licensed to RBP; applications pending with expiry, where granted, up to 2028);
- (F) RBP-8000 – cocaine esterase for treating cocaine intoxication (patent coverage up to 2029 in the US (and 2027 outside the US)); and
- (G) arbaclofen placarbil – a novel transported prodrug of R-baclofen (patent coverage up to 2025 in the US (and 2024 outside the US); patent applications exclusively licensed to RBP; applications pending with expiry, where granted, up to 2030).

Furthermore, and while not a patent right, the Indivior Group also has data exclusivity for Suboxone Tablet in the EU.

The Indivior Group is involved in ongoing litigation relating to its intellectual property portfolio. For more information, please refer to paragraph 19 of Part XV (*Additional Information*) of this Prospectus.

## **11. Sales, marketing and distribution**

The extent of the Indivior Group's focus on sales, marketing and distribution is demonstrated by the fact that selling and distribution expenses constitute the largest category of its expenses, accounting for 47% of its total costs and expenses in 2013 (2012: 44%; 2011: 42%). Please refer to paragraphs 6.3 and 7 of Part X (*Operating and Financial Review*) of this Prospectus for further details of selling and distribution expenses.

### ***Sales and marketing***

The Indivior Group's current commercial activity in the US is entirely dedicated to Suboxone Film. The Indivior Group's sales organisation in the US comprises over 200 trained and experienced pharmaceutical professionals many of whom also have clinical backgrounds. This includes 170 clinical liaisons (65% of whom have over five years' experience with the Indivior Group) 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. The Board believes 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 specialised treatment centres. These activities are supported by dedicated and experienced professionals in the Indivior Group's managed care group who create access to treatment for patients by partnering with US commercial payers and federal and local governmental payers.

In the rest of the world, the Indivior Group's 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.

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

In each of the Indivior Group's markets, the Indivior Group's 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 maximise market access, and to deliver the Indivior Group's market growth commitments.

### ***Distribution***

At present, the Indivior Group distributes its products globally using contracted third-party distribution services. In the EU, the Indivior Group utilises 12 distribution partners across 31 countries. In North America, the Indivior Group uses two distribution partners, one in the US and one in Canada. In Developing Markets, the Indivior Group uses nine distribution partners across 11 countries.

## **12. Manufacturing**

### ***Active Pharmaceutical Ingredients***

The active pharmaceutical ingredients used in the Indivior Group's products are manufactured at the FCP located in Hull, UK. The FCP is currently owned by RB Health, a member of the RB Group. The process of transferring ownership of the equipment within the FCP to the Indivior Group is underway and is scheduled to complete between Q2 2015 and Q2 2016. In relation to the FCP, RB Pharmaceuticals Limited will enter into a long-term lease with RB Health for the building and the surrounding land. The employees working at the FCP will also transfer to the Indivior Group.

The FCP manufactures the buprenorphine 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 the Indivior Group's current buprenorphine HCl requirements with approximately 35% available capacity remaining. The FCP utilises caustic materials as part of the manufacturing process, as well as a thermal reaction; however, these aspects of the process are tightly controlled and, the Board believes, represent low risk to the surrounding environment. Upon transition of FCP control to the Indivior Group, the Indivior Group will produce buprenorphine HCl for use in the manufacture of Subutex Tablet, Suboxone Tablet, Suboxone Film, Temgesic and Buprenex. The Indivior Group is currently engaged in validating an alternate source of buprenorphine HCl supply for Suboxone Film.

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 the Indivior Group's 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, the Indivior Group will enter into a seven year supply agreement with RB Health, whereby RB Health will assume responsibility for the formulation, compressing, and finished good packaging of Subutex Tablet and Suboxone Tablet, as well as the formulation, filling, and terminal sterilisation of Temgesic and Buprenex.

### ***Suboxone Film***

Suboxone Film is manufactured under an exclusive licence 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 the Indivior Group's 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 is currently approved at one facility and the Indivior Group is executing a project plan to enable both manufacture and primary packaging at the second facility. The second facility is currently approved for primary packaging of the majority of US Suboxone Film volume.

Serialisation and secondary packaging of global Suboxone Film output is performed by Sharp Packaging Solutions, located in Allentown, Pennsylvania, under a supply agreement that expires in December 2016. As part of the secondary packaging process Sharp prints and aggregates unique serialisation codes, as provided by the Indivior Group's serialisation vendor COVECTRA, to every level of packaging from each individual Suboxone Film strip (primary packaging) to the pallet.

All finished Suboxone Film product from Sharp is shipped to the Indivior Group's US third-party distribution service provider, Integrated Commercialization Solutions, located in Brooks, Kentucky, and either distributed for sale within the US or exported to other markets where it is approved for sale.

### **13. Employees**

As at 31 October 2014, the Indivior Group employed 709 people worldwide. Of these, 425 were located in North America and 284 were located in the rest of the world. Of the Indivior Group's 709 employees, approximately 393 were employed in commercial sales and marketing positions; 126 were employed full time in research and development, clinical and regulatory positions; 86 were employed in general management and other support positions; 76 were employed in medical affairs positions; and 28 were employed in supply and quality assurance positions.

Certain of the Indivior Group's employees are represented by unions or works councils. The Board believes that the Indivior Group has a good relationship with its employees and with the unions and works councils that represent certain employees.

### **14. Insurance**

The Indivior Group has insurance policies that provide coverage for activities related to the Indivior Group's operations, including business interruption, product liability and professional indemnity insurance.

### **15. Principal investments**

In 2014, the Indivior Group has made the following initial licensing payments:

- (A) \$20 million upfront payment and \$5 million for existing inventory, in relation to the exclusive worldwide licensing agreement with XenoPort, Inc. for the development and commercialisation of arbaclofen placarbil, a product candidate for the treatment of alcohol use disorder; and
- (B) \$4 million upfront payment in relation to the agreement with AntiOp, Inc. to co-develop a naloxone nasal spray to aid in the reversal of opioid overdose.

Each licensing arrangement has further gated payments based on research and development and commercial success criteria in keeping with industry practice.

### **16. Dividend policy**

The Board intends to recommend a dividend for the 2015 financial year equivalent to 40% of net income after tax. The dividend will be split, in proportions to be determined, between an interim dividend, payable in October 2015, and the balance, to be paid (subject to approval at the Company's first annual general meeting) in June 2016. The intention of this dividend policy is to limit possible dilution of dividend income received by Shareholders in the short term as a result of the Demerger. The Board will review its dividend policy for the financial years after 2015 having regard to the Company's capital allocation strategy, financial position and future growth potential, including the strong product pipeline.

## **17. Recent developments and prospects**

Please refer to paragraphs 4 and 5 of Part X (*Operating and Financial Review*) of this Prospectus for details of the Indivior Group's recent developments and prospects.

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

After the Demerger Effective Time, RB and Indivior will operate as separate companies and neither company will have a shareholding in the other.

Pursuant to the terms of the Transitional Services Agreement, Reckitt Benckiser plc (on behalf of the RB Group) has agreed to provide RBP Global Holdings Limited (on behalf of the Indivior Group) with certain services which will be provided on commercial terms and on an arms' length basis. These services include (i) the continued provision by Reckitt Benckiser plc 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. Please refer to paragraph 21 of Part XV (*Additional Information*) of this Prospectus for further information.

In addition to the Transitional Services Agreement, entities within the RB Group and the Indivior Group intend to enter into a long-term manufacturing agreement under which the RB Group will manufacture tablet and injectable products on behalf of the Indivior Group and a long-term lease whereby the Indivior Group will lease the FCP from the RB Group. Please refer to paragraph 21 of Part XV (*Additional Information*) of this Prospectus for further information on both these agreements and related ancillary agreements.

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 the Indivior Group's products in jurisdictions where the Indivior Group does not yet have a commercial presence will continue until such time as they are terminated in accordance with the terms of the Transitional Services Agreement.

Notwithstanding the foregoing, Indivior has the ability to carry on an independent business as its main activity, strategic control over the commercialisation of its products and its ability to earn revenue and freedom to implement its business strategy.

## PART VII

### REGULATORY OVERVIEW

The Indivior Group's activities are subject to a rigorous regulatory framework on a local and international level that conditions and affects the Indivior Group's 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 the Indivior Group's business and the reimbursement schemes applicable to its products in the key markets in which the Indivior Group operates.

#### **1. United States**

##### **1.1 Overview**

Pharmaceutical companies operate in a highly regulated environment. In the US, the Indivior Group 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 CBP and state agencies such as boards of pharmacy. Applicable legal requirements govern to varying degrees the research, development, manufacturing, commercialisation and sale of the Indivior Group's 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.

##### **1.2 Food and Drug Administration**

The FDA's authority to regulate pharmaceuticals comes primarily from the FFDCA. In addition to reviewing NDAs for branded drugs and ANDAs 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 or fail to include required information.

In order to market and sell a new drug product in the US, 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 FDCA section 505(b)(2) for a drug product that has some differences from an already-approved drug product. A section 505(b)(2) NDA must demonstrate that the proposed product is safe and effective notwithstanding the differences from the approved drug product.

(A) *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 characterises 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 New Drug Application, 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 characterisation 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 ongoing 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 programmes are intended to obtain more information about the risks of harm, benefits and optimal use of the drug product by observing 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 US or outside the US, 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 minimise and manage the risks of harm to participants; and (iii) ongoing 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 paediatric 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 paediatric 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 significant 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 significant 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 US 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 approval process. For US fiscal year 2015, the user fee rate has been set at \$2,335,200 for an NDA and \$1,167,600 for an NDA not requiring clinical data, generally certain section 505(b)(2) NDAs. The FDA has committed to review and act upon new NDAs within six months for applications given priority review and ten months for standard review, with two additional months added to each of these time periods for new molecular entities.

#### (B) *ANDA process*

The path leading to FDA approval of an ANDA is very different from that of an NDA. By statute, the FDA waives the requirement for a drug manufacturer to 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. ANDAs 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, the US Congress passed into law the Generic Drug User Fee Act to address the FDA's backlog, which at the time was over 2,000 ANDAs. This legislation granted the FDA authority to collect, for the first time, user fees from generic drug manufacturers who submit ANDAs for review and approval, and the fees collected help the FDA fund the drug approval process. For US fiscal year 2015, the user fee rate is set at \$58,730 for an ANDA and \$29,370 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 anticipates that the review process timeframe will not begin to improve until US fiscal year 2015.

Aside from the backlog described above, the timing of FDA approval of ANDAs depends on other factors, including whether an ANDA holder has challenged any listed patents to 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 in paragraph 1.2(C) of this Part VII (*Regulatory Overview*).

(C) *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 the data in the 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 an 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 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 paediatric exclusivity if the RLD is studied for paediatric patients based on a written response from the FDA.

(D) *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 ensure 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 Programme") 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.

ANDAs 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.

(E) *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 and medical devices 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 ANDAs. 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 US, the FDA may issue an import alert to prevent shipments into 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 licences 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.

(F) *Reporting requirements*

Pharmaceutical manufacturers are subject to adverse event reporting requirements during clinical trials and following approval. To comply with these requirements, manufacturers must have robust procedures for surveillance, receipt, evaluation and reporting of adverse events.

(G) *Labelling and marketing*

For all pharmaceuticals sold in the US, 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 US 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.

### 1.3 ***Import and export requirements***

To import pharmaceuticals into the US, 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 US are subject to foreign countries’ import requirements and the exporting requirements of the FDA. For example, international sales of drugs manufactured in the US that are not approved by the FDA for use in the US 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 US and that the manufacturing facilities are in compliance with cGMP. To obtain this certificate, the drug manufacturer must apply to the FDA.

#### 1.4 ***Drug Enforcement Administration***

The DEA is the federal agency responsible for domestic 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. The Indivior Group 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 US to import finished dosage forms of controlled substances manufactured outside the US, 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 forms of controlled substances in the US often manufacture or have them manufactured in the US.

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.

#### 1.5 ***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 licence, 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 organisations authorised in DATA 2000 to sponsor such training, or by any other organisation 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 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.

#### 1.6 **Government benefit programmes**

Statutory and regulatory requirements for Medicaid, Medicare, Tricare and other government healthcare programmes govern provider reimbursement levels for government beneficiaries, including requiring that all pharmaceutical companies pay rebates to individual states based on a percentage of their net sales arising from Medicaid programme-reimbursed 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 programmes that impact the Indivior Group's business. For example, the Medicare Prescription Drug Improvement and Modernisation Act 2003 created a new out-patient prescription drug coverage programme 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 programme ("**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 programme.

In addition, the Affordable Care Act provides for major changes to the US healthcare system, which may transform the delivery and payment for healthcare services in the US. 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. Since much of the implementation is yet to take place, 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. The Indivior Group intends 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, the Board believes that the impact to the Indivior Group's 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 in the Medicaid Fee-For-Service Programme and Medicaid Managed Care plans. 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 Programme) to new entities.

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

The Indivior Group is subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the US, 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 programmes 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 programme, 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, the Indivior Group must report to the federal government information on financial payments made to physicians and certain healthcare institutions, and also on drug samples distributed. In addition, if the Indivior Group receives 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 programmes. These laws apply to hospitals, physicians and other potential purchasers of the Indivior Group's products and are potentially applicable to the Indivior Group as both a manufacturer and a supplier of products reimbursed by federal healthcare programmes. In addition, some states in the US have enacted compliance and reporting requirements that apply to drug manufacturers.

The Indivior Group must comply with the Foreign Corrupt Practices Act 1977 and similar worldwide anti-bribery laws in non-US jurisdictions, which generally prohibit companies and their intermediaries from making improper payments to non-US officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of the Indivior Group's customer relationships outside the US are with governmental entities and are therefore subject to such anti-bribery laws.

## **2. European Union**

### **2.1 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.

### **2.2 Clinical trials and marketing approval**

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and GCP. Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorisation from the competent authority and a positive opinion from an independent ethics committee.

After completion of the required clinical testing, a drug manufacturer must obtain a marketing authorisation 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 centralised procedure gives rise to marketing authorisations 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 authorisation 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 authorisation. The centralised procedure is compulsory for medicinal products that (i) are derived from biotechnology processes; (ii) contain a new active substance (not yet approved on 20 November 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. For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralised marketing authorisation to the EMA, as long as the CHMP agrees that (i) the medicine concerned contains a new active substance (not yet approved on 20 November 2005); (ii) the medicine is a significant therapeutic, scientific, or technical innovation; or (iii) its authorisation under the centralised procedure would be in the interest of public health.

For those medicinal products for which the centralised procedure is not available, the applicant must submit marketing authorisation applications to the national medicines regulators through one of three procedures: (i) a national procedure, which results in a marketing authorisation in a single EU member state; (ii) the decentralised 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 authorised in at least one other EU member state, and in which the EU member states are required to grant an authorisation recognising the existing authorisation 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 decentralised procedure will be triggered.

Marketing authorisation 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 authorisation of a reference product for which regulatory data exclusivity has expired. If a marketing authorisation is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity during which generic marketing authorisation 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.

In the EU, companies developing a new medicinal product must agree a Paediatric Investigation Plan (“**PIP**”) with the EMA and must conduct paediatric 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 authorisation application for the product must include the results of paediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the paediatric clinical trials must be completed at a later date. Products that are granted a marketing authorisation on the basis of the paediatric 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 paediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

### 2.3 ***Pharmacovigilance and risk management***

The holder of a marketing authorisation 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 authorisation applications must include a risk management plan (“**RMP**”) describing the risk management system that the company will put in place and documenting measures to prevent or minimise the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorisation. Such risk-minimisation measures or post-authorisation obligations may include additional safety monitoring, more frequent submission of PSURs or the conduct of additional clinical trials or post-authorisation safety studies.

### 2.4 ***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.

### 2.5 ***Manufacturing***

Medicinal products may only be manufactured in the EU, or imported into the EU from another country, by the holder of a manufacturing authorisation 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, 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 UK, 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 licence 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.

## 2.6 **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 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.

## 3. **Rest of the world**

### 3.1 **Current markets**

After the US and the EU, the Indivior Group's largest markets are Canada and Australia, where it markets its products pursuant to standards set by Health Canada and the Therapeutic Goods Administration respectively. The Indivior Group also markets its 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 US and the EU, although the precise requirements may vary from country to country.

The Indivior Group also markets its 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 authorisation from large, developed markets (such as the US) before they will initiate or complete their review. Some countries also require the applicant to conduct local clinical trials as a condition of marketing authorisation. 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.

### 3.2 **China**

The Indivior Group is currently seeking regulatory approval to market its products in China, where pharmaceutical companies and the drug development and marketing processes are heavily regulated. The Indivior Group will need to comply with China's Drug Administration Law, which singles out narcotic drugs and psychotropic drugs for special controls, as well as 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, licence maintenance, manufacturing, import and distribution, and post-marketing surveillance. The Indivior

Group's 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.

#### **4. Environmental**

The Indivior Group's operations, like those of other pharmaceutical companies, involve the use of substances regulated under environmental laws, primarily in manufacturing processes and, as such, the Indivior Group is subject to numerous federal, state, local and non-US 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 the Indivior Group reimburses the government for costs incurred at these sites or otherwise pays 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.

## PART VIII

### DIRECTORS AND CORPORATE GOVERNANCE

#### 1. Directors

The current members of the Board and their principal functions within the Indivior Group, together with a brief description of business experience and principal business activities outside the Indivior Group, are set out below. The business address of each Director is 10710 Midlothian Turnpike, Suite 430, Richmond, VA 23235, USA.

##### **Howard Pien – *Chairman***

Howard has worked in the pharmaceutical and biotechnology industries for over 30 years. He is currently a board director of the development-stage biopharmaceuticals companies Bellerophon, Immunogen, Juno and Sage; Vanda, a commercial-stage public company specialising in CNS (four years as Chairman); and is an adviser to the Life Sciences Practice of Warburg Pincus, a private equity firm. Howard's 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 2009, Howard was the Chairman and CEO of Medarex, Inc., a public biotechnology company, until it was acquired by Bristol-Myers Squibb. From 2003 to 2006, he was the Chairman and CEO of Chiron, a public biotechnology company, which was acquired by Novartis. His previous board directorships include Talon, Arresto, Ikaria and ViroPharma (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, prior to that, SmithKline Beecham as President of US, International, and Pharmaceuticals. Prior to GSK, Howard worked for Abbott Labs for six years and Merck & Co., Inc. for five years.

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

##### **Shaun Thaxter – *Chief Executive Officer***

Shaun was appointed CEO of RBP in 2009 with a remit to build a global company through the acquisition of the global marketing rights from Merck & Co., Inc. and ensured a successful integration to accelerate RBP towards its vision. He has spearheaded the successful growth and development of RBP since launching the US Suboxone business in 2003. Following his formal appointment as President of RBP in 2005, Shaun has led RBP through sustained growth, building a life-cycle management pipeline and expanded addiction franchise which grew from zero to a peak of \$1.3 billion net revenue. Today, RBP successfully operates in 46 countries around the world.

Shaun joined Reckitt & Colman 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.

Shaun 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.

##### **Cary Claiborne – *Chief Financial Officer***

Cary was appointed CFO of Indivior in November 2014. Prior to joining Indivior, Cary was the CFO of Sucampo Pharmaceuticals, Inc., a public global biopharmaceutical company focused on

discovery, development and commercialisation, from 2011 to 2014. From 2009 to 2010, Cary 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, Cary 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, a diversified energy company. From 2000 to 2001, he was Vice President – FP&A of The Home Depot, Inc. Prior to Home Depot, Cary worked for MCI Corporation for three years.

Cary 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 and GE since 1982. Cary is also a member of the board of directors of MedicAlert Foundation, where he also serves as the Chairman of the Finance Committee.

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

#### **Rupert Bondy – Senior Independent Director**

Rupert 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.

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

Rupert 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 masters degree in Law.

#### **Yvonne Greenstreet – Independent Non-Executive Director**

Yvonne has over 20 years' global experience in the pharmaceutical industry, spanning research and development, strategy and commercial development. Yvonne serves on the boards of directors of Pacira Pharmaceuticals and Advanced Accelerator Applications. She is also on the Advisory Board of the Bill and Melinda Gates Foundation.

Between 2011 and 2013, Yvonne was Senior Vice President and Head of Medicines Development at Pfizer 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 GSK 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. Yvonne previously held various positions of increasing responsibility at GSK, including Senior Vice President for Medicine Development and Chief Medical Officer for Europe.

Yvonne trained as a physician and obtained her MBChB from Leeds University in England and her MBA from INSEAD, France. She was recognised by Fast Company as one of the 100 most creative people in business in the US in 2013 and by FierceBiotech as one of the top 10 women in Biotechnology in 2012.

**Adrian Hennah – Non-Executive Director**

Adrian is the Chief Financial Officer of RB, which he joined in January 2013. He is also a Non-Executive Director of Reed Elsevier plc and Reed Elsevier NV.

Adrian was Chief Financial Officer of Smith & Nephew plc from June 2006 to December 2012. Prior to Smith & Nephew plc, Adrian was Chief Financial Officer of Invensys plc for four years and spent 18 years at GSK, where he held a number of senior management and financial roles. Earlier in his career, Adrian worked at PwC (then Price Waterhouse) in both audit and consultancy.

Adrian has a degree in Law from Cambridge University and is a Sloan Fellow of the London Business School.

Adrian is not considered to be an independent non-executive director for the purposes of the UK Corporate Governance Code.

**A. Thomas McLellan – Independent Non-Executive Director**

Tom 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, Tom has published over 400 articles and chapters on addiction research. He has received several awards including Life Achievement Awards from the American, Swedish, Italian and British Societies of Addiction Medicine and from the American Public Health Association (2010).

Between 2009 and 2011, Tom was unanimously confirmed by the US 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.

Tom holds a BA from Colgate University and his MS and PhD from Bryn Mawr College. He received postgraduate training in psychology at Oxford University in England.

**Lorna Parker – Independent Non-Executive Director**

Lorna is a senior adviser at BC Partners, 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.

Lorna's executive career was primarily in executive search, as a partner at Spencer Stuart. Lorna 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, Lorna worked for Advent (venture capital) and Kleinwort Benson (investment banking).

Lorna has an MA in Economics from Cambridge University and an MBA from Stanford Business School, where she was a Harkness Fellow.

**Daniel J. Phelan – Independent Non-Executive Director**

Dan is a Board Director of TE Connectivity (formerly Tyco Electronics) 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. He is also an Executive Director of Executive Networks and is a member of the Board of Trustees of Rutgers University.

Dan retired from GSK in December 2012 after 31 years, during which 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 14 years.

Dan is a graduate of Rutgers College. He holds a Master's 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.

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

**Christian S. Schade – Independent Non-Executive Director**

Chris is Chief Executive Officer of Novira Therapeutics Inc., a privately held biopharmaceutical company. He is a board director of Integra Life Sciences, a member of its Audit Committee and Chairman of its Finance Committee. Chris also chairs the Board of Trustees at Princeton Academy School.

Chris was previously Executive Vice President and Chief Financial Officer of Omthera Pharmaceuticals, Inc., a specialty pharmaceutical company, prior to its disposal in July 2013 to AstraZeneca. He was EVP and CFO at NRG Energy from March 2010 to September 2011. Chris 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 Co.'s \$2.4 billion acquisition of Medarex in September 2009 and the subsequent merger-integration process.

Prior to Medarex, Chris 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 and JP Morgan Chase & Co.

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

**Daniel Tassé – Independent Non-Executive Director**

Daniel is Chairman and Chief Executive Officer of Ikaria, Inc., and a Director of Bellerophon Therapeutics. He has served as Ikaria's President and Chief Executive Officer since 2008 and was appointed Chairman of the Board of Directors in October 2009. Daniel oversaw the spin-out of Bellerophon Therapeutics from Ikaria in 2013 creating two companies to best leverage the scientific, financial and marketing strengths of the company.

Daniel is a member of the Healthcare Leadership Council, a board director of the Roundtable on Critical Care Policy and Chairman of the Foundation on National Critical Care Policy. He is also a member of the Board of Directors and Health Section Governing Board of the Biotechnology Industry Organization (BIO), where he participates on the Bioethics, Regulatory Environment and Reimbursement Committees, and a Board Director of PhRMA, where he participates on the FDA and Biomedical Research Committee.

Prior to joining Ikaria, Daniel served as General Manager of the Pharmaceuticals and Technologies Business Unit of Baxter International. Earlier in his career, he held a number of senior management positions at GSK and was Vice President and Regional Director for Australasia from 2001 to 2004.

Daniel holds a BSc in Biochemistry from the University of Montreal.

## **2. Senior management**

The current Senior Managers with responsibility for day-to-day management of the Indivior Group's business are set out below. The business address of each of the Senior Managers is 10710 Midlothian Turnpike, Suite 430, Richmond, VA 23235, USA.

### **Mark Crossley – Chief Strategic Planning Officer**

Mark 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 Strategic Planning Officer.

Prior to joining Reckitt Benckiser Pharmaceuticals, Mark spent 13 years at Procter & Gamble in both corporate and current business roles including Associate Director Strategic and Business Planning, Finance Director Female Beauty, and 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 United States Coast Guard.

Mark graduated from the United States Coast Guard Academy with a BS in Management and Economics, and from Boston College with an MBA. He is a National Association of Corporate Directors Governance Fellow.

### **Richard Simkin – Chief Commercial Officer**

Richard has over 20 years' global commercial business experience. He began his career with Reckitt & Colman in 1987 and has held various roles in operations, sales and marketing with increasing responsibility.

Prior to his role with RBP, Richard 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. Richard has also held a number of general manager positions within the RB Group, most recently as General Manager, Portugal in 2008.

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

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

### **Christian Heidbreder – Chief Scientific Officer**

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

Christian 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. Christian subsequently held positions of increasing responsibility at SmithKline-Beecham's Neuroscience Department in Harlow, GSK's R&D Centre of Excellence for Drug Discovery in Psychiatry in Verona, and Altria Client Services' Health Sciences Department in Richmond, Virginia.

Christian was appointed Global R&D Director at RBP in 2009 with a remit to lead global strategies (including Strategic Portfolio Management, Preclinical and Clinical Development,

Health Economics Research, Chemistry, Manufacturing & Controls, and Regulatory Affairs) to drive the development of new pharmacotherapies in the area of addiction and related co-morbidities.

Christian 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**

Javier has been practising law for nearly 15 years and has spent more than 10 of those as in-house counsel in the pharmaceuticals industry.

Javier began his legal career in 2000 as a litigation associate at the law firm of Thelen Reid & Priest 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, Javier served as Corporate Counsel to the clinical development function, the US diagnostic imaging business and the oncology and specialised therapeutics global business units. In 2008, Javier joined Reckitt Benckiser LLC as Senior Counsel to the healthcare category and helped successfully manage the integration of Adams Respiratory Therapeutics and its portfolio of OTC 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, Javier was appointed VP General Counsel of RBP in 2011 with a remit to build and lead a strategically focused, high-performing team of legal and corporate compliance professionals.

Javier 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 practise law in New York, New Jersey and Virginia (corporate counsel).

## **3. Corporate governance**

### **3.1 The UK Corporate Governance Code**

The UK Corporate Governance Code sets out standards of good practice in relation to leadership and effectiveness, remuneration, accountability and relations with shareholders. The UK Corporate Governance Code recommends that at least half the board of directors of a UK listed company (excluding the chairman) should comprise ‘independent’ non-executive directors, being individuals determined by the board of directors to be independent in character and judgement and free from relationships or circumstances which may affect, or could appear to affect, the directors’ judgement. It also recommends that a UK company’s remuneration and audit and risk committees should comprise at least three independent non-executive directors, and that its nomination committee should comprise a majority of independent directors. The Audit Committee is not fully compliant with the UK Corporate Governance Code since Adrian Henna is not considered to be an independent non-executive director. Given his recent and relevant financial experience, the Board considers that this is appropriate. The Company will otherwise comply from Admission, and intends to continue to comply, with the requirements of the UK Corporate Governance Code.

### **3.2 Board composition and independence**

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 the Indivior Business and the Indivior Group's 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 document, the Board comprises 11 members, including the chairman, 8 non-executive directors and 2 executive directors. The Board regards the chairman and each of the other non-executive directors except Adrian Hennah as independent for the purposes of the UK Corporate Governance Code. Rupert Bondy will be the Company's senior independent director.

### 3.3 **Audit, Remuneration and Nomination Committees**

As envisaged by the UK Corporate Governance Code, the Board has established audit, remuneration and nomination committees, whose terms of reference are formally documented and updated as necessary.

#### (A) *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 the Indivior Group's 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 will normally meet at least four times a year at the appropriate times in the reporting and audit cycle.

The terms of reference of the Audit Committee cover such issues as membership and the frequency of meetings, as mentioned above, together with quorum requirements and the right to attend meetings. The responsibilities of the Audit Committee covered in the terms of reference are: external audit, internal audit, financial reporting, internal controls and risk management. The terms of reference also set out the authority of the committee to carry out its responsibilities.

The UK Corporate Governance Code recommends that the Audit Committee comprises at least three members who are all independent non-executive directors and includes one member with recent and relevant financial experience. The members of the Audit Committee are Christian S. Schade, Adrian Hennah, Yvonne Greenstreet and Daniel Tassé, all of whom are considered to be independent for the purposes of the UK Corporate Governance Code except for Adrian Hennah. Given his recent and relevant financial experience, the Board considers that Adrian Hennah's membership of the Audit Committee is appropriate. The committee is chaired by Christian S. Schade.

#### (B) *Remuneration Committee*

The Remuneration Committee has responsibility for determination of specific remuneration packages for the chairman, the executive directors and the members of the executive management of the Company, including salary, incentive payments (including annual bonus and long-term incentives), pension and other benefits in kind. The Remuneration Committee also has responsibility for share-based incentive arrangements. The Remuneration Committee will meet at least twice a year.

The terms of reference of the Remuneration Committee cover such issues as membership and the frequency of meetings, as mentioned above, together with the

quorum requirements and the right to attend meetings. The responsibilities of the Remuneration Committee covered in its terms of reference relate to the following: determining and monitoring policy on and setting levels of remuneration, approving the design of and determining targets for performance-related pay schemes and reviewing the design and implementation of all share-based incentive arrangements (including determining whether awards will be made thereunder) and reviewing the outcome of employee consultation on executive pay. The terms of reference also set out the reporting responsibilities and the authority of the committee to carry out its responsibilities.

The UK Corporate Governance Code recommends that the Remuneration Committee comprises at least three members who are all independent non-executive directors, one of whom may be the chairman (but who may not chair the Remuneration Committee). The members of the Remuneration Committee are Daniel J. Phelan, Rupert Bondy, Lorna Parker and Daniel Tassé, all of whom are considered to be independent for the purposes of the UK Corporate Governance Code. The committee is chaired by Daniel J. Phelan.

(C) *Nomination Committee*

The Nomination Committee is responsible for considering and making recommendations to the Board in respect of appointments to the Board, the Board committees and the chairmanship of 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 changes necessary. The Nomination Committee's terms of reference deal with such things as membership, quorum and reporting responsibilities. It also considers succession planning, taking into account the skills and expertise that will be needed on the Board in the future. The Nomination Committee will meet at least once a year.

The UK Corporate Governance Code recommends that a majority of the members of the Nomination Committee should be independent non-executive directors. The members of the Nomination Committee are Rupert Bondy, A. Thomas McLellan, Lorna Parker and Daniel J. Phelan, all of whom are considered to be independent for the purposes of the UK Corporate Governance Code. The committee is chaired by Rupert Bondy.

#### **4. Model Code**

From Admission, the Company shall require the Directors and other persons discharging managerial responsibilities within the Indivior Group to comply with the Model Code, and shall take all proper and reasonable steps to secure their compliance.

#### **5. Takeover regulation**

The City Code is issued and administered by the Takeover Panel. The Company will, following Admission, be subject to the City Code and, therefore, its Shareholders will, following Admission, be entitled to the protections afforded by the City Code. For more information about the City Code (in particular the rules on mandatory bids), please refer to Part XV (*Additional Information*).

## PART IX

### SELECTED FINANCIAL INFORMATION

The selected financial information for the Indivior Group set out below has been extracted without material adjustment from Part XII (*Historical Financial Information*). Investors should read the whole of this Prospectus before making an investment decision and not rely solely on the summarised information in this Part IX (*Selected Financial Information*).

#### COMBINED INCOME STATEMENT

The table below sets out certain combined income statement information relating to the Indivior Group for the three years ended 31 December 2011, 2012 and 2013 and for the six-month period ended 30 June 2014 and, for comparative purposes, unaudited financial information for the six-month period ended 30 June 2013, prepared in accordance with IFRS.

	Year ended 31 December			Six-month period ended 30 June	
	2011	2012	2013	2013	2014
	\$m	\$m	\$m	\$m	\$m
Net revenues	1,254	1,339	1,216	618	574
Cost of sales	(81)	(94)	(104)	(53)	(49)
<b>Gross profit</b>	<b>1,173</b>	<b>1,245</b>	<b>1,112</b>	<b>565</b>	<b>525</b>
Selling, distribution and administrative expenses	(266)	(320)	(341)	(185)	(158)
Research and development expenses	(35)	(41)	(76)	(25)	(41)
<b>Profit on ordinary activities before taxation</b>	<b>872</b>	<b>884</b>	<b>695</b>	<b>355</b>	<b>326</b>
Taxation	(258)	(277)	(206)	(105)	(93)
<b>Net income</b>	<b>614</b>	<b>607</b>	<b>489</b>	<b>250</b>	<b>233</b>

#### COMBINED BALANCE SHEET

The table below sets out certain combined balance sheet information relating to the Indivior Group for the three years ended 31 December 2011, 2012 and 2013 and for the six-month period ended 30 June 2014, prepared in accordance with IFRS.

	As of 31 December			As of 30 June
	2011	2012	2013	2014
	\$m	\$m	\$m	\$m
Intangible assets	135	117	94	107
Total non-current assets	230	208	198	212
Cash and cash equivalents	7	25	7	11
Total current assets	329	349	228	243
<b>Total assets</b>	<b>559</b>	<b>557</b>	<b>426</b>	<b>455</b>
Total current liabilities	(305)	(396)	(451)	(467)
Total non-current liabilities	–	(16)	(41)	(41)
<b>Total liabilities</b>	<b>(305)</b>	<b>(412)</b>	<b>(492)</b>	<b>(508)</b>
<b>Total invested capital</b>	<b>254</b>	<b>145</b>	<b>(66)</b>	<b>(53)</b>

## COMBINED CASH FLOW

The table below sets out certain combined cash flow information relating to the Indivior Group for the three years ended 31 December 2011, 2012 and 2013 and for the six-month period ended 30 June 2014 and for comparative purposes, unaudited financial information for the six-month period ended 30 June 2013, prepared in accordance with IFRS.

	<i>Year ended 31 December</i>			<i>Six-month period ended 30 June</i>	
	<i>2011</i>	<i>2012</i>	<i>2013</i>	<i>2013</i>	<i>2014</i>
	<i>\$m</i>	<i>\$m</i>	<i>\$m</i>	<i>\$m</i>	<i>\$m</i>
Net cash provided by operating activities	715	866	791	483	295
Net cash used in investing activities	(25)	(3)	(3)	–	(25)
Net cash used in financing activities	(697)	(845)	(806)	(503)	(266)
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(7)</b>	<b>18</b>	<b>(18)</b>	<b>(20)</b>	<b>4</b>

## PART X

### OPERATING AND FINANCIAL REVIEW

*The following discussion of the Indivior Group's financial condition and results of operations should be read in conjunction with the combined historical financial information as at and for the years ended 31 December 2011, 2012 and 2013, and the six months ended 30 June 2013 and 2014 (collectively the "periods under review") and related notes, included in Part XII (Historical Financial Information) of this document and the other information relating to the business of the Indivior Group contained in this document. The historical financial information set out in this document has been prepared in respect of the Indivior Group, which is the group of companies that operated the Indivior Business during the periods covered by the historical financial information set out in this document. References to the Indivior Group in this Part X (Operating and Financial Review) and elsewhere in this document where historical financial information has been stated in relation to the Indivior Group should be read accordingly. Following the Demerger, the companies that operate the Indivior Business will be direct subsidiaries or subsidiary undertakings of the Company, which was incorporated on 26 September 2014 in connection with the Demerger and will serve as the holding company for the Indivior Group following the Demerger. As the Demerger is expected to become effective on 23 December 2014, the Indivior Group's report and accounts for 2014 to be published in 2015 will be prepared on the same basis as the combined historical financial information included in this document, and results on a stand-alone basis will only be provided for periods following 1 January 2015.*

*The following discussion includes forward-looking statements that reflect the Indivior Group's plans, estimates and beliefs and involves risks and uncertainties. The Indivior Group's 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 Part II (Risk Factors) of this document and paragraph 6 "Forward-looking statements" of Part V (Presentation of Information) of this document.*

*References below to "2011", "2012" and "2013" are to the financial years ended 31 December 2011, 31 December 2012 and 31 December 2013, respectively. References below to "H1 2013" and "H1 2014" are to the six months ended 30 June 2013 and 30 June 2014, respectively. References below to "Q3 2013" and "Q3 2014" are to the three months ended 30 September 2013 and 30 September 2014, respectively. The financial information presented in tabular form in the following discussion has been rounded to the nearest decimal. Therefore the sum of the numbers in a column may not conform exactly to the total figure given for that column.*

#### **1. Overview**

##### **1.1 Introduction to the Indivior Group**

The Indivior Group is a global specialty pharmaceutical business specialising in the treatment of addiction and its co-morbidities. Its products, which are currently sold in up to 44 countries, comprise Suboxone Film, Suboxone Tablet and Subutex Tablet, all of which are treatments for opioid dependence.

- (A) Suboxone film initially launched in the US in 2010. It is the only product currently approved by the FDA for the treatment of opioid dependence pursuant to DATA 2000 in both the induction and the maintenance phases. 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 US 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 US in August 2012, and in Australia in May 2014. Suboxone Film was

also approved in the US in April 2014 for use in the induction phase of buprenorphine-based opioid dependence treatment. Suboxone Film accounted for 75% and 79% of the Indivior Group's net revenues in 2013 and H1 2014 respectively and currently maintains a share of 60% in the US market for buprenorphine-based treatments for opioid dependence based on volume (mg).

- (B) Suboxone Tablet is a fixed-dose combination of buprenorphine and naloxone in the ratio of four parts buprenorphine to one part naloxone. Initially, Suboxone Tablet containing 2mg buprenorphine and 0.5mg naloxone, and 8mg buprenorphine and 2mg naloxone, was approved in the US in October 2002 for maintenance treatment of opioid dependence. In the US, Suboxone Tablet lost the exclusivity afforded by its orphan drug status in October 2009. Suboxone Tablet is approved in 48 countries worldwide and marketed in 41 countries, with marketing approval pending in additional countries, but was voluntarily withdrawn from the US market in March 2013.
- (C) 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 US and launched in April 2003, but were voluntarily withdrawn from the US market in September 2011. The Indivior Group currently markets Subutex Tablet in 24 countries.

The Indivior Group also sells two legacy products: Temgesic sublingual tablets and injections outside the US for the treatment of moderate to severe pain, as well as Buprenex injection in the US for the relief of moderate to severe pain. The Indivior Group also supplies 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".

The Indivior Group aims to continue efforts to expand its range of products beyond its core opioid dependence treatment business. In addition to extension candidates for its opioid dependence treatments, the Indivior Group has a pipeline of new drug candidates for the treatment of alcohol dependence, cocaine intoxication, schizophrenia and opioid overdose.

The Indivior Group generated net revenues of \$574 million in H1 2014 (H1 2013: \$618 million; 2013: \$1,216 million; 2012: \$1,339 million; 2011: \$1,254 million). Its core geographic market (based on the country where the sale originates) is the US which accounted for 77% in H1 2014 (H1 2013: 78%; 2013: 78%; 2012: 80%; 2011: 77%).

## **2. Presentation of historical financial information**

### **2.1 Basis of preparation**

**General.** The Indivior Group represents a combined reporting entity comprising the assets and liabilities used in managing and operating the pharmaceuticals business of the RB Group, including legal entities, branches and operations. The Indivior Group's combined historical financial information has been presented on a stand-alone basis and has been carved out from the consolidated financial statements of the RB Group by applying the principles underlying the consolidation procedures of IFRS 10 "Consolidated Financial Statements" as of and for each of the three years ended 31 December 2013, 2012 and 2011 and each of the six months ended 30 June 2014 and 2013. The combined historical financial information of the Indivior Group may not be indicative of its future performance and does not necessarily reflect what the results of operations, financial position and cash flows would have been had the Indivior Group operated as a stand-alone, publicly traded group during the periods under review.

The combined historical financial information has been prepared in accordance with IFRS and the Companies Act that applies to companies reporting under IFRS and IFRIC interpretations. The combined historical financial information has also been prepared in compliance with the requirements of the Prospectus Directive Regulation and the Listing Rules. As IFRS does not provide for the preparation of combined financial information, certain accounting conventions commonly used for the preparation of historical financial information for inclusion in investment circulars as described in the Annexure to SIR 2000 (“Investment Reporting Standard applicable to public reporting engagements on historical financial information”) (the “**Annexure**”) issued by the UK Audit Practices Board have been applied.

In addition, the combined historical financial information has been prepared on a going concern basis. The Board believes that following the Demerger, the pharmaceuticals business will continue to be able to meet its liabilities as they fall due.

Transactions between the Indivior Group and the RB Group have been included in the combined historical financial information and are considered to be effectively settled for cash in the combined historical financial information at the time the transaction is recorded. The total net effect of the settlement of these intercompany transactions is reflected in the combined statements of cash flows as a financing activity and in the combined statements of financial position as owners’ net investment. All intercompany transactions within the Indivior Group have been eliminated.

**Allocation from owners.** The combined historical financial information of the Indivior Group includes expense allocations for certain functions provided to the Indivior Group by the RB Group, 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 Indivior Group in all periods under review and are included in the combined historical financial information.

The combined historical financial information of the Indivior Group also includes a portion of the RB Group’s costs relating to RB’s operations as a public company, which historically were not allocated to the Indivior Group. The total expenses allocated are not necessarily indicative of the expenses that would have been incurred had the Indivior Group been a public company during historical periods and they are not necessarily indicative of expenses that will be incurred in the future. It is not practicable to estimate the expenses the Indivior Group would have incurred for the periods under review had it not been a member of the RB Group during each of these periods.

**General corporate expenses.** Historically, RB allocated certain of its corporate expenses to the Indivior Group on the basis of direct usage when identifiable, with the remainder allocated on a pro rata basis. As the RB Group uses a centralised cash management system, allocated costs and expenses have generally been deemed to have been paid by the Indivior Group to the RB Group in the year in which the costs were incurred.

**Cash and cash equivalents and cash management.** Historically, RBP’s excess cash was remitted to RB through cash pooling arrangements. Transfers to and from RB are recorded as adjustments to owners’ net investment.

**Income taxes.** Current income taxes, other than taxes owed to tax authorities, are deemed to have been remitted, in cash, by or to RB in the year the related income taxes were recorded.

### 3. Significant factors affecting the Indivior Group's results of operations

The Indivior Group has one business segment being the manufacture and distribution of products for the treatment of opioid dependence. Substantially all the Indivior Group's net revenues are derived from sales of Suboxone Film, Suboxone Tablet and Subutex Tablet.

The US market is the largest contributor to the Indivior Group's gross sales and net revenues. Sales rebates and other offsets to gross sales (reflected in net revenues) are principally a US market phenomenon. The following table sets out a breakdown of net revenues as between the US and the rest of the world.

	Net revenues				
	2011	2012	2013	H1 2013 (unaudited)	H1 2014
US	969	1,072	950	485	443
Rest of world (including UK)	285	267	266	133	131
Total Indivior Group net revenues	1,254	1,339	1,216	618	574

The Indivior Group's results of operations have been affected during the periods under review, and will continue to be affected in future, by the following factors:

#### 3.1 Market factors

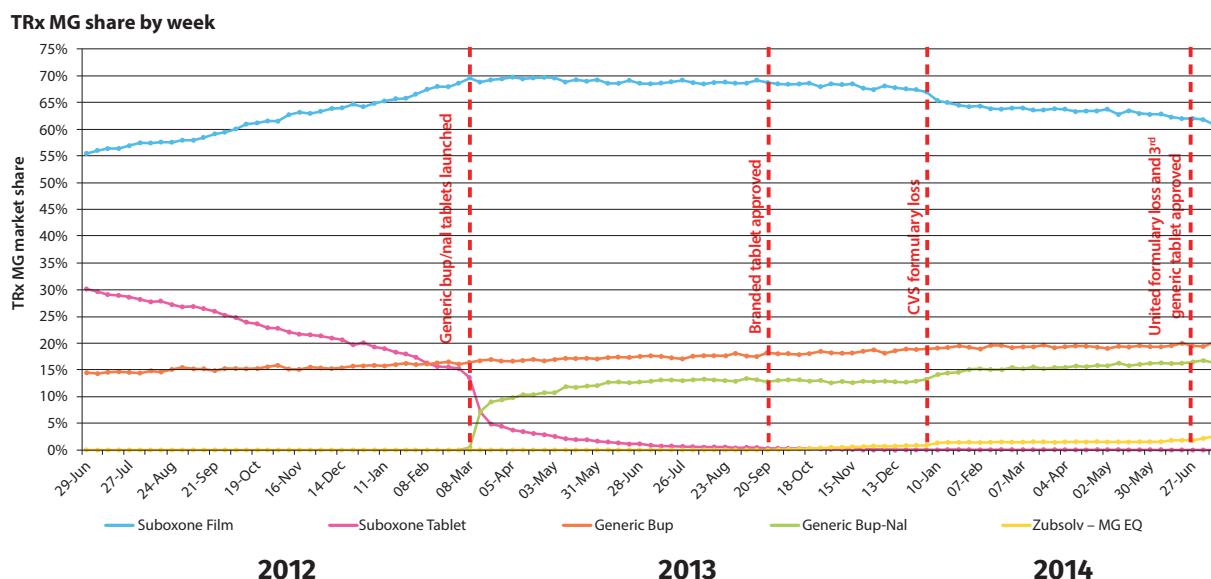
##### Market growth and market share

The Indivior Group's net revenue is impacted by the share of the market it holds, 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. To increase access to treatment for patients, Indivior is engaged with government agencies, key opinion leaders in addiction and healthcare professionals to bring patient outcomes to the forefront of decision making. Additionally, Indivior is 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.

**US.** The opioid dependence treatment market in the US has experienced consistent growth with an annual growth rate in the range of 10% in each of the past two years.

The Indivior Group has maintained a buprenorphine market share of 60% (based on volume (mg)) during the periods under review. In March 2013, the Indivior Group voluntarily withdrew Suboxone Tablet from the market due to paediatric safety concerns. This, combined with the launch of competing tablets, resulted in the Indivior Group's market share of buprenorphine products reducing from over 80% in December 2012 to approximately 70% (based on volume (mg)) at the end of the second quarter of 2013 and to 62% at the end of the second quarter of 2014, with two generic buprenorphine and naloxone tablets (generic equivalents of Suboxone tablet) entering the market in March 2013 and a branded buprenorphine and naloxone tablet entering the market in September 2013. Competitive pressures can drive pricing and can also influence decisions of third-party payers regarding inclusion of products on their list of approved drugs covered by insurance. For example, decisions by CVS Caremark and United Healthcare to remove Suboxone Film from their formularies, both effective during 2014, had a nominally adverse net impact on market share.

The following chart sets out the development of market share in the US.



Source: Source Healthcare Analytics Pharmaceutical Audit Suite Weekly Data

**Rest of World.** The rest of world operations, which comprises countries in the EU, Asia, Australia and Africa, contributed 23% and 22% to the Indivior Group's net revenues in H1 2014 and 2013, respectively. The main driver of rest of world revenues is the EU. The EU opioid addiction treatment market is relatively mature, with the numbers of patients in treatment being relatively stable over the past five years.

The Indivior Group's market share of buprenorphine in the EU dropped from 74% in 2012 to 70% in 2013 and 68% in H1 2014 based on volume (mg). This loss in market share was primarily due to EU member state governments' austerity measures and generic first initiatives.

### **Distribution channels; pricing; product mix**

**Distribution channels.** In the US, the Indivior Group has distribution agreements with the three largest wholesalers, which accounted for 90% of the Indivior Group's gross sales in 2013 (2012: 90%; 2011: 91%). These wholesalers, in turn, distribute the Indivior Group's products through various channels including the following:

- **Commercial Managed care.** This category comprises insurance programmes 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 Medicare Part D Program, a social insurance programme administered by the US government.
- **Medicaid.** Medicaid is a jointly funded, Federal-State health insurance programme 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. The Indivior Group is 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 Department of Veterans Affairs and the Department of Defense, or under the Public Health Service's 340B Drug Pricing

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, discount coupons are provided by Indivior to customers where cash is used for payment.

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

**Pricing.** The Indivior Group offers various types of price reductions for its products, particularly in the US, which is reflected in net revenues. For the rest of the world, the difference between gross sales and net revenues is nominal. In the US, the Indivior Group offers:

- Medicaid, federal and commercial managed care rebates. These are rebates granted to Medicaid, US federal agencies and commercial managed care providers that purchase products from the Indivior Group. 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.
- 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 the Indivior Group's market share and subsequently increased pricing pressure through greater rebates. Consolidation among third-party payers also contributed to increased pricing pressure. As such, during these periods, net pricing has decreased. The recent launch of a branded buprenorphine and naloxone film in November 2014 and the expected launch in the near term of an additional generic Suboxone tablet approved by the FDA in September 2014 could have a similar effect in the latter part of 2014 and/or in 2015.

**Product mix.** Product mix affects the level of the Indivior Group's cost of sales and its net revenue.

### 3.2 **Research and development**

Research and innovation continues to be a key strategic priority for the Indivior Group as its long-term success depends to a great extent on its ability and investment in new product development for the treatment of addiction and its co-morbidities. Please refer to paragraph 9 of Part VI (*Information on the Indivior Group and its Industry*) for details of the Indivior Group's ongoing research and development projects.

The Indivior Group's R&D function conducts all Phase I studies internally and operates an outsourced business model in relation to Phase II and III trials where the Indivior Group has service agreements in place with a number of contract research organisations. The Indivior Group has increased its investment in research and development projects from \$35 million in 2011 to \$76 million in 2013 and \$41 million in H1 2014.

While the aggregate cost to complete the numerous pharmaceutical projects currently in development is expected to be material, the total cost to complete will depend upon the Indivior Group's ability to successfully complete each project, the rate at which each project advances, the nature and extent of cost-sharing arrangements, 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.

### 3.3 ***Patent and other intellectual property protection for the Indivior Group's products***

The success of the Indivior Group depends, in part, on its ability to obtain and maintain patent and other intellectual property protection. See paragraph 10 of Part VI (*Information on the Indivior Group and its Industry*) for details of the Indivior Group's intellectual property protection. RBP owns the Suboxone Film patent, which expires in the US in March 2030. In addition, MSRX, owns two patents related to Suboxone Film (covering a film production comprising an opiate and a defined polymer component and the uniformity of the film's content), which expire in February 2023 and April 2024 and are exclusively licensed to the Indivior Group until the expiry of the patents. The expiry of, or any failure of the Indivior Group to protect, its material patent and other intellectual property or failure to obtain granted patents of suitable scope from its patent applications could have a material adverse effect on its results of operations. Please refer to the risk factors entitled "Failure to obtain and maintain patents and protect other proprietary rights, including in-licences of such rights from third parties, may adversely affect the Indivior Group" for further details.

### 3.4 ***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 US 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:

- Two manufacturers launched generic Suboxone tablets 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 had gained a 3% share (based on volume (mg)) of the buprenorphine market in the US by October 2014.
- In June 2014, the FDA approved a third generic Suboxone tablet, which was launched in August 2014.
- In September 2014, the FDA approved a fourth generic Suboxone tablet, which has yet to launch.
- BDSI recently launched its branded buccal film product, Bunavail™, in November 2014. In September 2014, the Indivior Group filed a patent infringement lawsuit against BDSI. Please refer to paragraph 19 of Part XV (*Additional Information*) of this

Prospectus for further details of the patent infringement lawsuit and related litigation.

In the EU, the strong methadone market as well as government austerity measures have reduced the Indivior Group's market share of buprenorphine from 74% in 2012 to 68% (based on volume (mg) in H1 2014).

### 3.5 **Government regulation**

The pharmaceutical industry is heavily regulated by governments and other regulatory bodies in the countries in which the Indivior Group operates. Regulation is imposed in respect of, but not limited to, ingredients, manufacturing standards, employment standards, product safety, marketing, packaging, labelling, storage, distribution, advertising, imports and exports, social and environmental responsibility and health and safety. Changes to the laws and regulations to which the Indivior Group and its operations are subject, whether as a result of new or more stringent requirements, or more stringent interpretations of existing requirements, could impose significant compliance costs and impact the way the Indivior Group conducts its business. Please see Part VII (*Regulatory Overview*) of this Prospectus for details of the regulatory environment to which the Indivior Group is subject.

### 3.6 **Legal and regulatory proceedings**

The Indivior Group's ability to anticipate, manage and successfully resolve regulatory investigations, resolve claims that are brought against it, avoid or otherwise resolve product liability claims, as well as the costs of litigation it brings as a plaintiff, have an impact on its results of operations. In particular:

- Beginning in December 2012, 12 US federal antitrust class action complaints were filed against RB, RBP and various other entities in the RB Group. The Indivior Group has filed motions to dismiss.
- In June 2013, the FTC commenced a non-public investigation of RB, RBP and various other entities in the RB Group by issuing a civil investigative demand focusing on business practices relating to Suboxone Film, Suboxone Tablet and Subutex Tablet, including those that are the subject of the allegations in the antitrust class actions described above. A similar investigation was commenced by the Attorney General of the State of New York in July 2013. Both investigations are ongoing and no decision has been made by either agency on whether to pursue any legal action for enforcement.
- 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
- From August 2013, three ANDAs were filed for generic Suboxone sublingual films. The Indivior Group has filed patent infringement lawsuits against all three ANDA applicants and at present two ANDA lawsuits are ongoing.
- Following confirmation that BDSI was preparing to launch its competing film product, the Indivior Group filed a patent infringement lawsuit against BDSI in September 2014. In anticipation of launching its product and being sued by the Indivior Group, BDSI filed a lawsuit 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. BDSI has also filed six requests, most recently on 28 October 2014, for inter partes review with the US Patent Office of

certain claims in a number of patents relating to Suboxone Film or film formulations. The US Patent Office has granted one request and is expected to make a decision on the second request in December 2014, with decisions on the more recent requests of 28 October expected around April 2015.

- In December 2013, the USAO-VAW executed a search warrant on RBP's headquarters in Richmond and conducted searches of the homes of four field-based employees. The USAO-VAW has since served a number of subpoenas relating to Suboxone Film, Suboxone Tablet, Subutex Tablet, buprenorphine and any real or potential competitor, among other issues. The investigation is ongoing and RBP is in the process of responding to the USAO-VAW by producing documents and other information.
- The Indivior Group is involved in a number of pieces of related litigation in China with Nanchang Lijian regarding the mark 赛宝松 ("Sai Bao Song", a transliteration of SUBOXONE) and which is owned in China by Nanchang Lijian.
- 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.

Please refer to paragraph 19 of Part XV (*Additional Information*) for further details of litigation and disputes. The Indivior Group provided \$41 million, \$41 million, \$16 million and nil, respectively, as at 30 June 2014, 31 December 2013, 31 December 2012 and 31 December 2011 in respect of legal provisions.

### 3.7 ***Relationships with certain third parties***

The Indivior Group's results of operations are dependent on its relationships with certain third parties:

- (A) MSRX is the global exclusive manufacturer and primary packager of Suboxone Film, operating under an exclusive licence and supply agreement between the Indivior Group and MSRX. MSRX also owns two of the three formulation patents in the US relating to Suboxone Film, which are licensed to the Indivior Group.
- (B) The Indivior Group's three largest customers (who are wholesale pharmaceutical companies in the US) accounted for 70% of its net revenues in H1 2014 (H1 2013: 75%; 2013: 70%; 2012: 71%; 2011: 68%). The largest customer accounted for 22% of its net revenues in H1 2014 (H1 2013: 26%; 2013: 24%; 2012: 29%; 2011: 34%).
- (C) The Indivior Group procures the naloxone API mainly from two suppliers, Macfarlan Smith and Mallinckrodt, for both Suboxone Film and Suboxone Tablet, which is then provided to MSRX and RB Health for the manufacture of Suboxone Film and Suboxone Tablet, respectively.

### 3.8 ***Foreign currency translations***

The Indivior Group's functional and presentation currency is US 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 US 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 recognised in the combined statement of income. Exchange rate movements recognised in the combined statement of income during H1

2014, H1 2013, 2013, 2012 and 2011 were \$3 million, \$1 million, \$3 million, \$2 million and \$(2) million, respectively.

	Year ended 31 December			Six-month period ended 30 June	
	2011	2012	2013	2013 (unaudited)	2014
USD/GBP period end exchange rate	1.5543	1.6255	1.6557	1.5422	1.6983
USD/GBP average exchange rate	1.6041	1.5852	1.5649	1.5445	1.6684

### 3.9 **The Demerger**

#### *Pre-demerger*

During the periods under review, the Indivior Group formed part of the RB Group. The combined historical financial information of the Indivior Group covering the periods under review includes expense allocations for certain functions provided to the Indivior Group by the RB Group, as well as allocations of RB Group corporate expenses, including general corporate expenses related to finance, legal, tax, treasury, information technology, human resources, communications, employee benefits and incentives, insurance, share based compensation and public company costs.

These costs are included within selling, distribution and administrative expenses in the Indivior Group's combined statements of income. The combined historical financial information of the Indivior Group also reflects a portion of the RB Group's costs relating to its operations as a public company, which have not historically been allocated to the Indivior Group, but have been included in the Indivior Group's combined historical financial information. The expenses allocated to the Indivior Group are based on estimates that the Board believes reasonably reflect the allocation of services provided to or the benefit received by the Indivior Group during the periods under review. However, the allocated expenses are not necessarily indicative of the expenses that would have been incurred had the Indivior Group performed these functions as a stand-alone entity, nor are they indicative of the expenses that will be charged or incurred in the future. The historical allocation of the corporate expenses of the RB Group to the Indivior Group has been calculated on the basis of direct usage when identifiable, with the remainder allocated on a pro-rata basis.

#### *Post-demerger*

Following the Demerger, the relationship between the Indivior Group and the RB Group will be governed by the Demerger Agreement and the Transitional Services Agreement, along with a number of ancillary agreements.

- Pursuant to the terms of the Transitional Services Agreement, Reckitt Benckiser plc (on behalf of the RB Group) has agreed to provide RBP Global Holdings Limited (on behalf of the Indivior Group) with certain services which will be provided on commercial terms and on an arms' length basis. These services include (i) the continued provision by Reckitt Benckiser plc 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. Conversely, fees paid by the Indivior Group to RB prior to the Demerger for providing a number of similar services will cease. The agreement provides for most of these services to be

provided for a maximum period, ranging from 3 to 36 months (but can be extended by any period agreed between the parties in writing). Please refer to paragraph 21 of Part XV (*Additional Information*) of this Prospectus for a description of the Transitional Services Agreement.

- The Demerger Agreement contains, among other things, mutual indemnities under which Indivior indemnifies the RB Group against liabilities arising in respect of the Indivior Business and RB indemnifies the Indivior Group against liabilities arising in respect of the business carried on by the RB Group other than the Indivior Business. These mutual indemnities are unlimited in terms of amount and duration. The Demerger Agreement also sets out how guarantees, indemnities or other assurances given by entities within the RB Group for the benefit of entities in the Indivior Group (or vice versa) will be dealt with following the Demerger. The related Demerger Tax Deed and US Tax Matters Agreement each contain indemnities between the two groups in relation to taxation. Please refer to paragraph 21 of Part XV (*Additional Information*) of this Prospectus for descriptions of these agreements.

As is customary for transactions of this type, the Board expects ongoing incremental expenditure to ensure the capability of a stand-alone UK public listed company and one-off expenditure and capital investment associated with the Demerger.

The Board estimates that the Indivior Group's recurring operating expenses will be higher than the recurring historical recharges to, and corporate allocations of, the RB Group in 2013 reflected in the Indivior Group's combined historical financial information. The Board estimates an increase in annual recurring expenses of approximately \$40-50 million (compared to 2013) in connection with the establishment of stand-alone public company functions and services, including but not limited to finance, information systems, human resources, manufacturing, insurance and Board costs.

As the Indivior Group transitions away from the historical services and organisational structure afforded by the RB Group, the Board believes that the Indivior Group may incur a total of \$25-35 million of non-recurring transitional costs over the next 12 months to establish its own stand-alone structure and capability.

In addition, the Board anticipates the Indivior Group will have additional capital expenditures of up to \$75 million over the next two to three financial years, primarily relating to information systems and the design and construction of a new research and development facility. The Indivior Group will also incur additional expenses to service its debt.

## **4. Current trading and prospects**

### **4.1 Trading update**

The Indivior Group's net revenues decreased 8% from \$295 million in Q3 2013 to \$270 million in Q3 2014, with low double-digit market growth being more than offset by loss in US market share and pricing pressure associated with branded and generic competitors. Profit before taxation decreased 24%, which was primarily attributable to lower net revenues and higher research and development expenses (due to continued advancement of the pipeline products). There has been no material change in the Indivior Group's trading trends between 30 September and 31 October 2014 compared to Q3.

### **4.2 Indivior Group outlook**

The Indivior Group expects the rate of growth in the US opioid addiction treatment market in the short term to be low double-digit. It anticipates that the recent approval of two additional generic competitors (one of which has already entered the US market) and the entry of an additional branded competitor in the US in the last quarter of 2014 will result in a rapid change in the dynamics of its US business and create downward pressure on

the Indivior Group's market share and pricing. These competitive pressures are likely to result in the loss of the majority of the Indivior Group's market share in its distribution channels that are the most price-sensitive (such as cash and commercial managed care channels, which together accounted for between 25-30% of Indivior's net revenue by channel during H1 2014). The Board believes, however, that the Indivior Group's value to patients, physicians and payers will help to ensure stronger resilience in less price-sensitive distribution channels. Accordingly, the increased pricing pressure associated with competition is likely to result in downward pressure on the Indivior Group's net revenue in 2015, potentially continuing into 2016, before the market adjusts to the increased competitive landscape and before it begins to benefit from expected pipeline launches. In Europe, the Board expects increased austerity measures associated with price reduction decrees and generic first initiatives to impact net revenue.

The Indivior Group does not expect a material change in its tax rate in the short term.

In addition to the transaction-related impacts detailed in paragraph 3.9 of this Part X (*Operating and Financial Review*), the Board expects the Indivior Group will have increased research and development expenses and a high single-digit percentage increase in selling, distribution and administrative expenses in 2015 as product candidates progress to later stages of development, as well as incremental legal costs associated with litigation (please refer to paragraph 19 of Part XV (*Additional Information*) for further details of litigation and disputes).

## **5. Recent developments**

On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. The Company expects to use approximately \$500 million from the proceeds of the term loan financing to pay a dividend to RB.

## **6. Key income statement items**

### **6.1 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.

The Indivior Group estimates and recognises returns, discounts, incentives and rebates in the period in which it recognises the underlying sales, as a reduction of gross sales. See Note 3 to the combined historical financial information in Part XII (*Historical Financial Information*) for the basis of calculation of the rebates provisions.

### **6.2 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.

### **6.3 Selling, distribution and administrative expenses**

Selling, distribution and administrative expenses comprise personnel costs (primarily, the clinical sales force), as well as marketing expenses, amortisation of distribution rights, travel and other selling and distribution related expenses, corporate overheads and other

administrative expenses. In H1 2013 and 2012, selling, distribution and administrative expenses also included expenses relating to recognition of legal provisions (\$23 million and \$16 million, respectively).

#### 6.4 **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.

#### 6.5 **Taxation**

Tax charges in the Indivior Group's combined historical financial information are based on the tax charges recorded by RB Group companies in their statutory accounts. These historical charges take into account the taxation arrangements within the RB Group and are not necessarily representative of the tax charges that would have been reported had the Indivior Group been an independent group or those which may arise in the future.

Income tax expense for the six months to June 2014 is recognised based on management's best estimate of the weighted average annual income tax rate expected for the full financial year. The estimated average annual tax rate used for the year to 31 December 2014 is 28.5% (the estimated average annual tax rate used to prepare the comparative disclosures for the six months ended 30 June 2013 was 29.6%).

### 7. **Results of operations**

The following table sets out information relating to the statement of comprehensive income, including as a percentage of net revenues for the Indivior Group during the periods under review.

	2011		2012		2013		H1 2013		H1 2014	
	(\$ m)	% of net revenues	(\$ m)	% of net revenues	(\$ m)	% of net revenues	(\$ m)	% of net revenues (unaudited)	(\$ m)	% of net revenues
Net revenues	1,254	100	1,339	100	1,216	100	618	100	574	100
Cost of sales	(81)	(6)	(94)	(7)	(104)	(9)	(53)	(9)	(49)	(9)
Gross profit	1,173	94	1,245	93	1,112	91	565	91	525	91
Selling, distribution and administrative expenses	(266)	(21)	(320)	(24)	(341)	(28)	(185)	(30)	(158)	(28)
Research and development expenses	(35)	(3)	(41)	(3)	(76)	(6)	(25)	(4)	(41)	(7)
Profit before taxation	872	70	884	66	695	57	355	57	326	57
Taxation	(258)	(21)	(277)	(21)	(206)	(17)	(105)	(17)	(93)	(16)
Net income	614	49	607	45	489	40	250	40	233	41

#### 7.1 **H1 2014 compared to H1 2013**

**Net revenues.** Net revenues decreased by \$44 million, or 7%, from \$618 million in H1 2013 to \$574 million in H1 2014. The decrease to \$574 million in H1 2014 was primarily due to double-digit market growth being more than offset by loss of market share in the US by volume (mg) and pricing pressure associated with competitors' branded and generic products, the Indivior Group's voluntary discontinuation of Suboxone Tablet in the US in March 2013 and negative product mix.

Net revenues in rest of world operations decreased, due primarily to a decrease in net revenues in the EU as a result of government austerity measures.

**Cost of sales.** Cost of sales decreased by \$4 million, or 8%, from \$53 million in H1 2013 to \$49 million in H1 2014. This decrease was primarily driven by decreased sales and negative product mix.

**Selling, distribution and administrative expenses.** Selling, distribution and administrative expenses decreased \$27 million, or 15%, from \$185 million in H1 2013 to \$158 million in H1 2014. This decrease was primarily due to the recognition of a legal provision of \$23 million in H1 2013.

**Research and development expenses.** Research and development expenses increased by \$16 million, or 64%, in H1 2014, which reflected increased investment in the Indivior Group's research and development pipeline as product candidates progressed to later stages of development.

**Taxation.** Tax expenses decreased by \$12 million, or 11%, from \$105 million in H1 2013 to \$93 million in H1 2014. This decrease was primarily due to lower profit before tax in H1 2014 compared to H1 2013 as well as a minor decrease in tax rate.

**Net income.** As a result of the foregoing factors, net income decreased by \$17 million, or 7%, from \$250 million in H1 2013 to \$233 million in H1 2014.

## 7.2 2013 compared to 2012

**Net revenues.** Net revenues decreased by \$123 million, or 9%, from \$1,339 million in 2012 to \$1,216 million in 2013. The decrease to \$1,216 million in 2013 was primarily due to double-digit US market growth being more than offset by loss of market share by volume (mg) in the US and pricing pressure associated with competitors' generic and branded products (launched in the first and third quarters of 2013, respectively), the Indivior Group's voluntary discontinuation of Suboxone Tablet in the US in March 2013 and negative product mix.

Net revenues in rest of world operations remained largely stable as increased sales attributable to market growth were largely offset by government-imposed price reductions in a number of European markets, government budget decreases and the results of price referencing analyses across different countries in the EU, as well as the entry of generic products.

**Cost of sales.** Cost of sales increased by \$10 million, or 11%, from \$94 million in 2012 to \$104 million in 2013. This increase was primarily attributable to product mix associated with conversion from Suboxone Tablet to Suboxone Film, and to a lesser extent to increased packaging costs in the EU in order to improve child resistance, as well as increases in air freight rates in line with rising fuel costs.

**Selling, distribution and administrative expenses.** Selling, distribution and administrative expenses increased by \$21 million, or 7%, from \$320 million in 2012 to \$341 million in 2013, or from 24% to 28% as a percentage of net revenues. This increase was primarily due to legal costs associated with the Indivior Group's patent infringement lawsuits and increased investment in compliance.

**Research and development expenses.** Research and development expenses increased by \$35 million, or 85%, from \$41 million in 2012 to \$76 million in 2013. This increase was primarily driven by the continued success of the Indivior Group's existing research and development pipeline and the incremental spend associated with product candidates progressing to later stages of development (for example, schizophrenia to Phase III clinical trials and buprenorphine 30-day depot to Phase IIB).

**Taxation.** Tax expenses decreased by \$71 million, or 26%, from \$277 million in 2012 to \$206 million in 2013. This decrease was primarily due to lower profit before tax in 2013 compared to 2012, and a lower rate of taxation in the UK (23.25% in 2013 compared to 24.5% in 2012) and in other markets.

**Net income.** As a result of the foregoing factors, net income decreased by \$118 million, or 19%, from \$607 million in 2012 to \$489 million in 2013.

### 7.3 **2012 compared to 2011**

**Net revenues.** Net revenues increased \$85 million, or 7%, from \$1,254 million in 2011 to \$1,339 million in 2012. The increase to \$1,339 million was attributable to double-digit market growth and price increases on Suboxone Film and Suboxone Tablet, and was partially offset by loss of market share (by volume (mg)) in the US to monotherapy, negative product mix (reflecting a higher proportion of sales of Suboxone Film), and the impact of increased accruals due to negative channel mix.

Net revenues in rest of world operations decreased due to primarily government-imposed price reductions in a number of EU markets, as well as the entry of generic products in the market.

**Cost of sales.** Cost of sales increased by \$13 million, or 16%, from \$81 million in 2011 to \$94 million in 2012. This increase was in line with increased volumes, and also reflected negative product mix associated with the conversion from Suboxone Film to Suboxone Tablet.

**Selling, distribution and administrative expenses.** Selling, distribution and administrative expenses increased by \$54 million, or 20%, from \$266 million in 2011 to \$320 million in 2012. This increase was primarily due to the recognition of a \$16 million legal provision in 2012, the full year impact of the licensing rights that were repurchased by RB from Merck in March 2010, and increased marketing and investment in clinical trials to support claims.

**Research and development expenses.** Research and development expenses increased by \$6 million, or 17%, from \$35 million in 2011 to \$41 million in 2012. This increase was due to the Indivior Group's continued progression of the existing research and development pipeline, as well as its investment in clinical trials for expansion into China.

**Taxation.** Tax expenses increased by \$19 million, or 7%, from \$258 million in 2011 to \$277 million in 2012. This increase was primarily due to increased profit before tax in 2012 compared to 2011 and increased tax as a result of country mix (reflecting higher taxes paid in the US due to increased sales).

**Net income.** As a result of the foregoing factors, net income decreased by \$7 million, or 1%, from \$614 million in 2011 to \$607 million in 2012.

## 8. **Liquidity and capital resources**

### 8.1 **Overview**

Historically, the Indivior Group's principal source of funding has been cash from operations and funding from RB. The principal uses of the Indivior Group's funds have been to fund its operating costs and expenses.

In the future the Indivior Group expects that its sources of funding will include cash from operations and debt and/or equity funding, including the Term Loan B and Revolving Credit Facility described in paragraph 8.4 of this Part X (*Operating and Financial Review*). The Indivior Group's expected uses of funds, in addition to funding its operating costs and expenses, will include funding its debt service obligations as well as paying dividends to its shareholders.

Cash management functions of the Indivior Group have historically been performed by entities in the RB Group. The majority of the cash generated by the Indivior Group historically was transferred to entities in the RB Group daily, with such entities then funding the Indivior Group's operating and investing activities as needed. The net of these cash transfers to and from the RB Group are reflected in "Owners' net investment" in the Indivior Group's combined statements of financial position.

The Company 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 the Company'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 and cash and covenants in the Indivior Group's facilities.

## 8.2 **Cash flow**

The following table summarises the principal components of the Indivior Group's cash flows for the periods under review:

	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>H1 2013</u>	<u>H1 2014</u>
				(unaudited)	
	(\$ m)	(\$ m)	(\$ m)	(\$ m)	(\$ m)
Net cash provided by operating activities	715	866	791	483	295
Net cash used in investing activities	(25)	(3)	(3)	—	(25)
Net cash used in financing activities	(697)	(845)	(806)	(503)	(266)
<b>Net (decrease)/ increase in cash and cash equivalents</b>	<u>(7)</u>	<u>18</u>	<u>(18)</u>	<u>(20)</u>	<u>4</u>

### *Net cash provided by operating activities*

Net cash provided by operating activities was \$295 million in H1 2014, a decrease of \$188 million, or 39%, compared to \$483 million in H1 2013. The decrease mainly reflected the impact of a \$29 million decrease in profit before taxation, \$98 million arising due to fluctuations in net working capital (primarily due to decreased trade receivables) and \$91 million arising due to fluctuations in provisions for liabilities and charges (reflecting a reduction in rebate provisions due to loss of market share, based on volume (mg)).

Net cash provided by operating activities decreased \$75 million, or 9%, from \$866 million in 2012 to \$791 million in 2013. This decrease was primarily due to a \$189 million decrease in profit before taxation and \$72 million arising due to fluctuations in provisions for liabilities and charges offset by a \$171 million fluctuation in net working capital that was mainly driven by trade and other receivables having decreased by \$142 million (in line with the decrease in profit before taxation and improved cash collections) and trade and other payables having increased by \$29 million (in connection with the upfront payment for an R&D project).

Net cash provided by operating activities in 2012 was \$866 million, an increase of \$151 million, or 21%, compared to \$715 million in 2011. This increase was primarily due to improved working capital management, which resulted in additional cash inflow of \$64 million compared to 2011. The increase was also due to a favourable movement of provisions for liabilities and charges of \$26 million (reflecting increases in legal provisions and an increase in rebate provisions) and a decrease in tax paid of \$47 million.

### *Net cash used in investing activities*

Net cash used in investing activities increased from nil in H1 2013 to \$25 million in H1 2014 mainly due to the purchase of new licences from Xenoport, Inc. during the period.

Net cash used in investing activities was \$3 million in each of 2013 and 2012 and reflected cash paid for purchases of property, plant and equipment.

Net cash used in investing activities was \$25 million in 2011, which reflected the re-acquisition of distribution rights to buprenorphine-based products in developing markets from Schering Plough.

#### *Net cash used in financing activities*

Net cash used in financing activities decreased by \$237 million, or 47%, from \$503 million in H1 2013 to \$266 million in H1 2014. This decrease was in line with declining cash generated by operating activities.

Net cash transferred to owners was \$806 million in 2013, a decrease of \$39 million, or 5%, from \$845 million transferred in 2012.

Net cash used in financing activities was \$845 million in 2012, an increase of \$148 million, or 21%, from \$697 million in 2011 in line with increased cash flows from operating activities.

### 8.3 **Net working capital**

The Indivior Group's net working capital has been decreasing primarily due to increasing rebates and returns provisions.

### 8.4 **Borrowings**

See Part XI (*Capitalisation and Indebtedness*) for details relating to the Indivior Group's capitalisation and indebtedness as at the dates indicated therein.

#### *Term Loan B and Revolving Credit Facility*

On 15 November 2014, RBP Global Holdings Limited entered into a commitment letter (the "**Commitment Letter**") with Deutsche Bank Securities Inc. and Morgan Stanley Senior Funding, Inc. as joint lead arrangers and bookrunners (in such capacities, the "**Arrangers**") and Deutsche Bank AG New York Branch and Morgan Stanley Senior Funding, Inc. as initial lenders (in such capacities, the "**Initial Lenders**") relating to the terms under which the Initial Lenders are prepared to initially lend, and on which the Arrangers shall subsequently arrange syndication in respect of, a \$750 million term "B" loan facility (the "**Term Loan B**") and a \$50 million revolving credit facility, including a \$10 million swingline facility and \$25 million letter of credit facility (the "**RCF**", together with the Term Loan B, the "**Facilities**"). Annexed to the Commitment Letter is the form of the credit agreement (the "**Draft Credit Agreement**") for the Facilities which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. Pursuant to the Commitment Letter RBP Global Holdings Limited has given customary representations to the Arrangers and the Initial Lenders in connection with provision of information to the Arrangers and the Initial Lenders. In addition, the Arrangers, the Initial Lenders and their respective affiliates, officers, directors, employees, agents, controlling persons, members advisors and representatives are provided with a customary indemnity against, among other things any loss, claim, damages, liabilities or expenses to which they may be subject in connection with the Commitment Letter, the Facilities and the related transactions.

Under the Commitment Letter, the Initial Lenders' commitment to lend is subject to the execution and delivery of the Credit Agreement and other definitive documentation and satisfaction of the conditions precedent set out in the Draft Credit Agreement. The conditions precedent under the Draft Credit Agreement are limited such that on satisfaction of specified documentary conditions precedent the Arrangers are obliged to lend the Term Loan B unless (i) any one of certain specified defaults is continuing, (ii) any one of certain specified representations is incorrect when made or deemed to be made, (iii) it is unlawful for an Arranger to perform its obligations, (iv) certain restructuring steps have not been achieved or the restructuring steps plan, this prospectus or any other related document has changed to the extent that a supplementary prospectus is required (unless the Arrangers have consented to such change), (v) there is a disposal of all or

substantially all of the assets of the Indivior Group, (vi) certain fees and expenses have not been paid in full (or will not be paid in full concurrently with the incurrence of the Term Loan B) or (vii) any non-permitted debt is outstanding upon closing of the Facilities. The conditions precedent under the Draft Credit Agreement are customary for this type of credit agreement.

The Draft Credit Agreement is governed by New York law. The borrower of the Term Loan B will be Indivior Finance S.à r.l., a Luxembourg-incorporated wholly owned subsidiary of RBP Global Holdings Limited. There will also be with respect to the Term Loan B a US co-borrower (which will be jointly and severally liable with respect to obligations under the Term Loan B), as is customary with such Term Loan B facilities. RBP Global Holdings Limited will be the borrower under the RCF. Under the Draft Credit Agreement the obligations of the borrowers under the Facilities are to be guaranteed by each borrower (other than with respect to its own obligations as a borrower), certain wholly owned subsidiaries of RBP Global Holdings Limited, and also by a newly formed English limited liability company that will become the immediate parent company of RBP Global Holdings Limited and a wholly owned subsidiary of Indivior. Each such guarantor will also grant security to support the guarantee. Such guarantee and security will not be granted by any wholly owned subsidiaries that are designated unrestricted subsidiaries or subject to certain other exceptions, in each case, in accordance with the Draft Credit Agreement or are immaterial subsidiaries (as defined in the Draft Credit Agreement). Such guarantees, and the obligations of the borrowers, are to be secured by substantially all the assets of the borrowers and the guarantors, subject to certain exceptions. Indivior will also, as of the completion of the Demerger, grant security over its shareholding in RBP Global Holdings Limited. It is, however, expected that Indivior will be released from all its obligations in respect of the Facilities upon the joinder of the intermediate holding company (required by the Draft Credit Agreement to be within 90 days of the Demerger Effective Time) which shall provide a guarantee and security over all or substantially all its assets, including the shares in RBP Global Holdings Limited.

Under the Draft Credit Agreement the borrowers under the applicable Facilities will be entitled to elect to pay interest on any loan (other than a swingline loan) either based on a "LIBO" base rate or (other than in the case of loans under the RCF 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 LIBOR but subject to a floor of 1.00%. The Alternate Base Rate is the higher of (i) the Federal Funds Effective Rate plus 0.50%, (ii) published LIBOR for an interest period of one month plus 1.00% or (iii) the "Prime Rate" which is a rate announced by the administrative agent with respect to the Facilities publicly as its prime rate. The Alternate Base Rate is subject to a floor of 2.00%. To the extent denominated in U.S. dollars, swingline loans are required to be based on the Alternate Base Rate.

The Term Loan B margin shall be either 4.50% in respect of a LIBO Rate loan or 3.50% in respect of an Alternate Base Rate Loan. The RCF margin is 4.00% in respect of a LIBO Rate loan or 3.00% in respect of an Alternative Base Rate Loan, but may be reduced in the event that the ratio of net total debt to adjusted EBITDA is reduced to levels set out in the Draft Credit Agreement. The margins are subject to a 0.50% step-up in the event that certain ratings criteria are not obtained prior to funding. Certain economic and other terms of the Draft Credit Agreement and related fee terms are subject to customary flex arrangements in relation to the syndication of the credit facilities after the closing of the Demerger.

The Draft Credit Agreement includes an accordion feature such that a minimum of \$250 million of additional incremental loans are permitted plus additional further incremental loans of first lien or second lien debt up to an amount based on various leverage ratios and subject to various conditions, including as to 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, a 50 basis point “MFN” provision with respect to the Term Loan B and RCF). In addition, refinancing facilities are permitted to refinance loans or replace commitments under the Draft Credit Agreement subject to various conditions including as to maturity, weighted average life to maturity, borrower identity, guarantors and security, terms and conditions, principal amount, intercreditor relations and priority.

The Term Loan B is subject to mandatory prepayment in respect of non-ordinary course asset sales and casualty events above a threshold (subject to customary re-investment rights) and proceeds of certain debt issues. Additionally 50% of the annual excess cash flow of RBP Global Holdings Limited and its restricted subsidiaries will be prepaid (subject to a step down to 25% or to 0% if certain leverage ratios are achieved).

Under the Draft Credit Agreement the borrowers and guarantors make representations and warranties, affirmative covenants and negative covenants customary for facilities of the type of the Facilities including a limitation on disposals, a limitation on mergers and acquisitions and other fundamental changes, limitations on share buybacks and redemptions, dividends and other “restricted payments”, a negative pledge, a limitation on indebtedness, a limitation on prepayments and redemptions of certain indebtedness, delivery of financial statements and other information and a limitation on loans and investments (including investments in non-guarantor subsidiaries of RBP Global Holdings Limited). These are subject to various carve outs, grace periods and qualifications. Additionally RBP Global Holdings Limited and its restricted subsidiaries are required to comply with a net first lien leverage ratio to be tested on the last day of each financial quarter.

Under the Draft Credit Agreement the Facilities are subject to customary events of default for facilities of this nature including as to non payment, breach of covenant, misrepresentation, cross event of default and cross acceleration, insolvency and insolvency events, material monetary judgments, pension defaults, material actual or asserted invalidity of guarantees or security, material loss of perfection and change of control.

## **9. Contractual obligations and commitments**

As at 30 June 2014, the Indivior Group had \$4 million in operating lease obligations, which are payable between one and five years.

In connection with the Indivior Group’s asset purchases and licensing of potential product candidates, the Indivior Group has agreed to pay certain additional amounts contingent upon the achievement of certain agreed development, regulatory, product or other milestones. Please refer to paragraph 15 of Part VI (*Information on the Indivior Group and its Industry*) and paragraph 21 of Part XV (*Additional Information*) of this Prospectus for further details.

## **10. Off-balance sheet arrangements**

As at 30 June 2014, the Group had no off-balance sheet arrangements.

## **11. Contingent liabilities**

In addition to the legal and regulatory proceedings set out in paragraph 3.6 of this Part X (*Operating and Financial Review*), the Indivior Group is involved in other legal proceedings and claims in the ordinary course of business. Given the limited information available to the Indivior Group regarding the foregoing civil and criminal investigations, 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.

## **12. Related party transactions**

### **12.1 *RB service charges and corporate allocations***

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. The Indivior Group's combined statements of income included in this Prospectus also include a portion of the RB Group's costs relating to its operations as a public company including, but not limited to, corporate governance and board oversight that have not historically been allocated to the Indivior Group. 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.

Note 2 to the Indivior Group's combined historical financial information set out in Part XII (*Historical Financial Information*) sets out the expenses included in the Indivior Group's combined statement of income for corporate allocations.

Please refer to paragraphs 2.1 and 3.9 of this Part X (*Operating and Financial Review*) for further information.

### **12.2 *Owners' net investment***

Net transfers to owners of the Indivior Group are included within the "Owners' net investment" line in the Indivior Group's combined statements of financial position. See Note 17 to the combined historical financial information in Part XII (*Historical Financial Information*).

## **13. Quantitative and qualitative disclosure about market risks**

A quantitative and qualitative analysis of the Indivior Group's exposure to market risks is included in Note 11 to the combined historical financial information in Part XII (*Historical Financial Information*).

## **14. Critical accounting policies and use of estimates**

The preparation of combined historical financial information in accordance with IFRS requires management to make estimates and assumptions that 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 are set out in Note 3 "Key estimates and judgements" to the combined historical financial information in Part XII (*Historical Financial Information*). Recent accounting pronouncements are set out in Note 3 "Standards issued but not yet effective" in the combined historical financial information.

## PART XI

### CAPITALISATION AND INDEBTEDNESS

#### 1. Capitalisation and Indebtedness of the Indivior Group

The Indivior Group's published financial information as at 30 September 2014 is presented on a combined basis as it has not constituted a separate legal group as of and for the nine-month period then ended. As a result, it is not possible to provide a meaningful analysis of share capital or reserves for the Indivior Group.

As at 30 September 2014 the Indivior Group had no debt. The following table sets out the unaudited consolidated net funds of the Indivior Group as at 30 September 2014, and has been extracted without material adjustment from the Indivior Group's unaudited accounting records:

	<i>Indivior Group as at 30 September 2014 (unaudited)<sup>(1)</sup></i>
<i>Combined net indebtedness</i>	<i>\$m</i>
Cash	32
Financial debt	—
Net Financial (indebtedness)/cash	32

**Notes:**

(1) As at 30 September 2014, the Indivior Group had no indirect or contingent indebtedness.

#### 2. Capitalisation and indebtedness of the Company

The Company was incorporated on 26 September 2014 with subscriber share capital of \$4, being 2 ordinary shares of \$2.00. On 30 October 2014 the Company issued £50,000 of redeemable fixed rate preference shares, which were redeemed on 4 November 2014.

Other than ordinary share capital of \$4.00 and £50,000 of redeemable fixed rate preference shares, the Company has had no indebtedness since incorporation.

## PART XII

### HISTORICAL FINANCIAL INFORMATION

#### SECTION A: PRICEWATERHOUSECOOPERS LLP'S REPORT ON THE HISTORICAL FINANCIAL INFORMATION FOR THE THREE YEARS ENDED 31 DECEMBER 2013 AND THE SIX MONTH PERIOD ENDED 30 JUNE 2014



The Directors (the “**Directors**”)  
Indivior PLC  
103-105 Bath Road  
Slough  
Berkshire SL1 3UH  
United Kingdom

Deutsche Bank AG, London branch  
Winchester House  
1 Great Winchester Street  
London EC2N 2DB  
United Kingdom

Morgan Stanley & Co. International PLC  
25 Cabot Square  
London E14 4QA  
United Kingdom

17 November 2014

Dear Sirs

#### **The pharmaceuticals business of Reckitt Benckiser Group PLC (the “Indivior Group”)**

We report on the financial information set out in Section B of Part XII (the “**Combined IFRS Financial Information Table**”) of the Indivior Group. The Combined IFRS Financial Information Table has been prepared for inclusion in the prospectus dated 17 November 2014 (the “**Prospectus**”) of Indivior PLC (the “**Company**”) on the basis of the accounting policies set out in note 2 to the Combined IFRS Financial Information Table. This report is required by item 20.1 of Annex I to the PD Regulation and is given for the purpose of complying with that item and for no other purpose.

#### **Responsibilities**

The Directors of the Company are responsible for preparing the Combined IFRS Financial Information Table in accordance with International Financial Reporting Standards as adopted by the European Union.

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*PricewaterhouseCoopers LLP, 1 Embankment Place, London, WC2N 6RH  
T: +44 (0) 2075 835 000, F: +44 (0) 2072 124 652, [www.pwc.co.uk](http://www.pwc.co.uk)*

PricewaterhouseCoopers LLP is a limited liability partnership registered in England with registered number OC303525. The registered office of PricewaterhouseCoopers LLP is 1 Embankment Place, London WC2N 6RH. PricewaterhouseCoopers LLP is authorised and regulated by the Financial Conduct Authority for designated investment business.

It is our responsibility to form an opinion as to whether the Combined IFRS Financial Information Table gives a true and fair view, for the purposes of the Prospectus and to report our opinion to you.

Save for any responsibility which we may have to those persons to whom this report is expressly addressed and for any responsibility arising under item 5.5.3R(2)(f) of the Prospectus Rules to any person as and to the extent there provided, to the fullest extent permitted by law we do not assume any responsibility and will not accept any liability to any other person for any loss suffered by any such other person as a result of, arising out of, or in connection with this report or our statement, required by and given solely for the purposes of complying with item 23.1 of Annex I to the PD Regulation, consenting to its inclusion in the Prospectus.

### **Basis of opinion**

We conducted our work in accordance with the Standards for Investment Reporting issued by the Auditing Practices Board in the United Kingdom. Our work included an assessment of evidence relevant to the amounts and disclosures in the financial information. It also included an assessment of significant estimates and judgements made by those responsible for the preparation of the financial information and whether the accounting policies are appropriate to the Company's circumstances, consistently applied and adequately disclosed.

We planned and performed our work so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial information is free from material misstatement whether caused by fraud or other irregularity or error.

Our work has not been carried out in accordance with auditing standards generally accepted in the United States of America or auditing standards of the Public Company Accounting Oversight Board (United States) and accordingly should not be relied upon as if it had been carried out in accordance with those standards.

### **Opinion**

In our opinion, the Combined IFRS Financial Information Table gives, for the purposes of the Prospectus dated 17 November 2014, a true and fair view of the state of affairs of the Indivior Group as at the dates stated and of its profits and cash flows for the periods then ended in accordance with International Financial Reporting Standards as adopted by the European Union.

### **Declaration**

For the purposes of Prospectus Rule 5.5.3R(2)(f) we are responsible for this report as part of the Prospectus and declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Prospectus in compliance with item 1.2 of Annex I to the PD Regulation.

Yours faithfully

PricewaterhouseCoopers LLP  
Chartered Accountants

**SECTION B: HISTORICAL FINANCIAL INFORMATION FOR THE THREE YEARS ENDED 31 DECEMBER 2013 AND THE SIX MONTH PERIOD ENDED 30 JUNE 2014**

**COMBINED STATEMENTS OF INCOME**

		Year ended 31 December			Six-month period ended 30 June	
					Unaudited	
	Notes	2011 \$m	2012 \$m	2013 \$m	2013 \$m	2014 \$m
Net revenues	4	1,254	1,339	1,216	618	574
Cost of sales		(81)	(94)	(104)	(53)	(49)
<b>Gross profit</b>		<u>1,173</u>	<u>1,245</u>	<u>1,112</u>	<u>565</u>	<u>525</u>
Selling, distribution and administrative expenses		(266)	(320)	(341)	(185)	(158)
Research and development expenses		(35)	(41)	(76)	(25)	(41)
<b>Profit on ordinary activities before taxation</b>		<u>872</u>	<u>884</u>	<u>695</u>	<u>355</u>	<u>326</u>
Taxation	6	(258)	(277)	(206)	(105)	(93)
<b>Net income</b>		<u>614</u>	<u>607</u>	<u>489</u>	<u>250</u>	<u>233</u>

**COMBINED STATEMENTS OF COMPREHENSIVE INCOME**

		Year ended 31 December			Six-month period ended 30 June	
					Unaudited	
		2011 \$m	2012 \$m	2013 \$m	2013 \$m	2014 \$m
<b>Net income</b>		614	607	489	250	233
<b>Other comprehensive (loss)/income</b>						
<i>Other comprehensive income to be reclassified to profit or loss in subsequent periods</i>						
Currency translation		(1)	4	–	(8)	1
<b>Total other comprehensive (loss)/income</b>		<u>(1)</u>	<u>4</u>	<u>–</u>	<u>(8)</u>	<u>1</u>
<b>Total comprehensive income</b>		<u>613</u>	<u>611</u>	<u>489</u>	<u>242</u>	<u>234</u>

# COMBINED STATEMENTS OF FINANCIAL POSITION

		As at 31 December			As at 30 June
	Notes	2011 \$m	2012 \$m	2013 \$m	2014 \$m
<b>Assets</b>					
Non-current assets:					
Intangible assets	7	135	117	94	107
Property, plant and equipment	8	11	13	13	13
Deferred tax assets	6	84	61	79	87
Other receivables	10	–	17	12	5
<b>Total non-current assets</b>		<b>230</b>	<b>208</b>	<b>198</b>	<b>212</b>
Current assets:					
Inventories	9	32	34	36	36
Trade and other receivables	10	276	290	185	196
Current tax receivables		14	–	–	–
Cash and cash equivalents	12	7	25	7	11
<b>Total current assets</b>		<b>329</b>	<b>349</b>	<b>228</b>	<b>243</b>
<b>Total Assets</b>		<b>559</b>	<b>557</b>	<b>426</b>	<b>455</b>
<b>Liabilities and invested capital</b>					
Current liabilities:					
Provisions for liabilities and charges	13	(200)	(293)	(305)	(291)
Trade and other payables	16	(105)	(103)	(129)	(123)
Current tax liabilities		–	–	(17)	(53)
<b>Total current liabilities</b>		<b>(305)</b>	<b>(396)</b>	<b>(451)</b>	<b>(467)</b>
Non-current liabilities:					
Provisions for liabilities and charges	13	–	(16)	(41)	(41)
<b>Total non-current liabilities</b>		<b>–</b>	<b>(16)</b>	<b>(41)</b>	<b>(41)</b>
<b>Total Liabilities</b>		<b>(305)</b>	<b>(412)</b>	<b>(492)</b>	<b>(508)</b>
<b>Net Assets/(Liabilities)</b>		<b>254</b>	<b>145</b>	<b>(66)</b>	<b>(53)</b>
Invested capital:					
Owners' net investment		255	142	(69)	(57)
Accumulated other comprehensive (loss)/income		(1)	3	3	4
<b>Total invested capital</b>		<b>254</b>	<b>145</b>	<b>(66)</b>	<b>(53)</b>

# COMBINED STATEMENTS OF INVESTED CAPITAL

		Owners' net investment \$m	Accumulated other comprehensive (loss)/ income \$m	Total invested capital \$m
	Notes			
<b>Balance at 1 January 2011</b>		186	–	186
Net income		614	–	614
Other comprehensive loss		–	(1)	(1)
New transfers to owners	17	(545)	–	(545)
<b>Balance at 31 December 2011</b>		255	(1)	254
Net income		607	–	607
Other comprehensive income		–	4	4
Net transfers to owners	17	(720)	–	(720)
<b>Balance at 31 December 2012</b>		142	3	145
Net income		489	–	489
Other comprehensive income		–	–	–
Net transfers to owners	17	(700)	–	(700)
<b>Balance at 31 December 2013</b>		(69)	3	(66)
Net income		233	–	233
Other comprehensive income		–	1	1
Net transfers to owners	17	(221)	–	(221)
<b>Balance at 30 June 2014</b>		(57)	4	(53)
<b>Balance at 31 December 2012</b>		142	3	145
Net income (unaudited)		250	–	250
Other comprehensive loss (unaudited)		–	(8)	(8)
Net transfers to owners (unaudited)		(450)	–	(450)
<b>Balance at 30 June 2013 (unaudited)</b>		(58)	(5)	(63)

# **COMBINED STATEMENTS OF CASH FLOWS**

		Year ended 31 December			Six-month period ended 30 June	
		2011	2012	2013	2013	2014
	Notes	\$m	\$m	\$m	\$m	\$m
<b>Cash Flows from Operating Activities:</b>						
Profit on ordinary activities before taxation		872	884	695	355	326
Adjustments to reconcile net cash provided by operating activities:						
Depreciation and amortisation		25	27	28	13	14
Provisions for liabilities and charges		83	109	37	79	(12)
Changes in assets and liabilities:						
Trade and other receivables		(105)	(32)	110	82	(4)
Inventories		(6)	(2)	(2)	3	–
Trade and other payables		10	(3)	26	3	(6)
Cash provided by operating activities		879	983	894	535	318
Tax paid		(164)	(117)	(103)	(52)	(23)
Net cash provided by operating activities		715	866	791	483	295
<b>Cash Flows for Investing Activities:</b>						
Purchase of property, plant and equipment		(4)	(3)	(3)	–	(1)
Purchase of intangible assets		(21)	–	–	–	(24)
Net cash used in investing activities		(25)	(3)	(3)	–	(25)
<b>Cash Flows from Financing Activities:</b>						
Net transfers to owners		(697)	(845)	(806)	(503)	(266)
Net cash used in financing activities		(697)	(845)	(806)	(503)	(266)
Net (decrease)/increase in cash and cash equivalents		(7)	18	(18)	(20)	4
Cash and cash equivalents at beginning of year		14	7	25	25	7
<b>Cash and cash equivalents at end of year</b>	12	7	25	7	5	11

## NOTES TO COMBINED HISTORICAL FINANCIAL INFORMATION

(Expressed in millions of US dollars, unless otherwise stated)

### 1. General information

Description of the business - The principal business of the pharmaceuticals business of Reckitt Benckiser Group PLC (the “**Indivior Group**”) is the development, manufacture and sale of buprenorphine-based prescription drugs for the treatment of opioid dependence.

The board of directors of RB announced on 28 July 2014 its intention to separate the Indivior Business from RB. The separation will be effected by way of a demerger of the pharmaceuticals business to a new company.

The combined historical financial information includes the financial results of the following subsidiaries which will represent the significant subsidiary undertakings and associated undertakings of the Company after the Demerger Effective time:

<u>Name</u>	<u>Country of incorporation or registration</u>	<u>Proportion of ownership interest</u>	<u>Principal activity</u>
RBP Global Holdings Ltd	England and Wales	100%	Holding and Finance company
RBP US Holdings Inc	US	100%	Holding and Finance company
RB Pharmaceuticals Pty Ltd	Australia	100%	Operating company
RB Pharmaceuticals Ltd	England and Wales	100%	Operating company
Reckitt Benckiser Pharmaceuticals Healthcare South Africa (Pty) Ltd	South Africa	100%	Operating company
RBP Finance LLC	US	100%	Finance company
RB Pharmaceuticals (EU) Ltd	England and Wales	100%	Operating company
RB Pharmaceuticals Ltd Hellas Branch	Greece	100%	Operating company
Reckitt Benckiser Pharmaceuticals France SAS	France	100%	Operating company
RB Pharmaceuticals (Italia) Srl	Italy	100%	Operating company
RB Pharmaceuticals (Deutschland) GmbH	Germany	100%	Operating company
Reckitt Benckiser Pharmaceuticals Solutions Inc.	US	100%	Operating company
Reckitt Benckiser Pharmaceuticals Inc.	US	100%	Operating company

### 2. Basis of preparation

#### ***Basis of preparation***

The Indivior Group represents a combined reporting entity comprising the assets and liabilities used in managing and operating the pharmaceuticals business of RB, including legal entities, branches and operations. The Indivior Group does not comprise a separate legal entity or separate group of entities. The combined historical financial information has been presented on a stand-alone basis, specifically for the purpose of this Prospectus, and has been carved out from the consolidated financial statements of RB by applying the principles underlying the

consolidation procedures of IFRS 10 “Consolidated Financial Statements” (“**IFRS 10**”) for each of the three years ended 31 December 2013, 2012 and 2011 and each of the six months ended 30 June 2014 and 2013. The Indivior Group’s combined historical financial information may not be indicative of the Indivior Group’s future performance and does not necessarily reflect what the results of operations, financial position and cash flows would have been had it operated as a stand-alone, publicly traded group during the periods presented.

The combined historical financial information has been prepared in accordance with the requirements of the Prospectus Directive Regulation, the Listing Rules and in accordance with this basis of preparation. This basis of preparation describes how the historical financial information has been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (“**IFRS**”), and the Companies Act that applies to companies reporting under IFRS and IFRIC interpretations.

IFRS does not provide for the preparation of combined historical financial information, or for the specific accounting treatment set out below, and, accordingly, in preparing the combined historical financial information certain accounting conventions commonly used for the preparation of historical financial information for inclusion in investment circulars as described in the Annexure to SIR 2000 (“Investment Reporting Standard applicable to public reporting engagements on historical financial information”) issued by the UK Audit Practices Board have been applied.

The combined historical financial information has been prepared on a going concern basis. Management has considered the planned separation of the pharmaceuticals business and expects that the appropriate funding will be available for future operations after the separation occurs. Management expects that following separation from RB, the pharmaceuticals business will continue operating and will continue to be able to meet its liabilities as they fall due.

The following summarises certain specific accounting treatments applied in preparing the combined historical financial information.

#### ***Net Investment from RB***

Transactions between the Indivior Group and RB and related entities have been included in this combined historical financial information and are considered to be effectively settled for cash in the combined historical financial information at the time the transaction is recorded. The total net effect of the settlement of these intercompany transactions is reflected in the combined statements of cash flows as a financing activity and in the combined statements of financial position as owners’ net investment. All intercompany transactions between entities within the pharmaceuticals business of RB have been eliminated.

#### ***Allocation from owners***

The combined historical financial information includes expense allocations for certain functions provided by RB, 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 Indivior Group in all periods presented and are included in the combined historical financial information.

The combined historical financial information of the Indivior Group also reflects a portion of RB’s group costs relating to its operations as a public company, including, but not limited to, corporate governance and board oversight expenses. These costs have not historically been allocated to the Indivior Group; however, they have been included in the combined historical financial information in all periods presented. The expenses allocated are not necessarily indicative of the expenses that would have been incurred had the Indivior Group performed these functions as a stand-alone entity, nor are they indicative of the expenses that will be charged or incurred in the future. It is not practicable to estimate the amount of expenses the

Indivior Group would have incurred for the periods presented had it not been an affiliated entity of RB in each of these periods. Actual costs that may have been incurred if the Indivior Group had been a stand-alone company would depend on a number of factors, including the organisational structure, what functions were outsourced or performed by employees and strategic decisions made in areas such as information technology and infrastructure.

### ***Corporate expenses***

RB had allocated certain of its corporate expenses to the Indivior Group on the basis of direct usage when identifiable, with the remainder allocated on a pro rata basis of revenues, operating profit, headcount or other measures of the Indivior Group and RB. During 2013, 2012 and 2011, the Indivior Group was allocated \$55m, \$54m and \$44m, respectively, of corporate expenses incurred by RB, which are included within Selling, distribution and administrative expenses in the combined statements of income. During the six-month periods ended 30 June 2014 and 2013, the Indivior Group was allocated \$15m and \$41m (unaudited), respectively, of corporate expenses incurred by RB, which are included within selling, distribution and administrative expenses in the combined statements of income. See note 17 to the combined historical financial information. Both the Indivior Group and RB consider the bases on which the expenses have been allocated to reasonably reflect the utilisation of services provided to or the benefit received by the Indivior Group during the periods presented.

As RB uses a centralised cash management system, allocated costs and expenses have generally been deemed to have been paid by the Indivior Group to RB in the year in which the costs were incurred.

### ***Cash and cash equivalents and cash management***

Cash and cash equivalents in the combined statements of financial position comprise the cash and cash equivalents of the Indivior Group's businesses, held locally and specifically in relation to the operations of the Indivior Group. Historically, RB has performed cash management functions on behalf of the Indivior Group. RB manages certain cash pooling activities among the Indivior Group's operating units, including the arrangement of borrowings from and loans to related parties and the transfer of cash balances to RB. None of RB's cash and cash equivalents has been allocated to the Indivior Group in the combined statements of financial position. Transfers to and from RB are recorded as adjustments to owners' net investment.

### ***Income taxes***

Current income taxes, other than taxes owed to tax authorities, are deemed to have been remitted, in cash, by or to RB in the year the related income taxes were recorded.

## **3. Summary of significant accounting policies**

As required by the Prospectus Directive Regulation rules, the combined historical financial information has been prepared based on those standards that will be effective for the Indivior Group in its next set of financial statements for the year ending 31 December 2014, and using the principal accounting policies outlined below.

The combined historical financial information has been prepared under the historical cost convention unless otherwise stated below.

### ***Standards issued but not yet effective***

Standards issued but not yet effective up to the date of issuance of the Indivior Group's combined historical financial information are listed below. The Indivior Group intends to adopt these standards and interpretations when they become effective.

(A) *IFRS 9 - Financial Instruments*

IFRS 9, as issued, reflects the first and second phases of the International Accounting Standards Board (the “**IASB**”) the IASB’s work on the replacement of IAS 39 and applies to classification and measurement of financial assets and financial liabilities as defined in IAS 39 and the new hedge accounting guidance. The standard was initially effective for annual periods beginning on or after 1 January 2013, but Amendments to IFRS 9 Mandatory Effective Date of IFRS 9 and Transition Disclosures, issued in December 2011 but not yet adopted by the EU, moved the mandatory effective date to 1 January 2018. In the next phases, the IASB will be addressing macro-hedging guidance and impairment of financial assets.

(B) *IFRS 14 - Regulatory Deferral Accounts*

IFRS 14, as issued, is to specify the financial reporting requirements for regulatory deferral account balances that arise when an entity provides goods or services to customers at a price or rate that is subject to rate regulation. The standard is effective for annual periods beginning on or after 1 January 2016.

(C) *IFRS 15 - Revenue from Contracts with Customers*

As the two main revenue recognition Standards, IAS 18 and IAS 11, have been difficult to apply to complex transactions and provided limited guidance on many important revenue topics such as accounting for multiple-element arrangements, and the US national standard-setter, the Financial Accounting Standards Board (FASB), initiated a joint project to clarify the principles for recognising revenue and to develop a common revenue standard for IFRS and US GAAP that would: (i) remove inconsistencies and weaknesses in previous revenue requirements; (ii) provide a more robust framework for addressing revenue issues; (iii) improve comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets; (iv) provide more useful information to users of financial statements through improved disclosure requirements; and (v) simplify the preparation of financial statements by reducing the number of requirements to which an entity must refer. The core principle of IFRS 15 is that an entity recognises revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for annual periods beginning on or after 1 January 2017

The Directors are considering the impact that of each of these standards and interpretations will have on the Indivior Group financial statements.

**Revenue recognition**

Revenue arising from the sale of goods is presented in the combined statements of income under Net revenues. Net revenues comprise 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 recognised when all 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 Indivior Group 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 Indivior Group.

The Indivior Group offers various types of price reductions on its products. In particular, products sold in the US are covered by various governmental programmes (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. A large portion of the rebates and chargeback incentives are offered

in the US. Cash discounts may also be granted for prompt payment. Returns, discounts, incentives and rebates, are estimated and recognised in the period in which the underlying sales are recognised as a reduction of net revenues.

These amounts are calculated as follows:

- (A) Provisions for rebates based on contract terms are estimated and accrued as each of the underlying sales transactions is recognised.
- (B) Provisions for price reductions under Government and State programmes, 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 recognised.
- (C) 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 Indivior Group 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 Indivior Group 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 Indivior Group believes that it has the ability to measure each of the above provisions reliably, using the following factors in developing its estimates:

- (A) the nature and patient profile of the underlying product;
- (B) the applicable regulations and/or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;
- (C) historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;
- (D) past experience and sales growth trends;
- (E) actual inventory levels in distribution channels, monitored by the Indivior Group using internal sales data and externally provided data;
- (F) the shelf life of the Indivior Group's products; and
- (G) market trends including competition, pricing and demand.

There may be adjustments to the provisions when the actual rebates are invoiced based on utilisation information submitted to the Indivior Group (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. Such estimates, however, involve judgements on aggregate future sales levels, distribution channel mix, distributor sales performance and market competition.

### **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, and 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.

### **Research and development**

Research expenditure on internal activities is charged to the combined 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:

- (A) 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;
- (B) there is an intention to complete the intangible asset or development project and use or sell it;
- (C) the Indivior Group has the ability to use the intangible asset or to sell it;
- (D) the intangible asset will generate probable future economic benefits;
- (E) there are available adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- (F) expenditure attributable to the intangible asset during its development is able to be reliably measured.

The Indivior Group 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.

Amounts capitalised are amortised over the useful life of the developed product.

### **Foreign currency translation**

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 in which they operate (the functional currency). The combined historical financial information is presented in USD, which is the Indivior 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 period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the combined statement of income.

	<i>Year ended 31 December</i>			<i>Six-month period ended 30 June</i>	
				<i>Unaudited</i>	
	<i>2011</i>	<i>2012</i>	<i>2013</i>	<i>2013</i>	<i>2014</i>
USD/GBP period-end exchange rate	1.5543	1.6255	1.6557	1.5422	1.6983
USD/GBP average exchange rate	1.6041	1.5852	1.5649	1.5445	1.6684

The amount of exchange differences recognised in the combined statement of income during the years ended 31 December 2013, 2012 and 2011 was \$3m, \$2m and \$(2)m, respectively. The amount of exchange differences recognised in the combined statement of income during the six-month period ended 30 June 2014 and 2013 was \$3m and \$1m (unaudited), respectively.

The financial statements of overseas entities, branches and operations are translated into USD 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 period.

The net effect of these translation adjustments is shown in the combined historical financial information as a component of accumulated other comprehensive income within invested capital.

### ***Cash and cash equivalents***

Cash and cash equivalents comprise cash balances and other deposits with a maturity of fewer than three months when deposited.

### ***Trade receivables***

Trade receivables are initially recognised at fair value and subsequently held at amortised cost, less provision for impairment. If there is objective evidence that the Indivior Group will not be able to collect the full amount of the receivable, a provision is recognised on the balance sheet. Significant financial difficulties of the debtor, probability that a debtor will enter bankruptcy or financial reorganisation, 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.

### ***Inventories***

Inventories are stated at the lower of cost or net realisable value. Cost comprises materials, direct labour and an appropriate portion of overhead expenses (based on normal operating capacity) and is determined on a first in, first out basis. Selling expenses and certain other overhead expenses are excluded. Net realisable value is the estimated selling price less applicable selling expenses.

Write-downs of inventory occur in the general course of business and are recognised in cost of sales.

### ***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 recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Indivior Group and the cost of the item can be reliably measured. Except for 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:

- (A) Property: not more than 50 years;
- (B) Owned plant and equipment: not more than 15 years.

In general, production plant and equipment and office equipment are written off over 10 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 statement of financial position date. Property, plant and equipment are reviewed for impairment if events or changes in circumstances indicate that the carrying amount may not be appropriate. 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 combined statement of income.

***Intangible assets***

Intangible assets are carried at cost less accumulated amortisation and accumulated impairment losses.

Payments made in respect of re-acquired distribution rights are capitalised when it is probable that the expected future economic benefits that are attributable to the asset will flow to the Indivior Group. The useful life of the re-acquired distribution rights is determined based on legal, regulatory, contractual, competitive, economic or other relevant factors. Re-acquired rights with finite lives are subsequently amortised using the straight-line method over their defined useful economic lives. Amortisation expense related to re-acquired distribution rights is included in Selling, distribution and administrative expenses.

Payments related to the acquisition of rights to a product or technology are capitalised if it is probable that future economic benefits from the asset will flow to the Indivior Group. Amortisation of the asset starts when it becomes available for use at which point the asset is amortised over its useful economic life. Prior to that date, the intangible asset is tested for impairment at least annually, irrespective of whether any indication of impairment exists.

***Impairment of assets***

Assets that have indefinite lives are tested annually for impairment. All assets are tested for impairment if there is an event or circumstance that indicates that their carrying value may not be recoverable. If an asset's carrying value exceeds its recoverable amount, an impairment loss is recognised in the combined statement of income. The recoverable amount is the higher of the asset's fair value less costs to sell and its value in use.

Value in use is calculated with reference to the future cash flows expected to be generated by an asset (or group of assets where cash flows are not identifiable to specific assets). The pre-tax discount rate used in the impairment test is based on a weighted average cost of capital for comparable companies operating in similar markets and geographies as the Indivior Group including, where appropriate, an adjustment for the specific risks associated with the relevant cash-generating unit. When an asset is written down to its recoverable amount the impairment loss is recognised in the combined statement of income in the year in which it is incurred. Should circumstances change which result in a reversal of a previous impairment, the value of the asset is increased and the reversal is recognised in the combined statement of income in the year in which it occurs. The increase in the carrying amount of the asset is limited to the amount which would have been recorded had no impairment been recognised in prior years.

***Trade and other payables***

These amounts represent liabilities for goods and services provided to the Indivior Group prior to the end of the financial year which are unpaid. The amounts are unsecured and are usually paid within 30–60 days of recognition. Trade payables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method.

***Provisions***

Provisions are recognised when the Indivior 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 valued at the present value of the Directors' best estimate of the expenditure required to settle the obligation at the statement of financial position date.

***Leases***

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are recognised as an expense in the combined statement of income on a straight-line basis over the lease term.

### ***Income taxes***

Income tax on the profit for the year comprises current and deferred tax. Income tax is recognised in the combined statement of income except to the extent that it relates to items recognised in other comprehensive income or directly in equity. In this case the tax is also recognised 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 statement of financial position date, and any adjustment to tax payable in respect of previous years.

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 combined historical financial information. 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 statement of financial position date and are expected to apply when the deferred tax asset or liability is settled. Deferred tax assets are recognised to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilised.

Deferred tax is provided on temporary differences arising on investments in subsidiaries except where the Indivior Group is able to control the timing of the reversal of the temporary difference 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.

### ***Invested capital***

Owners' net investment in the combined statements of financial position represents RB's historical investment in the Indivior Group, the Indivior Group's accumulated net earnings after income taxes, and the net effect of transactions with and allocations from RB.

### ***Segment Reporting***

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The Indivior Group's chief operating decision maker is the Indivior Group's Chief Executive Officer ("**CEO**"). The CEO reviews financial information presented on a combined basis for evaluating financial performance and allocating resources. Accordingly, the Indivior Group reports as a single reporting segment. The entity-wide disclosures as required by IFRS 8 are presented in note 4.

### ***Key estimates and judgements***

The preparation of combined historical financial information in accordance with IFRS requires management to make estimates and assumptions that 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 combined historical financial information are set out below.

### ***Provisions for returns, discounts, incentives and rebates***

The Indivior Group offers various types of price reductions on its products. In particular, products sold in the US are covered by various programmes (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 recognised in the period in which the underlying sales are recognised, as a reduction of sales revenue. The Indivior Group 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.

#### *Allocation of costs*

The Indivior Group receives various administrative services from RB. The combined historical financial information reflects allocated expenses associated with these centralised RB support functions and also includes other allocated overhead costs related to the support functions. These allocations are based on a number of measures including revenues, operating profit, headcount or other measures of the Indivior Group and RB. The use of alternative measures could result in different allocated expenses. For more details of cost allocations see note 17 to the combined historical financial information.

#### *Income taxes*

Judgement is required in determining the provision for income taxes. There are many transactions and calculations whose ultimate tax treatment is uncertain. The Indivior Group recognises liabilities for anticipated tax issues based on estimates of whether additional taxes are likely to be due. The Indivior Group recognises 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 6 to the combined historical financial information.

#### *Impairment of assets*

The Indivior Group assesses impairment of non-financial assets at each reporting date by evaluating conditions specific to the Indivior Group 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 Indivior Group 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, on past experience, and to the best of management's knowledge at the date of preparation of the financial information. The assessment of provisions can involve a series of complex judgements 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 realisation of those risks could differ from the Indivior Group's estimates.

### **4. Segment information**

As specified in note 3, 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, and therefore operates as one reportable segment. Revenues are attributed to countries based on the country where the sale originates.

The following table represents revenue attributed to countries based on the country where the sale originates:

	<i>Year ended 31 December</i>			<i>Six-month period ended 30 June Unaudited</i>	
	<i>2011 \$m</i>	<i>2012 \$m</i>	<i>2013 \$m</i>	<i>2013 \$m</i>	<i>2014 \$m</i>
Net Revenues:					
United States	969	1,072	950	485	443
United Kingdom	30	31	28	15	12
All other countries	255	236	238	118	119
	<u>1,254</u>	<u>1,339</u>	<u>1,216</u>	<u>618</u>	<u>574</u>

The table below lists the Indivior Group's 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.

	<i>Year ended 31 December</i>			<i>Six-month period ended 30 June</i>
	<i>2011 \$m</i>	<i>2012 \$m</i>	<i>2013 \$m</i>	<i>2014 \$m</i>
Non-current assets:				
United States	48	49	50	75
United Kingdom	98	81	57	45
	<u>146</u>	<u>130</u>	<u>107</u>	<u>120</u>

### **Significant customers**

Revenues for the years ended 2013, 2012 and 2011 and for the six-month periods ended 30 June 2014 and 2013 included revenues derived from significant customers that amount to 10% or more of the Indivior Group's revenues as follows (in percentages of total revenue):

	<i>Year ended 31 December</i>			<i>Six-month period ended 30 June Unaudited</i>	
	<i>2011</i>	<i>2012</i>	<i>2013</i>	<i>2013</i>	<i>2014</i>
Customer					
Customer A	34%	29%	24%	26%	22%
Customer B	28%	27%	28%	29%	28%
Customer C	6%	15%	18%	20%	20%

## 5. Operating costs and expenses information

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

	Year ended 31 December			Six-month period ended 30 June	
	2011	2012	2013	2013	2014
	\$m	\$m	\$m	\$m	\$m
Employee benefit expense	99	110	133	63	64
Depreciation and amortisation	25	27	28	13	14
Operating lease rentals	1	2	2	1	1

Included in employee benefit expense is key management compensation as set out below. Key management comprises the Indivior Group's leadership team.

	Year ended 31 December			Six-month period ended 30 June	
	2011	2012	2013	2013	2014
	\$m	\$m	\$m	\$m	\$m
Salaries and short-term employee benefits	2	3	5	3	5
Total key management compensation	2	3	5	3	5

The monthly average number of people employed by the Indivior Group, including Directors, in the period was:

	Year ended 31 December			Six-month period ended 30 June	
	2011	2012	2013	2013	2014
Operations	492	536	547	537	567
Management	74	91	102	79	78
Research and development	50	50	51	75	81
Average number of employees	616	677	700	691	726

## 6. Income taxes

Tax included in the combined statement of income

	Year ended 31 December			Six-month period ended 30 June	
	2011	2012	2013	2013	2014
	\$m	\$m	\$m	\$m	\$m
Current tax charge	305	251	224	114	101
Adjustments in respect of prior periods	(3)	–	(1)	–	–
Total current tax	302	251	223	114	101
Origination and reversal of temporary differences	(44)	26	(17)	(9)	(8)
Total deferred tax	(44)	26	(17)	(9)	(8)
Total tax included in the combined statement of income	258	277	206	105	93

The standard rate of corporation tax in the UK changed from 24% to 23% with effect from 1 April 2013. Accordingly, the Indivior Group's profits for the year ended 31 December 2013 are taxed at 23.25% (2012: 24.5%, 2011: 26.5%). UK income tax of \$94m (2012: \$108m, 2011: \$141m) is included within current tax and is calculated at 23.25% (2012: 24.5%, 2011: 26.5%) of the estimated assessable profit for the year. Taxation for other jurisdictions is calculated at the rates prevailing in the relevant jurisdictions.

The Finance Act 2013 contained legislation reducing the UK corporation tax rate from 23% to 21% from 1 April 2014, and from 21% to 20% from 1 April 2015, the effects of which are included in this financial information for periods ending after 2 July 2013, the date of substantive enactment of the Finance Act 2013.

Income tax expense for the six months to June 2014 is recognised based on management's best estimate of the weighted average annual income tax rate expected for the full financial year. The estimated average annual tax rate used for the six months ended 30 June 2014 is 28.5% (the estimated average annual tax rate used to prepare the comparative disclosures for the six months ended 30 June 2013 was 29.6%).

UK income tax for the six-month period ended 30 June 2014 of \$44m (30 June 2013: \$46m unaudited) is included within current tax.

### **Tax reconciliation**

The total tax charge for the year can be reconciled to the accounting profit as follows:

	Year ended 31 December			Six-month period ended 30 June Unaudited	
	2011 \$m	2012 \$m	2013 \$m	2013 \$m	2014 \$m
Profit before tax	872	884	695	355	326
Tax at the notional UK corporation tax rate (2014: 21.5%, 2013: 23.25%, 2012: 24.5%, 2011: 26.5%)	231	216	162	81	70
Effects of:					
Tax at rates other than the UK corporation tax rate	35	54	38	20	21
Adjustments to amounts carried in respect of unresolved tax matters	–	7	14	7	–
Adjustment in respect of prior periods	(3)	–	(1)	–	–
Other permanent differences	(5)	–	(7)	(3)	2
Total tax included in the combined statement of income	258	277	206	105	93

The tax charge is expected to be impacted by items in the nature of those listed above for the foreseeable future.

Following the enactment of legislation in the UK to reduce the corporation tax rate to 21% from 1 April 2014 and 20% from 1 April 2015, the total tax charge in 2013 includes the impact on the combined statement of income of calculating the UK deferred tax balances at the lower UK corporation tax rates. The impact of this rate change is a £nil reduction in the tax charge in the combined statement of income.

## Analysis of deferred tax

	Intangible assets \$m	Total \$m	
<b>Deferred tax liabilities</b>			
At 1 January 2011	3	3	
At 31 December 2011	3	3	
At 1 January 2012	3	3	
Charge for the year	1	1	
At 31 December 2012	4	4	
At 1 January 2013	4	4	
Charge for the year	2	2	
At 31 December 2013	6	6	
At 1 January 2014	6	6	
Charge for the period	–	–	
At 30 June 2014	6	6	
At 1 January 2013	4	4	
Charge for the period (unaudited)	1	1	
At 30 June 2013 (unaudited)	5	5	
	Accelerated tax depreciation \$m	Other temporary differences \$m	Total \$m
<b>Deferred tax assets</b>			
At 1 January 2011	34	10	44
Credit for the year	34	10	44
Exchange difference	(1)	–	(1)
At 31 December 2011	67	20	87
At 1 January 2012	67	20	87
Charge for the year	(16)	(9)	(25)
Exchange difference	3	–	3
At 31 December 2012	54	11	65
At 1 January 2013	54	11	65
Credit for the year	11	7	18
Exchange difference	2	–	2
At 31 December 2013	67	18	85
At 1 January 2014	67	18	85
Credit for the period	8	–	8
At 30 June 2014	75	18	93
At 1 January 2013	54	11	65
Credit for the period (unaudited)	9	–	9
At 30 June 2013 (unaudited)	63	11	74

Deferred tax assets and liabilities have been offset where they relate to income taxes levied by the same taxation authority. Unused tax credits of \$40m (2013: \$40m, 2012: \$54m, 2011: \$17m)

have not been recognised at 30 June 2014 as the likelihood of future economic benefit is not sufficiently assured. These assets will be recognised if utilisation of the losses and other temporary differences becomes reasonably certain. No deferred tax liability has been recognised 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 Indivior Group.

Tax charges in the combined historical financial information have been determined based on the tax charges recorded by RB companies in their statutory accounts as well as certain adjustments made for RB group consolidation purposes. The tax charges recorded in the combined statement of income have been affected by the taxation arrangements within the RB group and are not necessarily representative of the tax charges that would have been reported had the Indivior Group been an independent group. They are not necessarily representative of the tax charges that may arise in the future.

## 7. Intangible assets

	<i>Re-acquired distribution rights \$m</i>	<i>Technology and licences acquired \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2014	222	30	252
Exchange differences	6	–	6
Additions	–	24	24
At 30 June 2014	<u>228</u>	<u>54</u>	<u>282</u>
	<i>Re-acquired distribution rights \$m</i>	<i>Technology and licences acquired \$m</i>	<i>Total \$m</i>
At 1 January 2014	158	–	158
Exchange differences	4	–	4
Amortisation for the period	13	–	13
At 30 June 2014	<u>175</u>	<u>–</u>	<u>175</u>
Carrying value at 30 June 2014	<u>53</u>	<u>54</u>	<u>107</u>

	<i>Re-acquired distribution rights \$m</i>	<i>Technology and licences acquired \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2013	218	30	248
Exchange differences	4	–	4
At 31 December 2013	222	30	252
Accumulated amortisation:			
At 1 January 2013	131	–	131
Exchange differences	2	–	2
Amortisation for the year	25	–	25
At 31 December 2013	158	–	158
Carrying value at 31 December 2013	64	30	94
	<i>Re-acquired distribution rights \$m</i>	<i>Technology and licences acquired \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2012	207	30	237
Exchange differences	11	–	11
At 31 December 2012	218	30	248
Accumulated amortisation:			
At 1 January 2012	102	–	102
Exchange differences	5	–	5
Amortisation for the year	24	–	24
At 31 December 2012	131	–	131
Carrying value at 31 December 2012	87	30	117
	<i>Re-acquired distribution rights \$m</i>	<i>Technology and licences acquired \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2011	186	30	216
Exchange differences	–	–	–
Additions	21	–	21
At 31 December 2011	207	30	237
Accumulated amortisation:			
At 1 January 2011	79	–	79
Amortisation for the year	23	–	23
At 31 December 2011	102	–	102
Carrying value at 1 January 2011	107	30	137
Carrying value at 31 December 2011	105	30	135

**Re-acquired distribution rights**

Re-acquired distribution rights are amortised over a period from six to seven years. The useful life of the re-acquired distribution rights was determined based on legal, regulatory, contractual, competitive, economic or other relevant factors. Amortisation expense was included in selling, distribution and administrative expenses for all years presented.

**Technology and licences acquired**

The licences acquired are not amortised as the Indivior Group has not yet filed for regulatory approval for the related products as at 30 June 2014. The licences are assessed for impairment at the end of each reporting period.

In May 2014, the Indivior Group entered into an exclusive worldwide licensing agreement with XenoPort Inc. for the development and commercialisation of a clinical-stage oral product candidate called arbaclofen placarbil for the treatment of alcohol use disorders. The total additions recognised in the period amounted to \$24m.

**8. Property, plant and equipment**

	<i>Property \$m</i>	<i>Plant and equipment \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2014	2	35	37
Additions	–	1	1
At 30 June 2014	2	36	38
Accumulated depreciation:			
At 1 January 2014	1	23	24
Depreciation for the period	–	1	1
At 30 June 2014	1	24	25
Carrying value at 30 June 2014	1	12	13
	<i>Property \$m</i>	<i>Plant and equipment \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2013	2	32	34
Additions	–	3	3
At 31 December 2013	2	35	37
Accumulated depreciation:			
At 1 January 2013	1	20	21
Depreciation for the year	–	3	3
At 31 December 2013	1	23	24
Carrying value at 31 December 2013	1	12	13

	<i>Property \$m</i>	<i>Plant and equipment \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2012	2	26	28
Exchange differences		3	3
Additions	–	3	3
At 31 December 2012	2	32	34
Accumulated depreciation:			
At 1 January 2012	–	17	17
Depreciation for the year	1	2	3
Exchange differences	–	1	1
At 31 December 2012	1	20	21
Carrying value at 31 December 2012	1	12	13

	<i>Property \$m</i>	<i>Plant and equipment \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2011	2	22	24
Additions	–	4	4
At 31 December 2011	2	26	28
Accumulated depreciation:			
At 1 January 2011	–	15	15
Exchange differences	–	–	–
Depreciation for the year	–	2	2
At 31 December 2011	–	17	17
Carrying value at 1 January 2011	2	7	9
Carrying value at 31 December 2011	2	9	11

Depreciation expense was included in selling, distribution and administrative expense for all periods presented.

## 9. Inventories

	<i>31 December</i>			<i>30 June</i>
	<i>2011 \$m</i>	<i>2012 \$m</i>	<i>2013 \$m</i>	<i>2014 \$m</i>
Raw materials, stores and consumables	6	8	8	7
Work in progress	14	11	15	16
Finished goods	12	15	13	13
Total inventories	32	34	36	36

During the six-month period ended 30 June 2014, the cost of inventories recognised as an expense and included as cost of sales amounted to \$48m (2013: \$103m, 2012: \$91m, 2011: \$78m). This includes inventory write-offs and losses of \$3m (2013: \$8m, 2012: \$3m, 2011: \$nil). The Indivior Group inventory provision at 30 June 2014 was \$4m (2013: \$5m, 2012: \$2m, 2011: \$2m).

## 10. Trade and other receivables

	31 December			30 June
	2011 \$m	2012 \$m	2013 \$m	2014 \$m
Non-current assets:				
Other receivables	–	17	12	5
Total non-current assets	–	17	12	5
Current assets:				
Trade receivables	265	282	177	190
Provision for impairment	(7)	(9)	(8)	(8)
Net trade receivables	258	273	169	182
Prepayments	17	17	14	11
Other receivables	1	–	2	3
Total trade and other receivables	276	290	185	196

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.

Other receivables consist of prepaid expense in relation to the Indivior Group's exclusive manufacturing agreement with MSRX.

As at 30 June 2014, trade receivables of \$19m (2013: \$20m, 2012: \$23m, 2011: \$21m) were past due but not impaired. The ageing analysis of trade receivables past due but not impaired is as follows:

	31 December			30 June
	2011 \$m	2012 \$m	2013 \$m	2014 \$m
Up to 3 months	13	11	9	7
Over 3 months	8	12	11	12
	21	23	20	19

As at 30 June 2014 trade receivables of \$12m (2013: \$11m, 2012: \$12m, 2011: \$8m) were considered to be impaired. The amount of provision at 30 June 2014 was \$8m (2013: \$8m, 2012: \$9m, 2011: \$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:

	31 December			30 June
	2011 \$m	2012 \$m	2013 \$m	2014 \$m
Up to 3 months	1	1	1	1
Over 3 months	7	11	10	11
	8	12	11	12

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 other

receivables do not contain impaired assets. They consist of items including reclaimable turnover tax and are from a broad range of countries within the Indivior Group.

The carrying amounts of total trade and other receivables are denominated in the following currencies.

	31 December			30 June
	2011	2012	2013	2014
	\$m	\$m	\$m	\$m
Sterling	8	7	7	8
US dollar	205	226	126	136
Euro	40	37	36	36
Other currencies	23	20	16	16
	<u>276</u>	<u>290</u>	<u>185</u>	<u>196</u>

The maximum exposure to credit risk at the period end is the carrying value of each class of receivable mentioned above. The Indivior Group does not hold any collateral as security.

## 11. Financial instruments and financial risk management

The Indivior Group's financial assets and liabilities include cash and cash equivalents, trade receivables and trade payables as set out in note 12, 10 and 16 respectively. Management have assessed that, as at 30 June 2014, 31 December 2013, 2012 and 2011, the fair values of the cash and cash equivalents, trade receivables and trade payables approximate their carrying amounts largely due to the short-term maturities of these instruments.

### *Financial risk management*

Financial risk management of the Indivior Group is mainly exercised and monitored at a RB Group level. RB has in place a risk management programme that uses foreign currency financial instruments to limit the impact of the effects of changes in foreign currency exchange rates on the financial performance of RB. The RB Group's financing and financial risk management activities are centralised into Group Treasury which manages financial exposures of the RB Group on account of changes in interest rates, credit risks and liquidity centrally in a manner consistent with underlying business risks.

### *Foreign exchange risk management*

The Indivior Group operates internationally and is exposed to foreign exchange risk arising from various currency exposures. Foreign exchange risk arises from future commercial transactions, recognised assets and liabilities and net investments in foreign operations.

The Indivior 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.

### *Capital risk management*

Capital risk management of the Indivior Group is also mainly exercised and monitored at the RB Group level. RB considers capital to be net debt plus total equity. The objectives for managing capital are to safeguard the RB Group's ability to continue as a going concern, in order to provide returns for shareholders. In addition, the Group Treasury function monitors net debt and seeks to pay down net debt using cash generated by the business to maintain an appropriate level of financial flexibility.

## 12. Cash and cash equivalents

The carrying amounts of cash and cash equivalents that include only cash held at bank accounts are denominated in the following currencies.

	31 December			30 June
	2011 \$m	2012 \$m	2013 \$m	2014 \$m
US dollar	4	22	1	7
Euro	1	2	4	3
Other currencies	2	1	2	1
	<u>7</u>	<u>25</u>	<u>7</u>	<u>11</u>

The maximum exposure to credit risk at the period end is the carrying value of cash and cash equivalents mentioned above.

## 13. Provisions for liabilities and charges

	Sales returns \$m	Rebates \$m	Other \$m	Total \$m
At 1 January 2011	10	105	2	117
Charge for the year	15	334	28	377
Utilised during the year	(15)	(253)	(26)	(294)
At 31 December 2011	<u>10</u>	<u>186</u>	<u>4</u>	<u>200</u>
At 1 January 2012	10	186	4	200
Charge for the year	14	411	54	479
Utilised during the year	(7)	(332)	(31)	(370)
At 31 December 2012	<u>17</u>	<u>265</u>	<u>27</u>	<u>309</u>
At 1 January 2013	17	265	27	309
Charge for the year	51	374	69	494
Utilised during the year	(37)	(372)	(48)	(457)
At 31 December 2013	<u>31</u>	<u>267</u>	<u>48</u>	<u>346</u>
At 1 January 2014	31	267	48	346
Charge for the period	7	206	45	258
Utilised during the period	(21)	(206)	(45)	(272)
At 30 June 2014	<u>17</u>	<u>267</u>	<u>48</u>	<u>332</u>

At 30 June 2014 "Other" provisions primarily consist of legal provisions in the amount of \$41m (2013: \$41m, 2012: \$16m, 2011: \$nil) 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.

## 14. 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.

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 and the Attorney General of the State of New York commenced non-public investigations of RB, RBP and various other entities in the RB Group focusing on business practices relating to Suboxone Film, Suboxone Tablet and Subutex Tablet, including alleged involvement in a scheme to delay FDA approval of generic versions of Suboxone Tablet. RBP has responded to both the FTC and to the Attorney General of the State of New York by producing documents and other information. The investigations are ongoing, and as yet no decision has been made by either agency on whether to pursue any legal action for enforcement.

In December 2013, the USAO-VAW executed a search warrant on RBP's headquarters in Richmond and conducted searches of the homes of four field-based employees. The USAO-VAW has since served a number of subpoenas relating to Suboxone Film, Suboxone Tablet, Subutex Tablet, buprenorphine and any real or potential competitor, among other issues. The investigation is ongoing and RBP is in the process of responding to the USAO-VAW by producing documents and other information.

Given the limited information available to the Indivior Group regarding the foregoing civil and criminal investigations, 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.

## 15. Commitments

### *Operating lease commitments*

The following table sets out the total future minimum lease payments under non-cancellable operating leases.

	31 December			30 June
	2011 \$m	2012 \$m	2013 \$m	2014 \$m
Property, plant and equipment:				
Between 1 and 5 years	1	1	4	4
After 5 years	3	3	–	–
	<u>4</u>	<u>4</u>	<u>4</u>	<u>4</u>

## 16. Trade and other payables

	31 December			30 June
	2011 \$m	2012 \$m	2013 \$m	2014 \$m
Current:				
Trade payables	36	35	54	52
Social security and other taxes	5	4	4	7
Accrued expenses	63	61	69	63
Other payables	1	3	2	1
Total trade and other payables	<u>105</u>	<u>103</u>	<u>129</u>	<u>123</u>

The carrying amounts of total trade and other payables are denominated in the following currencies.

	31 December			30 June
	2011 \$m	2012 \$m	2013 \$m	2014 \$m
Sterling	38	32	31	26
US dollar	44	53	78	76
Other currencies	23	18	20	21
	<u>105</u>	<u>103</u>	<u>129</u>	<u>123</u>

## 17. Related party transactions and owners' net investment

### **Parent company service charges and corporate allocations**

Historically, RB has provided services to and funded certain expenses for 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. The combined statements of income also include a portion of RB's group costs relating to its operations as a public company, including, but not limited to, corporate governance and board oversight, not historically allocated to the Indivior Group. These service charges and corporate expense allocations are based on a number of utilisation 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. This combined historical financial information does not necessarily include all the expenses that would have been incurred had the Indivior Group been a separate, stand-alone entity. As such, the financial information herein may not necessarily reflect the combined financial position, results of operations and cash flows of the Indivior Group in the future or what they would have been had the Indivior Group been a separate, stand-alone entity during the periods presented. Management believes that the methods used to allocate expenses to the Indivior Group are reasonable.

The following table sets out the expense included in the combined statement of income for corporate allocations.

	Year ended 31 December			Six-month period ended 30 June Unaudited	
	2011 \$m	2012 \$m	2013 \$m	2013 \$m	2014 \$m
Corporate allocations included in: Selling, distribution and administrative expenses	<u>44</u>	<u>54</u>	<u>55</u>	<u>41</u>	<u>15</u>

**Owners' net investment**

Net transfers to owners are included within Owners' net investment on the combined statements of invested capital. The components of the net transfers to Owners as of 30 June 2014, 31 December 2013, 2012 and 2011 are as follows:

	31 December			30 June
	2011	2012	2013	2014
	\$m	\$m	\$m	\$m
Intercompany dividends	–	(100)	(239)	–
Cash pooling and general financing activities	(848)	(958)	(728)	(332)
Corporate allocations, including income tax provision	303	338	267	111
Total net transfers to owners	(545)	(720)	(700)	(221)

RB uses a centralised approach to cash management and financing of its operations. The majority of the Indivior Group's cash is transferred to RB daily and RB funds the Indivior Group's operating and investing activities as needed. Cash transfers to and from RB's cash management accounts are reflected in "Owners' net investment".

Cash and cash equivalents in the presented combined statements of financial position represent cash held locally by entities included in the Indivior Group's combined historical financial information. Transfers of cash to and from RB's cash management system are reflected as a component of Owners' net investment on the combined statements of financial position. All significant intercompany transactions between the Indivior Group and RB have been included in this combined historical financial information and are considered to be effectively settled for cash in the combined historical financial information at the time the transaction is recorded. The total net effect of the settlement of these intercompany transactions is reflected in the combined statements of cash flow as a financing activity and in the combined statements of financial position as Owners' net investment.

**18. Post-balance sheet events**

Subsequent to the period end, the RB Group announced its intention to demerge the Indivior Group, and on 15 November 2014 RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. The Company expects to use approximately \$500 million from the proceeds of the term loan financing to pay a dividend to RB.

**SECTION C: PRICEWATERHOUSECOOPERS LLP'S REPORT ON THE UNAUDITED COMBINED CONDENSED INTERIM FINANCIAL STATEMENTS FOR THE THREE AND NINE MONTHS ENDED 30 SEPTEMBER 2014**



**Independent review report to Indivior plc**

**Our conclusion**

We have reviewed the unaudited combined condensed interim financial statements, set out in Section D of Part XII (*Historical Financial Information*) of the prospectus (the “**Prospectus**”) of the pharmaceuticals business of Reckitt Benckiser Group plc (“**Indivior Group**”) for the three and nine months ended 30 September 2014. Based on our review, nothing has come to our attention that causes us to believe that the unaudited combined condensed interim financial statements are not prepared, in all material respects, in accordance with International Accounting Standard 34 as adopted by the European Union.

This conclusion is to be read in the context of what we say in the remainder of this report.

**What we have reviewed**

The unaudited combined condensed interim financial statements, which are prepared by Indivior Group, comprise:

- the unaudited combined condensed statements of income and statements of comprehensive income for the three and nine months ended 30 September 2014;
- the unaudited combined condensed statement of financial position as at 30 September 2014;
- the unaudited combined condensed statements of invested capital as at 30 September 2014;
- the unaudited combined condensed statement of cash flows for the three and nine months ended 30 September 2014; and
- the explanatory notes to the unaudited combined condensed interim financial statements.

As disclosed in note 2, the financial reporting framework that has been applied in the preparation of the financial information set out in Section B of Part XII (the “**Combined IFRS Financial Information Table**”) is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union.

The unaudited combined condensed interim financial statements included in Section D of Part XII (*Historical Financial Information*) has been prepared in accordance with International Accounting Standard 34, ‘Interim Financial Reporting’, as adopted by the European Union.

*PricewaterhouseCoopers LLP, 1 Embankment Place, London, WC2N 6RH*  
T: +44 (0) 2075 835 000, F: +44 (0) 2072 124 652, [www.pwc.co.uk](http://www.pwc.co.uk)

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### ***What a review of unaudited combined condensed interim financial statements involves***

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

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

Our work has not been carried out in accordance with auditing standards generally accepted in the United States of America or auditing standards of the Public Company Accounting Oversight Board (United States) and accordingly should not be relied upon as if it had been carried out in accordance with those standards.

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### ***Responsibilities for the unaudited combined condensed interim financial statements and the review***

#### ***Our responsibilities and those of the directors***

The Prospectus, including the unaudited combined condensed interim financial statements, is the responsibility of, and has been approved by, the directors of Indivior plc (the “**Directors**”). The Directors are responsible for preparing the Prospectus in accordance with the Prospectus Rules of the United Kingdom’s Financial Conduct Authority.

Our responsibility is to express to the company a conclusion on the unaudited combined condensed interim financial statements included in the Prospectus based on our review. This report, including the conclusion, has been prepared for and only for Indivior plc for the purpose of complying with the Prospectus Rules and for no other purpose.

Save for any responsibility which we may have to those persons to whom this report is expressly addressed and for any responsibility arising under item 5.5.3R(2)(f) of the Prospectus Rules to any person as and to the extent there provided, to the fullest extent permitted by law we do not assume any responsibility and will not accept any liability to any other person for any loss suffered by any such other person as a result of, arising out of, or in connection with this report or our statement, required by and given solely for the purposes of complying with item 23.1 of Annex I to the PD Regulation, consenting to its inclusion in the Prospectus.

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#### ***Declaration***

For the purposes of Prospectus Rule 5.5.3R(2)(f) we are responsible for this report as part of the Prospectus and declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Prospectus in compliance with item 1.2 of Annex I to the PD Regulation.

**SECTION D: UNAUDITED COMBINED CONDENSED INTERIM FINANCIAL STATEMENTS FOR THE THREE AND NINE MONTHS ENDED 30 SEPTEMBER 2014**

**UNAUDITED COMBINED CONDENSED INTERIM STATEMENTS OF INCOME**

		<i>Three months ended 30 September Unaudited</i>		<i>Nine months ended 30 September Unaudited</i>	
		<i>2013 \$m</i>	<i>2014 \$m</i>	<i>2013 \$m</i>	<i>2014 \$m</i>
Net revenues	4	295	270	913	844
Cost of sales		(25)	(24)	(78)	(73)
<b>Gross profit</b>		<b>270</b>	<b>246</b>	<b>835</b>	<b>771</b>
Selling, distribution and administrative expenses		(81)	(92)	(266)	(250)
Research and development expenses		(15)	(22)	(40)	(63)
<b>Profit on ordinary activities before taxation</b>		<b>174</b>	<b>132</b>	<b>529</b>	<b>458</b>
Taxation	6	(52)	(39)	(157)	(132)
<b>Net income</b>		<b>122</b>	<b>93</b>	<b>372</b>	<b>326</b>

**UNAUDITED COMBINED CONDENSED INTERIM STATEMENTS OF COMPREHENSIVE INCOME**

		<i>Three months ended 30 September Unaudited</i>		<i>Nine months ended 30 September Unaudited</i>	
		<i>2013 \$m</i>	<i>2014 \$m</i>	<i>2013 \$m</i>	<i>2014 \$m</i>
<b>Net income</b>		<b>122</b>	<b>93</b>	<b>372</b>	<b>326</b>
<b>Other comprehensive income</b>					
Other comprehensive income to be reclassified to profit or loss in subsequent periods					
Currency translation	5	(1)	(1)	(1)	–
<b>Total other comprehensive income/(loss)</b>	<b>5</b>	<b>(1)</b>	<b>(1)</b>	<b>(1)</b>	<b>–</b>
<b>Total comprehensive income</b>		<b>127</b>	<b>92</b>	<b>371</b>	<b>326</b>

# **UNAUDITED COMBINED CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION**

		As at 31 December	As at 30 September Unaudited
	Notes	2013 \$m	2014 \$m
<b>Assets</b>			
Non-current assets:			
Intangible assets	7	94	98
Property, plant and equipment		13	12
Deferred tax assets	6	79	89
Other receivables	8	12	4
<b>Total non-current assets</b>		<u>198</u>	<u>203</u>
Current assets:			
Inventories		36	45
Trade and other receivables	8	185	196
Current tax receivable		–	–
Cash and cash equivalents	9	7	32
<b>Total current assets</b>		<u>228</u>	<u>273</u>
<b>Total Assets</b>		<u>426</u>	<u>476</u>
<b>Liabilities and invested capital</b>			
Current liabilities:			
Provisions for liabilities and charges	10	(305)	(308)
Trade and other payables		(129)	(126)
Current tax liabilities		(17)	(46)
<b>Total current liabilities</b>		<u>(451)</u>	<u>(480)</u>
Non-current liabilities:			
Provisions for liabilities and charges	10	(41)	(41)
<b>Total non-current liabilities</b>		<u>(41)</u>	<u>(41)</u>
<b>Total Liabilities</b>		<u>(492)</u>	<u>(521)</u>
<b>Net Liabilities</b>		<u>(66)</u>	<u>(45)</u>
Invested capital:			
Owners' net investment		(69)	(48)
Accumulated other comprehensive income		3	3
<b>Total invested capital</b>		<u>(66)</u>	<u>(45)</u>

# **UNAUDITED COMBINED CONDENSED INTERIM STATEMENTS OF INVESTED CAPITAL**

		<i>Owners' net investment</i>	<i>Accumulated other comprehensive income Unaudited</i>	<i>Total invested capital</i>
	<i>Notes</i>	<i>\$m</i>	<i>\$m</i>	<i>\$m</i>
<b>Balance at 1 January 2014</b>		(69)	3	(66)
Net income (unaudited)		326	–	326
Other comprehensive income (unaudited)		–	–	–
Net transfers to owners (unaudited)	12	(305)	–	(305)
<b>Balance at 30 September 2014 (unaudited)</b>		<u>(48)</u>	<u>3</u>	<u>(45)</u>
<b>Balance at 30 June 2014</b>		(57)	4	(53)
Net income (unaudited)		93	–	93
Other comprehensive loss (unaudited)		–	(1)	(1)
Net transfers to owners (unaudited)	12	(84)	–	(84)
<b>Balance at 30 September 2014 (unaudited)</b>		<u>(48)</u>	<u>3</u>	<u>(45)</u>

# **UNAUDITED COMBINED CONDENSED INTERIM STATEMENTS OF CASH FLOWS**

		<i>Three months ended 30 September Unaudited</i>		<i>Nine months ended 30 September Unaudited</i>	
	<i>Notes</i>	<i>2013 \$m</i>	<i>2014 \$m</i>	<i>2013 \$m</i>	<i>2014 \$m</i>
<b>Cash Flows from Operating Activities:</b>					
Profit on ordinary activities before taxation		174	132	529	458
Adjustments to reconcile net cash provided by operating activities:					
Depreciation and amortisation		7	6	20	20
Provisions for liabilities and charges		(20)	17	59	5
Changes in assets and liabilities					
Trade and other receivables		10	1	92	(3)
Inventories		(5)	(9)	(2)	(9)
Trade and other payables		12	3	15	(3)
Cash provided by operating activities		<u>178</u>	<u>150</u>	<u>713</u>	<u>468</u>
Tax paid		<u>(28)</u>	<u>(31)</u>	<u>(80)</u>	<u>(54)</u>
Net cash provided by operating activities		<u>150</u>	<u>119</u>	<u>633</u>	<u>414</u>
<b>Cash Flows from Investing Activities:</b>					
Purchase of property, plant and equipment		–	–	–	(1)
Purchase of intangible assets		–	–	–	(24)
Net cash used in investing activities		<u>–</u>	<u>–</u>	<u>–</u>	<u>(25)</u>
<b>Cash Flows from Financing Activities:</b>					
Net transfers to owners		<u>(144)</u>	<u>(98)</u>	<u>(647)</u>	<u>(364)</u>
Net cash used in financing activities		<u>(144)</u>	<u>(98)</u>	<u>(647)</u>	<u>(364)</u>
Net increase/(decrease) in cash and cash equivalents		6	21	(14)	25
Cash and cash equivalents at beginning of year		<u>5</u>	<u>11</u>	<u>25</u>	<u>7</u>
<b>Cash and cash equivalents at end of year</b>	<b>9</b>	<u>11</u>	<u>32</u>	<u>11</u>	<u>32</u>

**NOTES TO THE UNAUDITED CONDENSED INTERIM FINANCIAL STATEMENTS**  
**(Expressed in millions of US dollars, unless otherwise stated)**

**1. General information**

The principal business of the pharmaceuticals business of Reckitt Benckiser Group PLC (the “**Indivior Group**”) is the development, manufacture and sale of buprenorphine-based prescription drugs for the treatment of opioid dependence.

The board of directors of RB announced on 28 July 2014 its intention to separate the Indivior Business from RB. The separation is effected by way of a demerger of the pharmaceuticals business to a new company.

The combined historical financial information includes the financial results of the following subsidiaries which will represent the significant subsidiary undertakings and associated undertakings of the Company after the Demerger Effective time:

<u>Name</u>	<u>Country of incorporation or registration</u>	<u>Proportion of ownership interest</u>	<u>Principal activity</u>
RBP Global Holdings Ltd	England and Wales	100%	Holding and Finance company
RBP US Holdings Inc	US	100%	Holding and Finance company
RB Pharmaceuticals Pty Ltd	Australia	100%	Operating company
RB Pharmaceuticals Ltd	England and Wales	100%	Operating company
Reckitt Benckiser Pharmaceuticals Healthcare South Africa (Pty) Ltd	South Africa	100%	Operating company
RBP Finance LLC	US	100%	Finance company
RB Pharmaceuticals (EU) Ltd	England and Wales	100%	Operating company
RB Pharmaceuticals Ltd Hellas Branch	Greece	100%	Operating company
Reckitt Benckiser Pharmaceuticals France SAS	France	100%	Operating company
RB Pharmaceuticals (Italia) Srl	Italy	100%	Operating company
RB Pharmaceuticals (Deutschland) GmbH	Germany	100%	Operating company
Reckitt Benckiser Pharmaceuticals Solutions Inc.	US	100%	Operating company
Reckitt Benckiser Pharmaceuticals Inc.	US	100%	Operating company

**2. Basis of preparation**

The Indivior Group represents a combined reporting entity comprising the assets and liabilities used in managing and operating the pharmaceuticals business of RB, including legal entities, branches and operations. The combined historical financial information has been presented on a stand-alone basis and have been carved out from the consolidated financial statements of RB by applying the principles underlying the consolidation procedures of IFRS 10 “Consolidated Financial Statements” (“IFRS 10”) for each of the three and nine months ended 30 September 2013 and 2014. The Indivior Group’s combined historical financial information may not be indicative of the Indivior Group’s future performance and do not necessarily reflect what the

results of operations, financial position and cash flows would have been had it operated as a stand-alone, publicly traded group during the periods presented.

The combined condensed interim financial information has been prepared in accordance with IAS 34, 'Interim financial reporting', as adopted by the European Union. The combined condensed interim financial statements should be read in conjunction with the combined historical financial statements for the years ended 31 December 2013, 2012 and 2011 and each for the six months ended 30 June 2014 and 2013, which have been prepared in accordance with the basis of preparation in note 2 to those financial statements and IFRSs as adopted by the European Union.

### 3. Summary of significant accounting policies

As required by the Prospectus Directive Regulation rules, the combined historical financial information has been prepared based on those standards that will be effective for the Indivior Group in its next set of financial statements for the year ending 31 December 2014, and using the principal accounting policies outlined below.

The combined historical financial information has been prepared under the historical cost convention unless otherwise determined by IFRS.

With the exception of the sections below, the accounting policies adopted in the preparation of the combined condensed historical financial statements are consistent with those described in 31 December 2013 financial statements.

#### **Foreign currency translation**

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 in which they operate (the functional currency). The combined historical financial information is presented in USD, which is the Indivior Group's presentation and functional 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 period end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the combined statement of income.

	<i>Three months ended 30 September Unaudited</i>		<i>Nine months ended 30 September Unaudited</i>		<i>Year ended 31 December</i>
	<i>2013</i>	<i>2014</i>	<i>2013</i>	<i>2014</i>	<i>2013</i>
USD/GBP period end exchange rate	1.6081	1.6318	1.6081	1.6318	1.6557
USD/GBP average exchange rate	1.5454	1.6702	1.6702	1.6702	1.5649

The amount of exchange differences recognised in the combined statement of income during the three and nine months ended 30 September 2013 and 2014 was \$(2)m, \$2m and \$(3)m and \$(1)m, respectively.

The financial statements of overseas entities, branches and operations are translated into USD 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 period.

The net effect of these translation adjustments is shown in the combined historical financial information as a component of accumulated other comprehensive income within invested capital.

#### 4. Segment information

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, and therefore operates as one reportable segment. Revenues are attributed to countries based on the country where the sale originates.

The following table represents revenue attributed to countries based on the country where the sale originates:

	<i>Three months ended 30 September Unaudited</i>		<i>Nine months ended 30 September Unaudited</i>	
	<i>2013 \$m</i>	<i>2014 \$m</i>	<i>2013 \$m</i>	<i>2014 \$m</i>
Net Revenues:				
United States	232	204	717	647
United Kingdom	9	9	24	21
All other countries	54	57	172	176
	<u>295</u>	<u>270</u>	<u>913</u>	<u>844</u>

The table below lists the Indivior Group's 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.

	<i>As at 31 December 2013 \$m</i>	<i>As at 30 September 2014 Unaudited \$m</i>
Non-current assets:		
United States	50	75
United Kingdom	57	35
	<u>107</u>	<u>110</u>

#### Significant customers

Revenues for the three and nine months ended 30 September 2013 and 2014 included revenues derived from significant customers that amount to 10% or more of the Indivior Group's revenues as follows (in percentages of total revenue):

	<i>Three months ended 30 September Unaudited</i>		<i>Nine months ended 30 September Unaudited</i>	
	<i>2013</i>	<i>2014</i>	<i>2013</i>	<i>2014</i>
Customer A	21%	23%	24%	22%
Customer B	26%	27%	28%	27%
Customer C	15%	16%	18%	19%

## 5. Operating costs and expenses information

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

	<i>Three months ended 30 September Unaudited</i>		<i>Nine months ended 30 September Unaudited</i>	
	<i>2013 \$m</i>	<i>2014 \$m</i>	<i>2013 \$m</i>	<i>2014 \$m</i>
Employee benefit expense	37	40	100	104
Depreciation and amortisation	7	6	20	20
Operating lease rentals	–	–	1	1

## 6. Income taxes

Tax included in the combined statement of income.

Income tax expense is recognised based on management's best estimate of the weighted average annual tax rate expected for the full financial year. The estimated average rate used for the nine-month period to 30 September 2014 is 28.8% (29.7% 30 September 2013).

Tax charges in the combined historical financial information have been determined based on the tax charges recorded by RB companies in their statutory accounts as well as certain adjustments made for RB group consolidation purposes. The tax charges recorded in the combined statement of income have been affected by the taxation arrangements within the RB Group and are not necessarily representative of the tax charges that would have been reported had the Company been an independent group. They are not necessarily representative of the tax charges that may arise in the future.

## 7. Intangible assets

	<i>Re-acquired distribution rights \$m</i>	<i>Technology and licences acquired \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2013	218	30	248
Exchange differences	4	–	4
At 31 December 2013	222	30	252
Accumulated amortisation:			
At 1 January 2013	131	–	131
Exchange differences	2	–	2
Amortisation for the year	25	–	25
At 31 December 2013	158	–	158
Carrying value at 31 December 2013	64	30	94

	<i>Re-acquired distribution rights \$m</i>	<i>Technology and licences acquired \$m</i>	<i>Total \$m</i>
Cost:			
At 1 January 2014	222	30	252
Exchange differences (unaudited)	(1)	–	(1)
Additions (unaudited)	–	24	24
At 30 September 2014 (unaudited)	<u>221</u>	<u>54</u>	<u>275</u>
Accumulated amortisation:			
At 1 January 2014	158	–	158
Exchange differences (unaudited)	1	–	1
Amortisation for the period (unaudited)	18	–	18
At 30 September 2014 (unaudited)	<u>177</u>	<u>–</u>	<u>177</u>
Carrying value at 30 September 2014 (unaudited)	<u>44</u>	<u>54</u>	<u>98</u>

## 8. Trade and other receivables

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.

Other receivables consist of prepaid expense in relation to the Indivior Group's exclusive manufacturing agreement with Monosol.

As of 30 September 2014 trade receivables of \$4m (2013: \$2m) were past due but not impaired.

## 9. Cash and cash equivalents

The carrying amounts of cash and cash equivalents that include only cash held at bank accounts are denominated in the following currencies.

	<i>As at 31 December 2013 \$m</i>	<i>As at 30 September Unaudited 2014 \$m</i>
US dollar	1	20
Euro	4	9
Other currencies	2	3
	<u>7</u>	<u>32</u>

The maximum exposure to credit risk at the period end is the carrying value of cash and cash equivalents mentioned above.

## 10. Provisions for liabilities and charges

	<i>Sales returns \$m</i>	<i>Rebates \$m</i>	<i>Other \$m</i>	<i>Total \$m</i>
At 1 January 2013	17	265	27	309
Charge for the year	51	374	69	494
Utilised during the year	(37)	(372)	(48)	(457)
At 31 December 2013	31	267	48	346
At 1 January 2014	31	267	48	346
Charge for the year (unaudited)	10	305	67	382
Utilised during the year (unaudited)	(18)	(294)	(67)	(379)
At 30 September 2014 (unaudited)	23	278	48	349

At 30 September 2014 Other provisions primarily consist of legal provisions in the amount of \$41m (2013: \$41m) 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.

## 11. Commitments

### *Operating lease commitments*

The total future minimum lease payments under non-cancellable operating leases were \$4m at 30 September 2014.

## 12. Related party transactions and owners' net investment

### *Parent company service charges and corporate allocations*

Historically, Reckitt Benckiser has provided services to and funded certain expenses for 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. The combined statements of income also include a portion of Reckitt Benckiser's group costs relating to its operations as a public company, including, but not limited to, corporate governance and board oversight, not historically allocated to the Indivior Group. These service charges and corporate expense allocations are based on a number of utilisation 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. This combined historical financial information does not necessarily include all the expenses that would have been incurred had the Indivior Group been a separate, stand-alone entity. As such, the financial information herein may not necessarily reflect the combined financial position, results of operations and cash flows of the Indivior Group in the future or what they would have been had the Indivior Group been a separate, stand-alone entity during the periods presented. Management believes that the methods used to allocate expenses to the Indivior Group are reasonable.

The following table sets out the expense included in the combined statement of income for corporate allocations.

	<i>Nine months ended 30 September 2013 Unaudited \$m</i>	<i>Nine months ended 30 September 2014 Unaudited \$m</i>
Corporate allocations included in:		
Selling, distribution and administrative expenses	48	26
	<u>48</u>	<u>26</u>

### **Owners' net investment**

Net transfers to Owners are included within Owners' net investment on the combined statements of Invested capital. The components of the net transfers to Owners as of 30 September 2013 and 2014 and 31 December 2013 are as follows:

	<i>As at 31 December 2013 \$m</i>	<i>As at 30 September 2014 Unaudited \$m</i>
Intercompany dividends	(239)	(24)
Cash pooling and general financing activities	(728)	(442)
Corporate allocations, including income tax provision	267	161
Total net transfers to owners	<u>(700)</u>	<u>(305)</u>

### **13. Seasonality**

Demand for the Indivior Group's products is not subject to significant seasonal fluctuations.

### **14. 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.

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 and the Attorney General of the State of New York commenced non-public investigations of RB, RBP and various other entities in the RB Group focusing on business practices relating to Suboxone Film, Suboxone Tablet and Subutex Tablet, including alleged involvement in a scheme to delay FDA approval of generic versions of Suboxone Tablet. RBP has responded to both the FTC and to the Attorney General of the State of New York by producing documents and other information. The investigations are ongoing, and as yet no decision has been made by either agency on whether to pursue any legal action for enforcement.

In December 2013, the USAO-VAW executed a search warrant on RBP's headquarters in Richmond and conducted searches of the homes of four field-based employees. The USAO-VAW has since served a number of subpoenas relating to Suboxone Film, Suboxone Tablet, Subutex Tablet, buprenorphine and any real or potential competitor, among other issues. The

investigation is ongoing and RBP is in the process of responding to the USAO-VAW by producing documents and other information.

Given the limited information available to the Indivior Group regarding the foregoing civil and criminal investigations, 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.

#### **15. Post-balance sheet events**

Subsequent to the period end, the RB Group announced its intention to demerge the Indivior Group, and on 15 November 2014 RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. The Company expects to use approximately \$500 million from the proceeds of the term loan financing to pay a dividend to RB.

## **PART XIII — UNAUDITED PRO FORMA FINANCIAL INFORMATION**

### **SECTION A: UNAUDITED PRO FORMA FINANCIAL INFORMATION**

The unaudited combined pro forma statement of the financial information set out below has been prepared to illustrate the effect of the Demerger on the net assets of the Indivior Group as if the Demerger had taken place on 30 September 2014 and the effect on the combined income statement of the Indivior Group for the year ended 31 December 2013 and the nine months ended 30 September 2014 as if the Demerger had taken place on 1 January 2013.

The information, which has been produced for illustrative purposes only, by its nature addresses a hypothetical situation and, therefore, does not represent the Indivior Group's actual financial position or results. The unaudited pro forma statements of net assets and income statements are compiled on the basis set out in the notes below and in accordance with the accounting policies to be adopted by the Indivior Group for the year ending 31 December 2014. The unaudited pro forma financial information does not constitute financial statements within the meaning of section 434 of the Companies Act.

Investors should read the whole of this Prospectus and not rely solely on the unaudited financial information in this Part XIII (*Unaudited Pro Forma Financial Information*). PricewaterhouseCoopers LLP's report on the unaudited pro forma financial information is set out in Section B of this Part XIII (*Unaudited Pro Forma Financial Information*).

## Unaudited pro forma statement of net assets at 30 September 2014

		<i>Adjustments</i>		
	<i>Indivior Group As at 30 September 2014 (Note 1) \$m</i>	<i>New Financing (Note 2) \$m</i>	<i>Cash retained by the Indivior Group (Note 3) \$m</i>	<i>Unaudited Pro Forma Total (Note 4) \$m</i>
<b>ASSETS</b>				
<b>Non-current assets</b>				
Intangible assets	98	–	–	98
Property, plant and equipment	12	–	–	12
Deferred tax assets	89	–	–	89
Other receivables	4	–	–	4
	<u>203</u>	<u>–</u>	<u>–</u>	<u>203</u>
<b>Current assets</b>				
Inventories	45	–	–	45
Trade and other receivables	196	–	–	196
Cash and cash equivalents	32	228	42	302
	<u>273</u>	<u>228</u>	<u>42</u>	<u>543</u>
<b>Total assets</b>	<b><u>476</u></b>	<b><u>228</u></b>	<b><u>42</u></b>	<b><u>746</u></b>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Provisions for liabilities and charges	(308)	–	–	(308)
Trade & other payables	(126)	–	–	(126)
Current tax liabilities	(46)	–	–	(46)
	<u>(480)</u>	<u>–</u>	<u>–</u>	<u>(480)</u>
<b>Non-current liabilities</b>				
Borrowings	–	(728)	–	(728)
Provisions for liabilities and charges	(41)	–	–	(41)
	<u>(41)</u>	<u>(728)</u>	<u>–</u>	<u>(769)</u>
<b>Total liabilities</b>	<b><u>(521)</u></b>	<b><u>(728)</u></b>	<b><u>–</u></b>	<b><u>(1,249)</u></b>
<b>Net (liabilities)/assets</b>	<b><u>(45)</u></b>	<b><u>(500)</u></b>	<b><u>42</u></b>	<b><u>(503)</u></b>

- (1) The financial information has been extracted without material adjustment from the combined financial information of the Indivior Group as set out in Part XII (Historical Financial Information) of this Prospectus. Indivior was incorporated on 26 September 2014 with subscriber share capital of \$4, being 2 ordinary shares of \$2. The insertion of a new holding company constitutes a group reconstruction and will be accounted for using merger accounting principles. The group reconstruction will not become effective until the Demerger Effective Time and the combined financial statements will be presented as if the Indivior Business and Indivior had always been part of the same group.
- (2) On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. An adjustment of \$728 million has been made to the pro forma statement of net assets to reflect the drawdown of the term loan presented net of issue costs of \$22 million. The proceeds of the financing will be used to pay a dividend to RB and for general corporate purposes. The issue costs will be paid by the Indivior Group from cash to be retained by the business as detailed in note 3.
- (3) At the Demerger Effective Time, it is expected that a cash balance of approximately \$302 million will be retained by the Indivior Group. This amount will consist of \$750 million gross proceeds raised from the new term loan

financing, less a dividend payment to RB expected to be approximately \$500 million, and cash retained for general corporate purposes. No adjustment has been made for the estimated demerger and related costs, which will be borne by RB.

(4) No adjustment has been made to reflect the trading results of the Indivior Group since 30 September 2014.

### Unaudited pro forma income statement for the year ended 31 December 2013

	<i>Indivior Group for the year ended 31 December 2013 (Note 1) \$m</i>	<i>New Financing (Note 2) \$m</i>	<i>Unaudited Pro Forma Total (Notes 3 and 4) \$m</i>
Net Revenues	1,216	–	1,216
Cost of Sales	(104)	–	(104)
<b>Gross Profit</b>	<b>1,112</b>	<b>–</b>	<b>1,112</b>
Selling, distribution and administrative expenses	(341)	–	(341)
Research & Development expenses	(76)	–	(76)
<b>Operating Profit</b>	<b>695</b>	<b>–</b>	<b>695</b>
Interest Expense	–	(44)	(44)
<b>Profit before Taxation</b>	<b>695</b>	<b>(44)</b>	<b>651</b>
Taxation	(206)	13	(193)
<b>Net Income</b>	<b>489</b>	<b>(31)</b>	<b>458</b>

- (1) The financial information has been extracted without material adjustment from the combined financial information of the Indivior Group as set out in Part XII (Historical Financial Information) of this Prospectus. Indivior was incorporated on 26 September 2014. Indivior has not traded since incorporation other than the gift of £50,000 and therefore the income statement of the Indivior Group for the year ended 31 December 2013 is equivalent to the aggregated income statements of the Indivior Group and Indivior for the same period.
- (2) On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. Interest expense of \$44 million comprises interest payable on the term loan and amortisation of the capitalised issue costs. Pro forma interest expense of \$41 million is calculated based on a 1% minimum LIBOR rate plus 4.5%. The pro forma interest expense only takes into account committed repayments under the term loan during the year ended 31 December 2013. Pro forma amortisation of \$3 million of issue costs in relation to the term loan and revolving credit facility is calculated based upon the 7-year term of the term loan, and the 5-year term of the revolving credit facility. The proceeds of the financing will be used to pay a dividend to RB and for general corporate purposes. Tax has been reflected at the effective tax rate of the Indivior Group for the period presented.
- (3) No adjustment has been made for the estimated demerger costs which will be borne by RB.
- (4) No adjustment has been made to reflect the trading results of the Indivior Group since 31 December 2013.

## Unaudited pro forma income statement for the nine-month period ended 30 September 2014

	Indivior Group for the nine-month period ended 30 September 2014 (Note 1) \$m	New Financing (Note 2) \$m	Unaudited Pro Forma Total (Notes 3 and 4) \$m
Net Revenues	844	–	844
Cost of Sales	(73)	–	(73)
<b>Gross Profit</b>	<b>771</b>	<b>–</b>	<b>771</b>
Selling, distribution and administrative expenses	(250)	–	(250)
Research & Development expenses	(63)	–	(63)
<b>Operating Profit</b>	<b>458</b>	<b>–</b>	<b>458</b>
Interest Expense	–	(33)	(33)
<b>Profit before Taxation</b>	<b>458</b>	<b>(33)</b>	<b>425</b>
Taxation	(132)	10	(122)
<b>Net Income</b>	<b>326</b>	<b>(23)</b>	<b>303</b>

- (1) The financial information has been extracted without material adjustment from the combined financial information of the Indivior Group as set out in Part XII (Historical Financial Information) of this Prospectus. Indivior was incorporated on 26 September 2014. Indivior has not traded since incorporation other than the gift of £50,000 and therefore the income statement of the Indivior Group for the nine-month period ended 30 September 2014 is equivalent to the aggregated income statements of the Indivior Group and Indivior for the same period.
- (2) On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. Interest expense of \$33 million comprises interest payable on the term loan and amortisation of the capitalised issue costs. Pro forma interest expense of \$31 million is calculated based on a 1% minimum LIBOR rate plus 4.5%. The pro forma interest expense only takes into account committed repayments under the term loan during the nine month period ended 30 September 2014. Pro forma amortisation of \$2 million of issue costs in relation to the term loan and revolving credit facility is calculated based upon the 7-year term of the term loan, and the 5-year term of the revolving credit facility. The proceeds of the financing will be used to pay a dividend to RB and for general corporate purposes. Tax has been reflected at the effective tax rate of the Indivior Group for the period presented.
- (3) No adjustment has been made for the estimated demerger costs which will be borne by RB.
- (4) No adjustment has been made to reflect the trading results of the Indivior Group since 30 September 2014.

## SECTION B: PRICEWATERHOUSECOOPERS LLP'S REPORT ON THE UNAUDITED PRO FORMA FINANCIAL INFORMATION



The Directors (the “**Directors**”)  
Indivior PLC  
103-105 Bath Road  
Slough  
Berkshire SL1 3UH  
United Kingdom

Deutsche Bank AG, London Branch  
Winchester House  
1 Great Winchester Street  
London EC2N 2DB  
United Kingdom

Morgan Stanley & Co. International PLC  
25 Cabot Square  
London E14 4QA  
United Kingdom

17 November 2014

Dear Sirs

### Indivior PLC (the “**Company**”)

We report on the pro forma financial information (the “**Pro Forma Financial Information**”) set out in Section A of Part XIII (*Unaudited Pro Forma Financial Information*) of the Company’s prospectus dated 17 November 2014 (the “**Prospectus**”) which has been prepared on the basis described in the notes to the Pro Forma Financial Information, for illustrative purposes only, to provide information about how the proposed demerger of the pharmaceuticals business of Reckitt Benckiser Group PLC (the “**Indivior Group**”) (the “**Demerger**”) might have affected the financial information presented on the basis of the accounting policies to be adopted by the Company in preparing the historical combined financial information for the period ending 31 December 2014. This report is required by item 20.2 of Annex I to the PD Regulation and is given for the purpose of complying with that PD Regulation and for no other purpose.

### Responsibilities

It is the responsibility of the directors of the Company to prepare the Pro Forma Financial Information in accordance with item 20.2 of Annex 1 to the PD regulation.

It is our responsibility to form an opinion, as required by item 20.2 of Annex I to the PD Regulation as to the proper compilation of the Pro Forma Financial Information and to report our opinion to you.

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*PricewaterhouseCoopers LLP, 1 Embankment Place, London, WC2N 6RH*  
*T: +44 (0) 2075 835 000, F: +44 (0) 2072 124 652, [www.pwc.co.uk](http://www.pwc.co.uk)*

PricewaterhouseCoopers LLP is a limited liability partnership registered in England with registered number OC303525. The registered office of PricewaterhouseCoopers LLP is 1 Embankment Place, London WC2N 6RH. PricewaterhouseCoopers LLP is authorised and regulated by the Financial Conduct Authority for designated investment business.

Save for any responsibility which we may have to those persons to whom this report is expressly addressed and for any responsibility arising under item 5.5.3R(2)(f) of the Prospectus Rules to any person as and to the extent there provided, to the fullest extent permitted by law we do not assume any responsibility and will not accept any liability to any other person for any loss suffered by any such other person as a result of, arising out of, or in connection with this report or our statement, required by and given solely for the purposes of complying with item 23.1 of Annex I to the PD Regulation, consenting to its inclusion in the Prospectus.

### **Basis of opinion**

We conducted our work in accordance with the Standards for Investment Reporting issued by the Auditing Practices Board in the United Kingdom. The work that we performed for the purpose of making this report, which involved no independent examination of any of the underlying financial information, consisted primarily of comparing the unadjusted financial information with the source documents, considering the evidence supporting the adjustments and discussing the Pro Forma Financial Information with the directors of the Company.

We planned and performed our work so as to obtain the information and explanations we considered necessary in order to provide us with reasonable assurance that the Pro Forma Financial Information has been properly compiled on the basis stated and that such basis is consistent with the accounting policies of the Indivior Group.

Our work has not been carried out in accordance with auditing standards or other standards and practices generally accepted in the United States of America and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

### **Opinion**

In our opinion:

- (a) the Pro Forma Financial Information has been properly compiled on the basis stated;  
and
- (b) such basis is consistent with the accounting policies of the Indivior Group.

### **Declaration**

For the purposes of Prospectus Rule 5.5.3 R(2)(f), we are responsible for this report as part of the Prospectus and we declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Prospectus in compliance with item 1.2 of Annex I to the PD Regulation.

Yours faithfully

PricewaterhouseCoopers LLP  
Chartered Accountants

## PART XIV

### TAXATION

#### 1. UNITED KINGDOM TAXATION CONSIDERATIONS

##### 1.1 General

The following statements do not constitute tax or legal advice and are intended only as a general guide to current UK tax law and HMRC published practice (which are both subject to change at any time, possibly with retrospective effect). They relate only to certain limited aspects of the UK taxation treatment of Shareholders and are intended to apply only, except to the extent stated below, to persons who are resident and, if individuals, domiciled in the UK for UK tax purposes, and who are absolute legal and beneficial owners of the Indivior Ordinary Shares (otherwise than through a New Individual Savings Account or a Self-Invested Personal Pension) and who hold them as investments (and not as securities to be realised in the course of a trade). They may not apply to certain Shareholders, such as dealers in securities, insurance companies and collective investment schemes, Shareholders who are exempt from taxation and Shareholders who have (or are deemed to have) acquired their Indivior Ordinary Shares by virtue of an office or employment. Such persons may be subject to special rules. Any references to tax rates are to those in force for the tax year 2014/15.

**Any person who is in any doubt as to their tax position, or who is subject to taxation in any jurisdiction other than the UK, should consult their own professional advisers without delay.**

The RB Shareholder Circular contains an explanation of certain UK tax consequences of the Demerger.

##### 1.2 Dividends

###### (A) General

There will be no UK withholding tax on dividends paid on the Indivior Ordinary Shares.

###### (B) Individual Shareholders within the charge to UK income tax

When the Company pays a dividend to a Shareholder who is an individual resident (for UK tax purposes) in the UK, the Shareholder will be entitled to a tax credit equal to one-ninth of the dividend received. The dividend received plus the related tax credit (the “**gross dividend**”) will be part of the Shareholder’s total income for UK income tax purposes and will be regarded as the top slice of that income. However, in calculating the Shareholder’s liability to income tax in respect of the gross dividend, the tax credit (which equates to 10% of the gross dividend) is set off against the tax chargeable on the gross dividend.

###### *Basic rate taxpayers*

In the case of a Shareholder who is liable to income tax at the basic rate, the Shareholder will be subject to tax on the gross dividend at the rate of 10%. The tax credit will, in consequence, satisfy in full the Shareholder’s liability to income tax on the gross dividend.

#### *Higher rate taxpayers*

To the extent that the gross dividend exceeds the threshold for the higher rate of income tax but is below the threshold for the additional rate of income tax, the Shareholder will be subject to tax on the gross dividend at the rate of 32.5%. This means that the tax credit will satisfy only part of the Shareholder's liability to income tax on the gross dividend, so that (to the extent that the gross dividend is taxed at 32.5%) the Shareholder will have to account for income tax equal to 22.5% of the gross dividend (which equates to 25% of the dividend received). For example, assuming the entire gross dividend exceeds the higher rate threshold and is below the additional rate threshold, a dividend of £90 from the Company would represent a gross dividend of £100 (after the addition of the tax credit of £10) and the Shareholder would be required to account for income tax of £22.50 on the dividend, being £32.50 (i.e. 32.5% of £100) less £10 (the amount of the tax credit).

#### *Additional rate taxpayers*

To the extent that the gross dividend exceeds the threshold for the additional rate of income tax, the Shareholder will be subject to tax on the gross dividend at the rate of 37.5%. This means that the tax credit will satisfy only part of the Shareholder's liability to income tax on the gross dividend, so that (to the extent that the gross dividend is taxed at 37.5%) the Shareholder will have to account for income tax equal to 27.5% of the gross dividend (which equates to approximately 30.6% of the dividend received). For example, assuming the entire gross dividend exceeds the additional rate threshold, a dividend of £90 from the Company would represent a gross dividend of £100 (after the addition of the tax credit of £10) and the Shareholder would be required to account for income tax of £27.50 on the dividend, being £37.50 (i.e. 37.5% of £100) less £10 (the amount of the tax credit).

#### (C) **Corporate Shareholders within the charge to UK Corporation Tax**

Shareholders within the charge to UK corporation tax which are "small companies" (for the purposes of UK taxation of dividends) will not generally be subject to tax on dividends from the Company.

Other Shareholders within the charge to UK corporation tax will not be subject to tax on dividends received from the Company so long as the dividends fall within an exempt class and certain conditions are met. The exemptions are not comprehensive and are subject to anti-avoidance rules. If the conditions for exemption are not, or cease to be, satisfied or such Shareholders elect for an otherwise exempt dividend to be taxable, the Shareholders will be subject to UK corporation tax on dividends received from the Company. Corporate tax is charged on dividends at the corporate tax rate applicable to that company.

#### (D) **No payment of tax credit**

A Shareholder who is not liable to tax on dividends from the Company will not be entitled to claim payment of the tax credit in respect of those dividends.

### 1.3 **Chargeable gains**

#### (A) **Individual Shareholders**

A disposal of Individual Ordinary Shares may give rise to a chargeable gain (or allowable loss) for the purposes of UK capital gains tax, depending on the circumstances and subject to any available exemption or relief.

No indexation allowance will be available to an individual Shareholder in respect of any disposal of Individual Ordinary Shares.

Capital gains tax will generally be charged at 18% to the extent that the total chargeable gains and, generally, total taxable income arising in a tax year, after all allowable deductions (including losses, the income tax personal allowance and the capital gains tax annual exempt amount), are less than the upper limit of the income tax basic rate band. To the extent that any chargeable gains (or part of any chargeable gains) arising in a tax year exceed the upper limit of the income tax basic rate band when aggregated with any such income (in the manner referred to above), capital gains tax will be charged at 28%.

**(B) Corporate Shareholders**

A disposal of Indivior Ordinary Shares may give rise to a chargeable gain (or allowable loss) for the purposes of UK corporation tax, depending on the circumstances and subject to any available exemption or relief. Indexation allowance may reduce the amount of any chargeable gain that is subject to corporation tax but may not create or increase any allowable loss.

**(C) Non-UK resident Shareholders**

Individuals who are temporarily non-resident may, in certain circumstances, be subject to tax in respect of gains realised while they are not resident in the UK.

Subject to the paragraph above, a Shareholder who is not resident in the UK will not normally be liable for UK tax on chargeable gains realised on a disposal of Indivior Ordinary Shares unless such Shareholder carries on:

- (i) (in the case of a Shareholder who is an individual) a trade, profession or vocation in the UK through a branch or agency and the Indivior Ordinary Shares have either been used in or for the purposes of the trade, profession or vocation, or have been used or held for the purposes of the branch or agency, or acquired for use by or for the purposes of the branch or agency; or
- (ii) (in the case of a Shareholder which is a company) a trade in the UK through a permanent establishment and the Indivior Ordinary Shares have either been used in or for the purposes of the trade, or have been used or held for the purposes of the permanent establishment, or acquired for use by or for the purposes of the permanent establishment.

**(D) Reduction of capital**

For the purposes of UK taxation of capital gains and corporation tax on chargeable gains, the Reduction of Capital should be treated as a reorganisation of the Company's share capital. The effect of this should be that a Shareholder's resultant holding of Indivior Ordinary Shares following the Reduction of Capital should be treated as the same asset, acquired at the same time and for the same consideration, as the holding of the Indivior Ordinary Shares held by that Shareholder prior to the Reduction of Capital.

#### **1.4 Stamp duty and SDRT**

The following statements are intended as a general guide to the current UK stamp duty and SDRT position, and apply regardless of whether or not a Shareholder is resident in the UK. It should be noted that certain categories of person, including market makers, brokers, dealers, and other specified market intermediaries, are entitled to exemption from stamp duty and SDRT in respect of purchases of securities in specified circumstances.

**General**

No stamp duty or SDRT will generally arise on the issue of Indivior Ordinary Shares. An instrument effecting the transfer on sale of Indivior Ordinary Shares will generally be liable to stamp duty at the rate of 0.5% (rounded up to the nearest multiple of £5) of the amount or value of the consideration payable. An unconditional agreement to transfer such shares will generally be liable to SDRT at the rate of 0.5% of the amount or value of the consideration payable, but such liability will be cancelled, or a right to a repayment in respect of the payment of such SDRT liability will arise, if the agreement is completed by a duly stamped transfer within six years of the agreement having become unconditional. Stamp duty and SDRT are normally the liability of the transferee.

**CREST**

No stamp duty or SDRT will arise on a transfer of Indivior Ordinary Shares into the CREST system provided that, in the case of SDRT, the transfer is not for money or money's worth. Paperless transfers of Indivior Ordinary Shares within CREST are liable to SDRT (at a rate of 0.5% of the amount or value of the consideration payable) rather than stamp duty, and SDRT on relevant transactions settled within the system or reported through it for regulatory purposes will be collected and accounted for to HMRC by the operator of CREST (such SDRT generally being payable by the transferee or purchaser).

***Depository receipt issuers and clearance services***

Where Indivior Ordinary Shares are transferred (in the case of stamp duty) or issued or transferred (in the case of SDRT) (a) to, or to a nominee or an agent for, a person whose business is or includes the provision of clearance services, or (b) to, or to a nominee or an agent for, a person whose business is or includes issuing depository receipts, stamp duty or SDRT (as applicable) will generally be payable at the higher rate of 1.5% on the amount or value of the consideration given or, in certain circumstances, the value of the Indivior Ordinary Shares. However, following the decision of the European Court of Justice in *HSBC Holdings and Vidacos Nominees* (Case 569/07) and the First-tier Tax Tribunal decision in *HSBC Holdings and The Bank of New York Mellon*, HMRC have confirmed that they will no longer seek to apply the 1.5% SDRT charge on an issue of shares or securities to a clearance service or depository receipt system on the basis that the charge is not compatible with EU Law. HMRC's view is that the 1.5% SDRT or stamp duty charge will continue to apply to a transfer of shares or securities to a clearance service or depository receipt system where the transfer is not an integral part of an issue of share capital.

Any liability for stamp duty or SDRT in receipt of a transfer into a clearance service or depository receipt system, or in respect of a transfer within such a service, which does arise, will strictly be accountable for by the clearance service or depository receipt system operator or their nominee, as the case may be, but will, in practice, be payable by the participants in the clearance service or depository receipt system.

There is an exception from the 1.5% charge on the transfer to, or to a nominee or agent for, a clearance service where the clearance service has made and maintained an election under section 97A(1) of the Finance Act 1986, which has been approved by HMRC. In these circumstances, a charge to SDRT at the rate of 0.5% of the amount or value of the consideration payable for the transfer will arise on any transfer of Indivior Ordinary Shares into such a clearance service and on subsequent agreements to transfer such Indivior Ordinary Shares within such a clearance service.

## **2. UNITED STATES TAXATION CONSIDERATIONS**

### **2.1 General**

The following is a discussion of certain US federal income tax consequences to US Holders, as defined below, of the receipt of Indivior Ordinary Shares pursuant to the Demerger and the ownership and disposition of Indivior Ordinary Shares so acquired. This discussion is not a complete analysis or listing of all the possible tax consequences of the receipt, acquisition, ownership and disposition of Indivior Ordinary Shares and does not address all tax considerations that might be relevant to particular holders in light of their personal circumstances or to persons that are subject to special tax rules. In particular, the information set out below deals only with US Holders that will hold Indivior Ordinary Shares as capital assets for US federal income tax purposes (generally, property held for investment), that will not own, and will not be treated as owning, immediately after the Demerger, 5% or more (by vote or value) of Indivior Ordinary Shares or RB Ordinary Shares and that will not own, and will not be treated as owning, at any time, 10% or more of Indivior Ordinary Shares or RB Ordinary Shares (by vote). In addition, this description of the material US federal income tax consequences does not address the tax treatment of special classes of US Holders, such as:

- (A) banks
- (B) financial institutions
- (C) regulated investment companies
- (D) real estate investment trusts
- (E) tax-exempt entities
- (F) insurance companies
- (G) persons holding Indivior Ordinary Shares as part of a hedging, integrated or conversion transaction, constructive sale or “straddle”
- (H) persons that acquire Indivior Ordinary Shares through the exercise or cancellation of employee stock options or otherwise as compensation for their services
- (I) US expatriates
- (J) persons subject to the alternative minimum tax
- (K) brokers, dealers or traders in securities or currencies
- (L) persons whose functional currency is not the US dollar.

This summary does not address estate and gift tax consequences or tax consequences under any state, local or non-US laws.

As used herein, “US Holder” means a beneficial owner of Indivior Ordinary Shares or RB Ordinary Shares that is: (1) a citizen of or an individual resident of the United States, as determined for US federal income tax purposes; (2) a corporation (or other entity treated as a corporation for US federal income tax purposes) created or organised under the laws of the United States or any state thereof or the District of Columbia; (3) an estate the income of which is subject to US federal income taxation regardless of its source; or (4) a trust (A) if a court within the United States is able to exercise primary jurisdiction over its administration and one or more US persons have authority to control all substantial decisions of the trust or (B) that has a valid election in effect under applicable Treasury regulations to be treated as a US person.

If a pass-through entity, including a partnership or other entity or arrangement treated as a partnership for US federal income tax purposes, is a beneficial owner of Indivior Ordinary Shares or RB Ordinary Shares, the US federal income tax treatment of an owner or partner will generally depend upon the status of such owner or partner and upon the activities of the pass-through entity. A US person that is an owner or partner of a pass-through entity that acquires Indivior Ordinary Shares should consult its own tax adviser regarding the tax consequences of owning and disposing of Indivior Ordinary Shares.

The following discussion is based upon the Code, US judicial decisions, administrative pronouncements, existing and proposed Treasury regulations and the Treaty, all as in effect as of the date hereof. All the preceding authorities are subject to change, possibly with retroactive effect, so as to result in US federal income tax consequences different from those discussed below. The Company has not requested, and will not request, a ruling from the IRS with respect to any of the US federal income tax consequences described below, and as a result there can be no assurance that the IRS will not disagree with or challenge any of the conclusions the Company has reached and describes herein.

The following discussion is for general information only and is not intended to be, nor should it be construed to be, legal or tax advice to any holder or prospective holder of Indivior Ordinary Shares and no opinion or representation with respect to the US federal income tax consequences to any such holder or prospective holder is made. A US Holder is urged to consult its own tax adviser as to the particular consequences to such US Holder under US federal, state and local, and applicable non-US tax laws of the receipt, acquisition, ownership and disposition of Indivior Ordinary Shares.

## 2.2 **Demerger**

Based on the Company's expectation, the receipt of Indivior Ordinary Shares by a US Holder pursuant to the Demerger should qualify as a tax-free distribution under Section 355(a)(1) of the Code. US Holders are advised that an advance ruling from the IRS regarding the Demerger has not been sought.

If the Demerger qualifies for non-recognition treatment under Sections 355 of the Code, as the Company expects, the following will result for US federal income tax purposes:

- (A) no gain or loss should be recognised by a US Holder upon the receipt of Indivior Ordinary Shares;
- (B) a US Holder should apportion its tax basis in the RB Ordinary Shares between such shares and the Indivior Ordinary Shares received in proportion to the relative fair market value of the RB Ordinary Shares and the Indivior Ordinary Shares on the date on which the Indivior Ordinary Shares are distributed; and
- (C) a US Holder's holding period for the Indivior Ordinary Shares should include the period during which the US Holder held the RB Ordinary Shares.

A US Holder that has a significant ownership in RB and receives Indivior Ordinary Shares pursuant to the Demerger is required to attach a statement to its US federal income tax return for the taxable year in which the Indivior Ordinary Shares are received setting out information showing the applicability of Section 355 of the Code to the receipt of Indivior Ordinary Shares. US Holders should consult their tax advisers in respect of the foregoing requirement.

If, contrary to the Company's expectation, the receipt of Indivior Ordinary Shares by US Holders does not qualify for non-recognition treatment under Section 355 of the Code, each US Holder that receives Indivior Ordinary Shares would have: (1) a taxable dividend (provided, as is expected, RB has sufficient current and accumulated earnings and profits as determined for US federal income purposes) in an amount equal to the fair market

value of Indivior Ordinary Shares distributed to such US Holder (without reduction for any portion of such US Holder's tax basis in its RB Ordinary Shares); and (2) a tax basis in Indivior Ordinary Shares received equal to the fair market value of such shares on the date of receipt, and the holding period for such shares would begin the day after the date of receipt. Further, there would be no adjustment in tax basis for a US Holder's RB Ordinary Shares. RB does not maintain calculations of its earnings and profits in accordance with US federal income tax principles, and a US Holder should therefore assume that any taxable distribution with respect to the RB Ordinary Shares would constitute ordinary income.

As discussed in greater detail in paragraph 2.3 below, under current law, assuming certain holding period and other requirements are met, US Holders that are individual citizens or residents of the US are subject to preferential US federal income tax rates on dividends.

The foregoing discussion of the US tax consequences of the Demerger for US Holders assumes that RB is not and has not been a PFIC. If RB is or has been a PFIC in any year in which a US Holder held RB Ordinary Shares, adverse consequences could result for such US Holder upon the receipt of Indivior Ordinary Shares. The Company believes that RB is not and has never been a PFIC.

### **2.3 Distributions**

Subject to the discussion of the PFIC rules below, the gross amount of any distribution paid by the Company will generally be subject to US federal income tax as foreign source dividend income (without reduction for any UK tax withheld from such distribution) to the extent paid out of the Company's current or accumulated earnings and profits, as determined under US federal income tax principles. Such amount will be includable in gross income by a US Holder as ordinary income on the date that such US Holder actually or constructively receives the distribution in accordance with its regular method of accounting for US federal income tax purposes. The amount of any distribution made by the Company in property other than cash will be the fair market value of such property on the date of the distribution. Dividends paid by the Company will not be eligible for the dividends received deduction allowed to corporations.

Subject to applicable exceptions with respect to short-term and hedged positions, and assuming certain holding period and other requirements are met, certain dividends received by non-corporate US Holders from a "qualified foreign corporation" may be eligible for reduced rates of taxation. A non-US corporation is treated as a qualified corporation if it is eligible for the benefits of a comprehensive income tax treaty with the US that the US Treasury Department determines to be satisfactory for these purposes and that includes an exchange of information provision. The US Treasury has determined that the Treaty meets these requirements. Under the Treaty, a UK corporation is eligible for the benefits of the Treaty if the principal class of its shares is listed on the London Stock Exchange and is regularly traded on one or more recognised stock exchanges (including the London Stock Exchange). If, as the Company anticipates, Indivior Ordinary Shares are regularly traded on the London Stock Exchange, the Company would be eligible for the benefits of the Treaty, and dividends paid on Indivior Ordinary Shares would be eligible for reduced rates of taxation. Dividends received by US Holders from a non-US corporation that was a PFIC in either the taxable year of the distribution or the preceding taxable year will not constitute qualified dividends. As discussed below in "Passive Foreign Investment Company Rules," the Company believes that it is not a PFIC.

To the extent that a distribution exceeds the amount of the Company's current and accumulated earnings and profits, as determined under US federal income tax principles, it will be treated first as a tax-free return of capital, causing a reduction in a US Holder's adjusted basis in the Indivior Ordinary Shares held by such US Holder (thereby increasing

the amount of gain, or decreasing the amount of loss, to be recognised by such US Holder upon a subsequent disposition of the Indivior Ordinary Shares), with any amount that exceeds its adjusted basis being taxed as a capital gain recognised on a sale or exchange (as discussed below). However, the Company does not intend to maintain calculations of its earnings and profits in accordance with US federal income tax principles, and a US Holder should therefore assume that any distribution by the Company with respect to Indivior Ordinary Shares will constitute ordinary dividend income.

#### **2.4 Sale, exchange or other taxable disposition of the Indivior Ordinary Shares**

Subject to the discussion of the PFIC rules below, a US Holder generally will recognise a gain or loss upon the taxable sale, exchange or other disposition of Indivior Ordinary Shares in an amount equal to the difference between (i) the amount realised upon the sale, exchange or other taxable disposition and (ii) its adjusted tax basis in the Indivior Ordinary Shares. Generally, such gain or loss will be capital gain or loss and will be long-term capital gain or loss if, on the date of the sale, exchange or other taxable disposition, a US Holder has held the Indivior Ordinary Shares for more than one year. A loss may nonetheless be a long-term capital loss regardless of a US Holder's actual holding period to the extent the US Holder receives qualified dividends prior to a sale or other disposition of its Indivior Ordinary Shares in excess of 10% of its basis in the Indivior Ordinary Shares. The deductibility of capital losses is subject to limitations under the Code.

Again or loss, if any, that a US Holder realises upon a sale, exchange or other taxable disposition of Indivior Ordinary Shares will be treated as having a US source for US foreign tax credit limitation purposes. Consequently, a US Holder may not be able to use any foreign tax credits arising from any UK tax imposed on the sale, exchange or other taxable disposition of Indivior Ordinary Shares unless such credit can be applied (subject to applicable limitations) against tax due on other income treated as derived from foreign sources or unless an applicable treaty provides otherwise and an election is properly made under the Code.

If a US Holder receives any foreign currency on the sale of Indivior Ordinary Shares, such US Holder may recognise ordinary income or loss as a result of currency fluctuations between the date of the sale of Indivior Ordinary Shares and the date the sale proceeds are converted into US dollars. For cash basis and electing accrual basis US Holders, any foreign currency exchange gain or loss shall be determined by translating the foreign currency into US dollars at the spot rate on the settlement date of the sale, notwithstanding that the Indivior Ordinary Shares may otherwise be treated as disposed of on the date of the sale or another date.

#### **2.5 Passive Foreign Investment Company Rules**

The foregoing discussion assumes that the Company is not, and will not be, a PFIC. If the Company is classified as a PFIC in any year during a US Holder's holding period, the US federal income tax consequences to such US Holder of the ownership and disposition of Indivior Ordinary Shares could be materially different from those described above. A non-US corporation will be considered a PFIC for any taxable year in which (i) 75% or more of its gross income is "passive income" or (ii) 50% or more of the average value of its assets produce (or are held for the production of) "passive income" (in each case, treating the Company as earning its proportionate share of the gross income, and holding its proportionate share of the assets, of each subsidiary corporation if the Company owns at least 25% (by value) of stock of such subsidiary corporation).

Based on the expected composition of its income, assets and operations, the Company does not expect to become a PFIC in 2014 or any subsequent year. However, the determination of PFIC status for any taxable year can only be made on an annual basis

after the end of such taxable year, and will depend on the composition of the Company's income, assets and operations from time to time. Accordingly, there can be no assurance that the Company will not be a PFIC for any taxable year.

If the Company were classified as a PFIC in any year during a US Holder's holding period, such US Holder would be subject to special adverse rules, including taxation at maximum ordinary income rates plus an interest charge on both gains on sale and certain dividends, unless such US Holder makes an election to be taxed under an alternative regime. Certain elections may be available to US Holders if the Company were classified as a PFIC.

Each US Holder is urged to consult its tax adviser concerning the US federal income tax consequences of holding Indivior Ordinary Shares if the Company is considered a PFIC in any taxable year.

## **2.6 Medicare tax on net investment income**

Certain US Holders that are individuals, estates or trusts (other than trusts that are exempt from tax) will be subject to a 3.8% tax on all or a portion of their "net investment income," which includes dividends on Indivior Ordinary Shares and net gains from the disposition of Indivior Ordinary Shares.

## **2.7 Information reporting and backup withholding**

In general, information reporting will apply to dividends paid to a US Holder in respect of Indivior Ordinary Shares and the proceeds received by such US Holder from the sale, exchange or other disposition of Indivior Ordinary Shares within the US unless such US Holder is a corporation or other exempt recipient. A backup withholding tax may apply to such payments if a US Holder fails to provide a taxpayer identification number or certification of exempt status or fails to report in full dividend and interest income. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a refund or credit against a US Holder's US federal income tax liability, provided that the required information is furnished to the IRS in a timely manner.

US return disclosure obligations (and related penalties for failure to disclose) apply to US individuals who hold certain specified foreign financial assets in excess of certain threshold amounts. The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also may include Indivior Ordinary Shares.

## PART XV

### ADDITIONAL INFORMATION

#### 1. Persons responsible

The Directors, whose names appear in Part III (*Directors, Secretary, Registered Office and Advisers*), and the Company accept responsibility for the information contained in this Prospectus. To the best of the knowledge of the Directors and the Company (each of whom has taken all reasonable care to ensure that such is the case), the information contained in this Prospectus is in accordance with the facts and this Prospectus does not omit anything likely to affect the import of such information.

#### 2. Incorporation and activity of the Company

The Company was incorporated on 26 September 2014 as a public limited company under the name Indivior PLC. The Company was incorporated and registered in England and Wales with registered number 9237894. The registered office and head office of the Company is 103-105 Bath Road, Slough, Berkshire SL1 3UH, telephone number: +44 (0)1753 217800.

The principal legislation under which the Company operates and under which the Indivior Ordinary Shares were created is the Companies Act.

#### 3. Corporate reorganisation

Prior to the date of this Prospectus, RB undertook a group reorganisation in order to ensure that the subsidiaries which comprise the Indivior Group were appropriately located within the RB Group in order for the Demerger to be effected. This corporate reorganisation was completed on 17 July 2014.

#### 4. Share capital of the Company

On incorporation, two ordinary shares of \$2.00 each in the capital of the Company were issued and have been fully paid up in cash. Subsequently, 50,000 redeemable fixed rate preference shares of £1 each (the **"Redeemable Shares"**) were issued and were fully paid up in cash. The Redeemable Shares were redeemed by the Company on 4 November 2014. 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.

The Indivior Ordinary Shares are in registered form and capable of being held in uncertificated form. No temporary documents of title have been or will be issued in respect of the Indivior Ordinary Shares. The Indivior Ordinary Shares will rank *pari passu* for dividends.

As at 13 November 2014, being the last practicable date prior to the date of this Prospectus, the Company held no treasury shares. No Indivior Ordinary Shares have been issued other than fully paid.

The initial Shareholders have resolved, subject to Admission, by a special resolution passed on 30 October 2014 (the **"Reduction Resolution"**) to reduce the share capital of Indivior by decreasing the nominal value of each Indivior Ordinary Share from \$2.00 to \$0.10 (the **"Reduction of Capital"**). The text of the Reduction Resolution is as follows:

"THAT conditional on the admission of the Company's shares to the premium listing segment of the Official List of the UKLA and their admission to trading on the main market for listed securities of the London Stock Exchange PLC, the issued share capital of the Company be reduced by cancelling and extinguishing \$1.90 of the nominal value of each

issued Ordinary Share of \$2.00 each and thereby reducing the nominal value of each such issued Ordinary Share from \$2.00 to \$0.10”.

The Reduction of Capital will require the confirmation of the Court under section 645 of the Companies Act and, if so confirmed, will create distributable reserves on the balance sheet which will provide Indivior with, among other things, capacity for the payment of future dividends.

The Reduction of Capital is expected to become effective on 21 January 2015.

The issued and fully paid share capital of the Company as at the date of this Prospectus is as follows:

	<u>Nominal Value</u>	<u>Number of shares issued</u>	<u>Amount</u>
Indivior Ordinary Shares	\$2.00	2	\$4.00

Following the implementation of the Demerger and on Admission, the issued and fully paid share capital of the Company, based on the number of RB Ordinary Shares (including treasury shares) in issue as at 13 November 2014 (the last practicable date prior to the publication of this Prospectus)) is expected to be:

	<u>Nominal Value</u>	<u>Number of shares issued</u>	<u>Amount</u>
Indivior Ordinary Shares	\$2.00	not more than 736,535,179	not more than \$1,473,070,358

The Indivior Ordinary Shares carry the right to receive dividends and distributions paid by the Company. The Shareholders have the right to receive notice of and to attend and vote at all general meetings of the Company.

The ISIN of the Indivior Ordinary Shares will be GB00BRS65X63 and the SEDOL number will be BRS65X6.

Further information on the rights attaching to the Indivior Ordinary Shares is set out in paragraph 5 of this Part XV (*Additional Information*).

## **5. Information about the Indivior Ordinary Shares**

### **5.1 Description of the type and class of securities**

The Indivior Ordinary Shares have a nominal value of \$2.00 each which, as explained above, will be reduced to \$0.10 following the Reduction of Capital. The Company has and, following the Demerger and on Admission, will have one class of Indivior Ordinary Shares, the rights of which are set out in the Articles, a summary of which is set out in paragraph 6 of this Part XV (*Additional Information*).

The Indivior Ordinary Shares are credited as fully paid and free from all liens, equities, charges, encumbrances and other interests. The Indivior Ordinary Shares rank in full for all dividends and distributions on Indivior Ordinary Shares of the Company declared, made or paid after their issue.

### **5.2 Legislation under which the Indivior Ordinary Shares were created**

The Indivior Ordinary Shares have been created under the Companies Act.

### 5.3 **Confirmations**

At the date of this Prospectus, and save as otherwise disclosed in this Part XV (*Additional Information*):

- (A) no share or loan capital of the Company has, since the incorporation of the Company, been issued or agreed to be issued, or is now proposed to be issued, fully or partly paid, either for cash or for a consideration other than cash, to any person;
- (B) no commission, discounts, brokerages or other special terms have been granted by the Company in connection with the issue or sale of any share or loan capital;
- (C) no share or loan capital of the Company is under option or agreed, conditionally or unconditionally, to be put under option; and
- (D) the Company held no treasury shares (as defined in the Companies Act).

### 5.4 **Listing**

Application will be made to the FCA for the Indivior Ordinary Shares to be admitted to the premium listing segment of the Official List. Application will also be made to the London Stock Exchange for the Indivior Ordinary Shares to be admitted to trading on its main market for listed securities. It is expected that Admission will become effective and that dealings in the Indivior Ordinary Shares will commence on the London Stock Exchange by no later than 8.00 a.m. on 23 December 2014.

Listing of the Indivior Ordinary Shares is not being sought on any stock exchange other than the London Stock Exchange.

### 5.5 **ADR facility**

The Company expects to establish an ADR facility in the US at the Demerger Effective Time. JPMorgan Chase Bank, N.A., as depositary for the Company's ADR facility, will issue the Indivior ADSs. Each Indivior ADS will represent an ownership interest in Indivior Ordinary Shares and a pro rata share of any other securities, cash or other property that may be held by the depositary, under the terms of the deposit agreement to be entered into between the Company, the depositary and the registered holders of Indivior ADSs from time to time.

On Demerger, the Indivior Ordinary Shares will not be listed on any securities exchange in the US, and the Company expects to rely on an exemption from registration under the Exchange Act provided by Rule 12g3-2(b) thereunder.

The Company will not treat Indivior ADS holders as its Shareholders and, accordingly, Indivior ADS holders will not have shareholders' rights, which are governed by English law. The rights of Indivior ADS holders will be governed by the deposit agreement and the depositary receipt, which will be governed by the laws of the State of New York. The deposit agreement will also set out the rights and obligations of the depositary.

The depositary's nominee will be the record holder of the Indivior Ordinary Shares underlying the Indivior ADSs and, therefore, Indivior ADS holders must rely on the depositary to exercise the rights of a Shareholder on their behalf. Indivior ADS holders may exercise their voting rights with respect to the Indivior Ordinary Shares underlying the Indivior ADSs only in accordance with the provisions of the deposit agreement. The depositary will not itself exercise any voting discretion in respect of Indivior Ordinary Shares. Upon receipt of instructions from an Indivior ADS holder pursuant to the deposit agreement, the depositary is required to endeavour (insofar as practicable and permitted under the Articles) to vote or cause to be voted the Indivior Ordinary Shares represented by the Indivior ADSs in accordance with such instructions.

Indivior ADS holders will be required to pay fees under the terms of the deposit agreement, including fees for cancellation of Indivior ADSs and upon distributions. The depositary has agreed to reimburse the Company for certain reasonably incurred expenses directly related to the ADR facility.

Indivior ADS holders should read the entire deposit agreement and the form of the depositary receipt. A copy of the deposit agreement will be filed as an exhibit to a registration statement on Form F-6 to be filed by or on behalf of the Company with the US SEC. Indivior ADS holders may find the registration statement and the deposit agreement on the US SEC's website at <http://www.sec.gov>.

#### **5.6 *Form and currency of the Indivior Ordinary Shares***

The Indivior Ordinary Shares will be in registered form and will be capable of being held in certificated and uncertificated form. The Registrar of the Company is Computershare Investors Services PLC.

Title to the certificated Indivior Ordinary Shares (if any) will be evidenced by entry in the register of members of the Company and title to uncertificated Indivior Ordinary Shares will be evidenced by entry in the operator register maintained by Computershare (which will form part of the register of members of the Company).

The Indivior Ordinary Shares are denominated in US dollars. The share price of the Indivior Ordinary Shares will be expressed in pounds sterling.

#### **5.7 *Rights attached to the Indivior Ordinary Shares***

Each Indivior Ordinary Share ranks equally in all respects with each other Indivior Ordinary Share and has the same rights (including voting and dividend rights and rights on a return of capital) and restrictions as each other Indivior 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 Indivior 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 Indivior Ordinary Shares are not redeemable. However, the Company may purchase or contract to purchase any of the Indivior Ordinary Shares on or off-market, subject to the Companies Act and the requirements of the Listing Rules. The Company may purchase Indivior 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 Indivior 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 paragraph 6 of this Part XV (*Additional Information*).

## 5.8 ***Authorities relating to the Indivior Ordinary Shares***

### *Authorities*

By resolutions of the Shareholders of the entire share capital in the Company, passed on 30 October 2014, in relation to the Company's share capital it was resolved that:

- (A) the Board be generally and unconditionally authorised to allot Indivior Ordinary Shares in the Company and to grant rights to subscribe for or convert any security into shares in the Company:
  - (i) as required for the purposes of the Demerger;
  - (ii) up to an aggregate nominal amount of \$480,236,813.33, which shall be reduced to \$24,011,840.66 following the Reduction of Capital, (such amount to be reduced by the nominal amount of any shares in the Company allotted or rights to subscribe for or to convert any security into shares in the Company granted under sub-paragraph (iii) below in excess of such sum); and
  - (iii) comprising equity securities (as defined in section 560(1) of the Companies Act) up to an aggregate nominal amount of \$960,473,626.66, which shall be reduced to \$48,023,681.33 following the Reduction of Capital, (such amount to be reduced by any allotments of any shares in the Company or grants of rights to subscribe for or to convert any security into shares in the Company made under sub-paragraph (ii) above) in connection with an offer by way of a rights issue:
    - (a) to holders of Indivior Ordinary Shares in proportion (as close as may be practicable) to their existing holdings; and
    - (b) to holders of other equity securities as required by the rights of those securities or as the Board otherwise considers necessary,and so that the Board may impose any limits or restrictions and make any arrangements which it considers necessary or appropriate to deal with treasury shares, fractional entitlements, record dates, legal, regulatory or practical problems in, or under the laws of, any territory or any other matter, such authorities to apply until the end of the Company's first annual general meeting (or, if earlier, until the close of business on 30 October 2015) but, in each case, during this period the Company may make offers and enter into agreements which would, or might, require shares to be allotted or rights to subscribe for or convert securities into shares to be granted after the authority ends and the Board may allot shares or grant rights to subscribe for or convert securities into shares under any such offer or agreement as if the authority had not ended.
- (B) subject to and conditional upon the passing of the resolution described in paragraph 5.8(A) above, the Board be given power to allot equity securities (as defined in the Companies Act) for cash under the authority given by the resolution described in paragraph 5.8(A) above and/or to sell Indivior Ordinary Shares held by the Company as treasury shares for cash as if section 561 of the Companies Act did not apply to any such allotment or sale, such power to be limited in the case of the authority granted under the resolution described in paragraph 5.8(A) above and/or in the case of any sale of treasury shares for cash, to the allotment of equity securities or sale of treasury shares:

- (i) up to a nominal amount of \$72,035,522.00 which shall be reduced to \$3,601,776.10 following the Reduction of Capital (otherwise than pursuant to the authority described in paragraph 5.8(B)(ii) below); and
- (ii) for cash in connection with an offer of, or invitation to apply for, equity securities:
  - (a) to holders of Indivior Ordinary Shares in proportion (as nearly as may be practicable) to their existing holdings; and
  - (b) to holders of other equity securities, as required by the rights of those securities, or as the Board otherwise considers necessary as permitted by the rights of those securities,

and so that the Board may impose any limits or restrictions and make any arrangements which it considers necessary or appropriate to deal with treasury shares, fractional entitlements, record dates, legal, regulatory or practical problems in, or under the laws of, any territory or any other matter,

such power to apply until the end of the Company's first annual general meeting (or, if earlier, until the close of business on 30 October 2015) but, in each case, during this period the Company may make offers, and enter into agreements, which would, or might, require equity securities to be allotted (and treasury shares to be sold) after the power ends and the Board may allot equity securities (and sell treasury shares) under any such offer or agreement as if the power had not ended.

- (C) the Company be authorised for the purposes of section 701 of the Companies Act to make one or more market purchases (as defined in section 693(4) of the Companies Act) of Indivior Ordinary Shares, such power to be limited:
  - (i) to a maximum number of 72,035,522 Indivior Ordinary Shares;
  - (ii) by the condition that the minimum price which may be paid for an Indivior Ordinary Share is its nominal value and the maximum price which may be paid for an Ordinary Share is the highest of:
    - (a) an amount equal to 5% above the average market value of an Indivior Ordinary Share for the five Business Days immediately preceding the day on which that Indivior Ordinary Share is contracted to be purchased; and
    - (b) the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out, in each case, exclusive of expenses.

such power to apply until the end of the Company's first annual general meeting (or, if earlier, until the close of business on 30 October 2015) but in each case so that the Company may enter into a contract to purchase Indivior Ordinary Shares which will or may be completed or executed wholly or partly after the power ends and the Company may purchase Indivior Ordinary Shares pursuant to any such contract as if the power had not ended.

## 5.9 **Description of restrictions on free transferability**

The Indivior Ordinary Shares are freely transferable and there are no restrictions on transfer in the UK.

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.

## **6. Summary of the Articles**

### **6.1 *Unrestricted objects***

The objects of the Company are unrestricted.

### **6.2 *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.

### **6.3 *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.

### **6.4 *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.

### **6.5 *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:

- (i) 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
- (ii) 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.

#### 6.6 **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.

#### 6.7 **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 authorised 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.

#### 6.8 **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.

#### **6.9 *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:

- (A) 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;
- (B) is in respect of only one class of share; and
- (C) if to joint transferees, is in favour 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).

#### **6.10 *Sub-division of share capital***

Any resolution authorising 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.

#### 6.11 **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. Upon listing, the Company will be 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.

#### 6.12 **Directors**

##### (A) *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.

##### (B) *Directors’ shareholding qualification*

A Director shall not be required to hold any shares in the Company.

##### (C) *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 authorised 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.

##### (D) *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.

(E) *Removal of Directors by special resolution*

The Company may by special resolution remove any Director before the expiration of his period of office.

(F) *Vacation of office*

The office of a Director shall be vacated if:

- (i) he resigns or offers to resign and the Board resolves to accept such offer;
- (ii) he is removed by notice given by all the other Directors and all the other Directors are not less than three in number;
- (iii) he is or has been suffering from mental or physical ill health and the Board resolves that his office be vacated;
- (iv) 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;
- (v) he becomes bankrupt or compounds with his creditors generally;
- (vi) he is prohibited by a law from being a Director;
- (vii) he ceases to be a Director by virtue of the Companies Act; or
- (viii) 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.

(G) *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.

(H) *Proceedings of the Board*

Subject to the provisions of the Articles, the Board may meet for the despatch 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.

(I) *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 authorised 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 authorised by the Board go beyond the ordinary duties of a Director may be paid such extra remuneration as the Board or any committee authorised 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.

(J) *Pensions and gratuities for Directors*

The Board or any committee authorised 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.

(K) *Directors' interests*

The Board may, subject to the provisions of the Articles, authorise 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:

- (i) be party to, or otherwise interested in, any contract with the Company or in which the Company has a direct or indirect interest;
- (ii) 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;
- (iii) 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);
- (iv) 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
- (v) 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 realised by reason of having an interest permitted as described above or by reason of having a conflict of interest authorised by the Board and no contract shall be liable to be avoided on the grounds of a Director having any such interest.

(L) *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 authorised by reason of a contravention of such provisions.

(M) *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).

(N) *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.

6.13 ***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 authorised in writing by the Shareholder.

**7. Mandatory bids and compulsory acquisition rules relating to Indivior Ordinary Shares**

Other than as provided by the City Code and Chapter 28 of the Companies Act, there are no rules or provisions relating to mandatory bids and/or squeeze-out and sell-out rules relating to the Company.

7.1 ***Mandatory bid***

The City Code applies to the Company. Under Rule 9 of the City Code, if an acquisition of interests in shares were to increase the aggregate holding of the acquirer and its concert parties to interests in shares carrying 30% or more of the voting rights in the Company, the acquirer and, depending on circumstances, its concert parties would be required (except with the consent of the Takeover Panel) to make a cash offer for the outstanding shares in the Company at a price not less than the highest price paid for interests in shares by the acquirer or its concert parties during the previous 12 months. This requirement would also be triggered by any acquisition of interests in shares by a person holding (together with its concert parties) shares carrying between 30% and 50% of the voting rights in the Company if the effect of such acquisition were to increase that person's percentage of the total voting rights in the Company.

## 7.2 **Squeeze-out**

Under the Companies Act, if a “takeover offer” (as defined in section 974 of the Companies Act) is made for the Indivior Ordinary Shares and the offeror were to acquire, or unconditionally contract to acquire, not less than 90% in value of the Indivior Ordinary Shares to which the offer relates and not less than 90% of the voting rights carried by the Indivior Ordinary Shares to which the offer relates, it could, within three months of the last day on which its takeover offer can be accepted, compulsorily acquire the remaining 10%. The offeror would do so by sending a notice to outstanding members telling them that it will compulsorily acquire their Indivior Ordinary Shares and then, six weeks later, it would execute a transfer of the outstanding Indivior Ordinary Shares in its favour and pay the consideration for the outstanding Indivior Ordinary Shares to the Company, which would hold the consideration on trust for outstanding members. The consideration offered to the members whose shares are compulsorily acquired under this procedure must, in general, be the same as the consideration that was available under the original offer unless a member can show that the offer value is unfair.

## 7.3 **Sell-out**

The Companies Act also gives minority members a right to be bought out in certain circumstances by an offeror who has made a takeover offer. If a takeover offer related to all the Indivior Ordinary Shares and, at any time before the end of the period within which the offer could be accepted, the offeror held or had agreed to acquire not less than 90% in value of the Indivior Ordinary Shares and not less than 90% of the voting rights carried by the Indivior Ordinary Shares, any holder of Indivior Ordinary Shares to which the offer related who had not accepted the offer could, by a written communication to the offeror, require it to acquire those Indivior Ordinary Shares. The offeror is required to give any member notice of his/her right to be bought out within one month of that right arising. The offeror may impose a time limit on the rights of minority members to be bought out, but that period cannot end less than three months after the end of the acceptance period or, if later, three months from the date on which notice is served on members notifying them of their sell-out rights. If a member exercises his/her rights, the offeror is entitled and bound to acquire those Indivior Ordinary Shares on the terms of the offer or on such other terms as may be agreed.

## 8. Subsidiary undertakings

After the Demerger the Company will be the holding company of the Indivior Group.

The significant subsidiary undertakings and associated undertakings of the Company will, after the Demerger Effective Time, be as follows:

<i>Name</i>	<i>Country of incorporation or registration</i>	<i>Proportion of ownership interest</i>	<i>Principal activity</i>
RBP Global Holdings Ltd	England and Wales	100%	Holding and Finance company
RBP US Holdings Inc	US	100%	Holding and Finance company
RB Pharmaceuticals Pty Ltd	Australia	100%	Operating company
RB Pharmaceuticals Ltd	England and Wales	100%	Operating company
Reckitt Benckiser Pharmaceuticals Healthcare South Africa (Pty) Ltd	South Africa	100%	Operating company
RBP Finance LLC	US	100%	Finance company
RB Pharmaceuticals (EU) Ltd	England and Wales	100%	Operating company
RB Pharmaceuticals Ltd Hellas Branch	Greece	100%	Operating company
Reckitt Benckiser Pharmaceuticals France SAS	France	100%	Operating company
RB Pharmaceuticals (Italia) Srl	Italy	100%	Operating company
RB Pharmaceuticals (Deutschland) GmbH	Germany	100%	Operating company
Reckitt Benckiser Pharmaceuticals Solutions Inc.	US	100%	Operating company
Reckitt Benckiser Pharmaceuticals Inc.	US	100%	Operating company

## 9. Major Shareholders

As at 13 November 2014 (being the last practicable date prior to the publication of this Prospectus) and insofar as is known to the Company, by reference to relevant notifications made in accordance with rule 5.1 of the Disclosure and Transparency Rules, the name of each person, other than a Director, who holds voting rights representing 3% or more of the total voting rights in respect of RB Ordinary Shares, and the amount of such person's holding of the total voting rights in respect of Indivior Ordinary Shares at the Demerger Effective Time and on Admission is expected to be as follows:

<i>Shareholder</i>	<i>Number of RB Ordinary Shares</i>	<i>Percentage of RB issued share capital</i>	<i>Number of Indivior Ordinary Shares on Admission</i>	<i>Percentage of Indivior issued share capital on Admission</i>
JAB Holdings B.V.	76,659,342	10.66%	76,659,342	10.66%
Massachusetts Financial Services Company	44,281,281	6.15%	44,281,281	6.15%

Save as disclosed in this paragraph 9 the Company is not aware of any person who, as at 13 November 2014 (being the last practicable date prior to the publication of this Prospectus),

directly or indirectly, has a holding which exceeds the threshold of 3% or more of the total voting rights attaching to the issued share capital of RB.

The Company is not aware of any persons who, as at 13 November 2014 (being the last practicable date prior to the publication of this document), directly or indirectly, jointly or severally, will exercise or could exercise control over the Company nor is it aware of any arrangements the operation of which may at a subsequent date result in a change in control of the Company.

None of the shareholders referred to in this paragraph 9 has or will have different voting rights from any other holder of Indivior Ordinary Shares in respect of any Indivior Ordinary Shares held by them.

## 10. Directors and Senior Managers

### 10.1 *Other directorships and partnerships*

The details of those companies and partnerships (excluding subsidiaries of those companies of which a Director or Senior Manager is or was also a director) outside the Indivior Group of which the Directors and Senior Managers are currently directors or partners, or have been directors or partners at any time during the previous five years prior to the date of this Prospectus, are as follows:

<u>Name</u>	<u>Position</u>	<u>Company/Partnership</u>	<u>Position still held (Y/N)</u>
Howard Pien	Director	Sage Therapeutics, Inc.	Y
	Director	Juno Therapeutics, Inc.	Y
	Director	ImmunoGen, Inc.	Y
	Director	Vanda Pharmaceuticals, Inc.	Y
	Director	Bellerophon Therapeutics, LLC	Y
	Chairman and CEO	Medarex, Inc.	N
	Director	Ikaria, Inc.	N
	Director	ViroPharma, Inc.	N
	Director	Talon Therapeutics, Inc.	N
	Director	Arresto BioSciences, Inc.	N
Cary Claiborne	Partner	Warburg Pincus	Y
	Director	MedicAlert Foundation	Y
	CFO	Sucampo Pharmaceuticals, Inc.	N
Yvonne Greenstreet	Director	New Generation Biofuels, Inc.	N
	Director	Pacira Pharmaceuticals, Inc.	Y
	Director	Advanced Accelerator Applications SA	Y
Adrian Hennah	Partner	Windhoek HC	Y
	CFO	Reckitt Benckiser Group plc	Y
	Non-executive Director	Reed Elsevier plc	Y
Lorna Parker	Non-executive Director	Reed Elsevier NV	Y
	CFO	Smith & Nephew plc	N
	CFO	Invensys plc	N
Lorna Parker	Director	Future Academies	Y
	Director	Place2Be	N

<u>Name</u>	<u>Position</u>	<u>Company/Partnership</u>	<u>Position still held (Y/N)</u>
Daniel J. Phelan	Director	TE Connectivity	Y
	Executive Director	Executive Networks, Inc.	Y
Christian S. Schade	CEO	Novira Therapeutics, Inc.	Y
	Director	Integra Life Sciences	Y
	CFO	Omthera Pharmaceuticals	N
	CFO	Medarex, Inc.	N
Daniel Tassé	Chairman and CEO	Ikaria, Inc.	Y
	Non-executive		
	Director	Bellerophon Therapeutics, LLC	Y
	CFO	NRG Energy	N

## 10.2 **Conflicts of interest**

Save as set out below, there are no actual or potential conflicts of interest between the duties owed by Directors or the Senior Managers to the Company and the private interests and/or other duties that they may also have:

Adrian Hennah is a director of RB and is not considered to be an independent non-executive director for the purposes of the UK Corporate Governance Code.

## 10.3 **Directors' and Senior Managers' confirmations**

As at the date of this Prospectus, none of the Directors or members of the Senior Management has during the last five years:

- (A) had any convictions in relation to fraudulent offences;
- (B) been associated with any bankruptcies, receiverships or liquidations acting in the capacity of any of the positions set out against the name of the Director in the paragraph above;
- (C) been subject to any official public incrimination and/or sanctions by any statutory or regulatory authorities including, where relevant, designated professional bodies; or
- (D) been disqualified by a court from acting as a member of the administrative management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer.

## 10.4 **Interests of Directors and Senior Managers in the Indivior Ordinary Shares**

As at the date of this Prospectus the Directors and Senior Managers have no interest in the share capital of the Company. From the Demerger Effective Time, the interests of the Directors and Senior Managers in the share capital of the Company, based on the number of RB Ordinary Shares owned as at 13 November 2014 (being the last practicable date prior to publication of this Prospectus), are expected to be as follows:

<u>Director</u>	<u>Shareholding</u>	<u>Percentage of issued share capital of Indivior</u>
Shaun Thaxter	55,803	0.0078%
Adrian Hennah	13,629	0.0019%
Richard Simkin	3,203	0.0004%

## 10.5 **Transactions with Directors and Senior Managers**

None of the Directors has or has had any interest in any transaction which is or was unusual in its nature or conditions or significant to the business which was effected by any member of the Indivior Group during the current or immediately preceding financial year, or which was effected during an earlier financial year and remains in any respect outstanding or unperformed.

None of the Directors has or had a beneficial interest in any contract to which any member of the Indivior Group was a party during the current or immediately preceding financial year.

There are no outstanding loans or guarantees granted or provided by any member of the Indivior Group for the benefit of any of the Directors.

## 11. **Director service contracts and letters of appointment**

### 11.1 **Executive directors' service contracts**

The executive directors have service contracts with the Indivior Group relating to the provision of services to the Indivior Group. The principal terms of the executive directors' contracts are summarised below.

#### (A) *General terms*

Shaun Thaxter was appointed as CEO with effect from 4 November 2014 and Cary Claiborne was appointed as CFO with effect from 10 November 2014. They are each entitled to a remuneration package comprising basic salary, discretionary performance-related bonus and benefits as set out below. Shaun Thaxter's base salary will be \$730,000 per annum and Cary Claiborne's base salary will be \$430,000 per annum. Each of their salaries are to be reviewed, but not necessarily increased, on an annual basis. They are each entitled to 25 working days' holiday, in addition to locally observed public holidays, in each holiday year.

Shaun Thaxter and Cary Claiborne shall participate in the Annual Performance Plan which is based on performance criteria established by the Company. Shaun Thaxter has a target bonus, expressed as a percentage of base salary, of 100% and a maximum bonus of 200%. Cary Claiborne has a target bonus, expressed as a percentage of base salary, of 60% and a maximum bonus of 180%. Any bonus is payable subject to Company performance and achievement of individual targets and is not payable if employment terminates for cause or by reason of resignation.

Shaun Thaxter and Cary Claiborne will also be able to participate in a discretionary Long Term Incentive Plan subject to the terms from time to time determined by the Remuneration Committee.

Shaun Thaxter and Cary Claiborne will also participate in the retirement and other benefit plans which are from time to time generally available to the Company's senior executives.

#### (B) *Termination provisions*

The service contracts of the executive directors can be terminated by not less than 12 months' notice by either party.

The Company may put the executive directors on garden leave during their notice period.

In addition, the employment of the executive directors is terminable with immediate effect in certain circumstances, including where they (i) fail without

reasonable cause to attend properly to their duties, or (ii) commit any serious or persistent breach of obligations or gross misconduct.

In the event of termination, the service contracts of the executive directors impose post-termination restrictions, for a period of six months following termination, to restrict them from soliciting customers, dealing with customers, interfering with suppliers, soliciting employees and from entering into active competition with the Company.

Particulars of the service contracts entered into with the executive directors as at 13 November 2014 (being the last practicable date prior to publication of this Prospectus) are set out below:

<i>Name</i>	<i>Position</i>	<i>Date of appointment to the Board</i>	<i>Notice period by Company (months)</i>	<i>Notice period by Director (months)</i>
Shaun Thaxter	CEO	4 November 2014	12	12
Cary Claiborne	CFO	10 November 2014	12	12

## 11.2 **Non-executive directors' letters of appointment and fees**

The non-executive directors are appointed by rolling letters of appointment. The key terms of the letter of appointment are set out below.

### (A) **General terms**

Each of the non-executive directors is entitled to receive a fee from the Company, paid monthly in a combination of shares and cash, the amount of which is determined by the Board. Each non-executive director's annual fee covers their role as a non-executive director and all other Board duties (including committee memberships and chairmanships). The Board has initially determined that the higher of £12,000 or 20% of non-executive directors' fees will be applied in the purchase of Indivior Ordinary Shares, and non-executive directors may elect to acquire additional Indivior Ordinary Shares with their fees.

In addition, each non-executive director is entitled to be reimbursed for all reasonable and properly documented expenses incurred in the performance of the non-executive director's duties. The non-executive directors do not participate in the discretionary bonus scheme or the Indivior LTIP.

### (B) **Term of office**

Particulars of the letters of appointment entered into with the Directors as at 13 November 2014 (being the last practicable date prior to publication of this Prospectus) are set out below:

<i>Name</i>	<i>Position</i>	<i>Date of appointment to the Board</i>	<i>Unexpired term (months)</i>	<i>Notice period by Company (months)</i>	<i>Notice period by Director (months)</i>
Howard Pien	Chairman	4 November 2014	36	One	One
Rupert Bondy	Senior Independent Director	4 November 2014	36	One	One
Yvonne Greenstreet	Independent Non-executive Director	4 November 2014	36	One	One

<i>Name</i>	<i>Position</i>	<i>Date of appointment to the Board</i>	<i>Unexpired term (months)</i>	<i>Notice period by Company (months)</i>	<i>Notice period by Director (months)</i>
Adrian Hennah	Non-executive Director	4 November 2014	36	One	One
A. Thomas McLellan	Independent Non-executive Director	4 November 2014	36	One	One
Lorna Parker	Independent Non-executive Director	4 November 2014	36	One	One
Daniel J Phelan	Independent. Non-executive Director	4 November 2014	36	One	One
Christian S. Schade	Independent Non-executive Director	4 November 2014	36	One	One
Daniel Tassé	Independent Non-executive Director	4 November 2014	36	One	One

### 11.3 **Directors' remuneration in FY 2013**

The amounts of remuneration paid (including basic salary and other emoluments) and benefits in kind granted to each of the Directors by the RB Group for services in all capacities to the Indivior Group in respect of FY 2013 are set out in the table below.

<i>Name</i>	<i>Position</i>	<i>Basic salary or fees (\$)</i>	<i>Bonus (\$)</i>	<i>Benefits in kind (\$)</i>	<i>Pension contributions (\$)</i>	<i>Total (\$)</i>
Shaun Thaxter	CEO	\$499,668.96	\$240,225.48	\$116,478.68	\$112,048.18	\$968,421.30

### 11.4 **Long Term Incentive Plan**

The Director listed below will exchange his awards granted in 2012 under the RB Long Term Incentive Plan, on a value-neutral basis for new awards over Indivior Ordinary Shares under the Indivior LTIP. The relevant maximum number of Indivior Ordinary Shares will be fixed on conversion and the actual, and therefore the maximum, value of those awards will be dependent on the price of Indivior Ordinary Shares at the time the awards vest. These awards will vest at the end of FY 2015, subject to performance against targets.

The table below sets out details of the outstanding LTIP awards for Mr Thaxter as at the date of this document.

<i>Executive Director</i>	<i>LTIP award</i>	<i>Final year of performance period (end of FY)</i>	<i>Exercise Price (£)</i>	<i>Number of RB Ordinary Shares</i>
Shaun Thaxter	Option	2015	39.14	28,000
	Restricted Shares	2015	N/A	14,000
	Restricted Shares	n/a	N/A	5,000

Note: the executive director's LTIP awards listed above will convert, on Admission, on a value-neutral basis to awards over Indivior Ordinary Shares and, although the relevant maximum number of Indivior Ordinary Shares will be fixed on conversion, the actual, and therefore the maximum, value of those awards will therefore be dependent on the price of Indivior Ordinary Shares at the time the awards vest. The award over 5,000 shares vests over time and is not subject to any performance condition and its replacement award will therefore also not be subject to any conditions.

## 12. Senior Managers' remuneration in FY 2013

The aggregate remuneration paid (including salary and other benefits) to the Senior Managers by the RB Group for services in all capacities to the Indivior Group in respect of FY 2013 was \$1,634,651.94.

## 13. Pensions

The RB Group operates a number of defined benefit and defined contribution pension schemes around the world covering many of its employees, which are principally funded.

Consequently Indivior will, with effect from the Demerger, operate its own pension schemes which will in the main be defined contribution. There will, however, be some exceptions such as an unfunded defined benefit scheme in Germany and an unfunded defined benefit scheme in France operating on a pay as you go basis with an insurance company.

There are approximately 85 employees who are currently active members of the RB Pension Scheme who will be employed within the Indivior Group after the Demerger. These employees will be offered membership of the new Indivior Pension Schemes for service on and after the Demerger.

## 14. Employee share plans

Indivior has established the following plans which are summarised below. However Indivior intends to review all its employee share arrangements as part of a wider remuneration review in 2015 and may, accordingly, seek shareholder approval of a new arrangement by way of replacement of existing arrangements as a result.

### 14.1 The Indivior Long Term Incentive Plan (the "Plan")

#### (A) Administration of the Plan

The Plan will be administered by the Remuneration Committee of the Board or, for awards not being made to Directors, such other committees authorised by the Company (the "**Committee**").

#### (B) Eligibility

Participants in the Plan will be selected by the Committee. Participants will be limited to employees and executive directors of the Company and its subsidiaries (the "**Group**").

#### (C) Awards

Awards may normally take one of three forms:

- (i) a conditional award, which is a deferred right to receive ordinary shares in the Company ("Shares");
- (ii) an option to acquire Shares at a price set by reference to their market value at the grant date; or
- (iii) an option to acquire Shares for no cost or a nominal amount.

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

Awards will be personal to the participant and may not be transferred. No payment will be required for the grant of an award.

(D) *Timing*

Awards may be granted in the six weeks following Admission and thereafter in the six weeks following announcement of the Company's results for any period, following any changes to legislation affecting share plans being announced or made and at other times if the Committee considers that exceptional circumstances exist.

(E) *Individual limit*

There is a limit on the market value (measured at the time of grant) of 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.

(F) *Plan limits*

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

For these purposes, Shares will be 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) Shares which are acquired by purchase in the market (rather than by subscription or from treasury); and (ii) Shares which an employee purchases at market value using his own funds.

No further awards may be granted under the Plan after 30 November 2024.

(G) *Performance targets*

Each award may, or in the case of executive directors of the Group must (except as noted at 11.4 above), be subject to one or more performance targets which will determine whether and to what extent the participant will receive Shares. Performance targets will normally be measured over a period of not less than three years. For executive directors the performance targets will be measured on one occasion only; there will be 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.

(H) *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 Shares will be released automatically upon vesting while in the case of options, the award will become 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.

Awards may be adjusted prior to their exercise if there is a material misstatement of the Group's 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.

(I) *Termination of employment*

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

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

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.

(J) *Change of control*

Special rules apply in the event of a change of control, including a change of control resulting from a scheme 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 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.

(K) *Listing*

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

(L) *Variation of Capital*

In the event of any variation in the share capital of the Company or in such other circumstances as the Committee considers appropriate/a demerger or special dividend distribution, awards may be adjusted in such manner as the Committee considers appropriate.

(M) *Benefits non-pensionable*

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

(N) *Amendments*

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

Except as described above or for minor amendments designed to ease the administration of the Plan, 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.

(O) *HMRC registered options*

The Plan will contain a part which will allow options to be granted which satisfy the conditions of Schedule 4 of the Income Tax (Earnings and Pensions) Act 2003.

14.2 ***The Indivior Savings-Related Share Option Plan (the "SAYE Plan")***

(A) *Administration*

The SAYE Plan will be operated and administered by the board of directors of the Company or a duly authorised committee thereof (the "**Board**").

(B) *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 SAYE Plan, will be 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 Group to participate.

(C) *Options*

Options will entitle the holder to acquire ordinary shares in the Company (the "**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 after 30 November, 2024.

(D) *Timing*

Invitations to participate may normally only be issued in the period beginning three weeks before and ending six weeks after the announcement of the results of the Company for any period, the date of any general meeting of the Company or at other times in exceptional circumstances.

(E) *Exercise price*

The exercise price may not be less than an amount equal to 80% of the market value of a Share, determined in accordance with the Taxation of Chargeable Gains Act 1992, for such dealing day or days as the Board may select in the 30-day period immediately preceding the date of grant.

(F) *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 Save-as-You-Earn (SAYE) 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 SAYE contracts linked to the SAYE Plan may not exceed such sum as may from time to time be permitted by statute and approved by the Directors.

(G) *Plan limits*

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

For these purposes, Shares are allocated when they are issued or, if earlier, when the right to receive or acquire the Shares is conferred on the employee. Rights which lapse, by reason of non-exercise or otherwise, cease to count. No account is taken of Shares which are acquired by purchase rather than by subscription except where such Shares were first issued to an employee trust for the purpose of satisfying a participant's rights. No account is taken of Shares which an employee purchases using his own funds except on the exercise of an option under an option scheme or where such Shares are acquired for an amount which is less than the market value of a fully paid up share of the same class.

(H) *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 SAYE contract is payable. In normal circumstances this will be the third or fifth anniversary of the starting date of the SAYE 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 SAYE contract and any interest or bonus payable under the contract.

(I) *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 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 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 Group for so long as he remains employed by a company which is an associated company of the Company.

(J) *Change of control*

The exercise of options will also be permitted in the event of a change in control, a reorganisation, 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.

(K) *Listing*

Application will be made for admission to the Official List of new Shares issued under the SAYE Plan 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. The Company will at all times keep available sufficient authorised and unissued share capital to satisfy outstanding options to subscribe for Shares.

(L) *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.

(M) *Benefits non-pensionable*

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

(N) *Amendments*

The Board may make such amendments to the SAYE Plan as are either necessary or desirable to ensure the SAYE Plan 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 SAYE Plan and to any option as may be necessary or desirable to obtain or maintain favourable tax, exchange control or regulatory treatment for participants or for any company in the Group.

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

#### 14.3 ***The Indivior Global Stock Profit Plan (the "GSPP")***

(A) *Administration*

The GSPP will be operated and administered by the board of directors of the Company or a duly authorised committee thereof (the "**Board**").

(B) *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.

(C) *Awards*

Awards under the GSPP will be either options or share appreciation rights (“**SARs**”). Options may be granted either to the individual participant or to a trustee on his behalf. Options will entitle the participant to acquire Shares. Options may be either options to subscribe for new Shares or options to purchase existing Shares.

SARs 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 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 will be 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.

(D) *Timing*

Invitations to participate may normally only be issued during the period of 30 days after 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, or the date of any general meeting of the Company or at other times in exceptional circumstances.

(E) *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 a 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.

(F) *The savings contract*

To participate in the GSPP, an eligible employee must enter into a savings contract (the “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.

(G) *Plan limits*

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

For these purposes Shares are allocated when they are issued or if earlier when the right to receive or acquire the Shares is conferred on the employee. Rights which lapse by reason of non-exercise or otherwise cease to count. No account is taken of Shares which are acquired by purchase rather than by subscription except where such Shares were first issued to an employee trust for the purpose of satisfying a participant’s rights.

(H) *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.

(I) *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 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 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.

(J) *Change of control*

In the event of a change of control (whether as a result of an offer or a scheme of arrangement under section 899 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.

(K) *Listing*

Application will be made for admission to the Official List of new Shares issued under the GSPP 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. The Company will at all times keep available sufficient authorised and unissued share capital to satisfy outstanding options to subscribe for Shares.

(L) *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.

(M) *Benefits non-pensionable*

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

(N) *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 favourable 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.

**15. Indemnity insurance**

Each of the Directors 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.

**16. Employees**

The Indivior Group employs approximately 700 people. The average monthly number of employees (including executive directors) employed by the Indivior Group for the years ended 31 December 2011, 2012 and 2013 was as follows:

	<i>Year ended 31 December</i>		
	<i>2011</i>	<i>2012</i>	<i>2013</i>
Total Employees	616	677	700

**17. Working Capital**

The Company is of the opinion that (taking into account the bank and other facilities available to the Indivior Group) the working capital available to the Indivior Group is sufficient for the Indivior Group's present requirements, that is, for at least the next 12 months from the date of the publication of this Prospectus.

**18. Significant change**

On 15 November 2014, RBP Global Holdings Limited signed a commitment letter to obtain a \$750 million term loan and a \$50 million revolving credit facility. Annexed to the commitment letter is the form of the credit agreement which RBP Global Holdings Limited and the Initial Lenders are thereby committed to entering into. The term loan of \$750 million will be drawn in full on 19 December 2014. It is expected that the revolving credit facility will remain undrawn. The Company expects to use approximately \$500 million from the proceeds of the term loan financing to pay a dividend to RB.

Save as described above, there has been no significant change in the trading or financial position of the Indivior Group since 30 September 2014, the date to which the Indivior Group's last unaudited 2014 interim financial statements were prepared.

There has been no significant change in the trading or financial position of the Company since 26 September 2014, being the date of its incorporation.

## **19. Litigation and disputes**

Save as disclosed below, there are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Company is aware), during a period covering at least the 12 months prior to the date of this Prospectus which may have, or have had in the recent past, significant effects on the Company's and/or the Indivior Group's financial position or profitability.

### **19.1 *US antitrust class action***

Beginning in December 2012, 12 US federal antitrust class action complaints were filed against RB, RBP and various other entities in the RB Group. The complaints alleged that the defendants, in violation of the Sherman Act, engaged in a scheme to delay FDA approval of generic versions of Suboxone Tablet. In June 2013, the complaints were consolidated in the US District Court for the Eastern District of Pennsylvania. In September 2013, RBP and the other defendants filed motions to dismiss the complaints. In December 2013, certain plaintiffs (who would have been members of the proposed class) elected to file a separate state court action in Pennsylvania. That action was stayed pending the outcome of the motion to dismiss in the federal class action lawsuit. The plaintiffs in both the federal and the state actions seek unspecified monetary damages.

### **19.2 *FTC and the State of New York civil investigations***

In June 2013, the FTC commenced a non-public investigation of RB, RBP and various other entities in the RB Group by issuing a civil investigative demand focusing on business practices relating to Suboxone Film, Suboxone Tablet and Subutex Tablet, including those that are the subject of the allegations in the antitrust class actions described above. A similar investigation was commenced by the Attorney General of the State of New York in July 2013. RBP has responded to both the FTC civil investigative demand and to a State of New York subpoena by producing documents and other information to the FTC and the Attorney General of the State of New York. The investigations are ongoing, and as yet no decision has been made by either agency on whether to pursue any legal action for enforcement. No provision has been recorded as the Board believes that, at this stage, it is not possible to estimate the likelihood or quantification of an outcome.

### **19.3 *USAO-NJ subpoena***

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. RBP has had no communication from USAO-NJ since March 2013 and it is not possible at this time to predict the potential impact, if any, on the Indivior Group

### **19.4 *USAO-VAW search warrant***

In December 2013, the USAO-VAW executed a search warrant on RBP's headquarters in Richmond and conducted searches of the homes of four field-based employees. The USAO-VAW has since served a number of subpoenas relating to Suboxone Film, Suboxone Tablet, Subutex Tablet, buprenorphine and any real or potential competitor, among other issues. The investigation is ongoing and RBP is in the process of responding to the USAO-VAW by producing documents and other information. The subject of the case relates to promotional messages about the Indivior Group's products and remuneration to physicians. It is not possible at this time to predict the potential impact, if any, on the Indivior Group.

### 19.5 ***Par, Watson and Alvogen patent disputes***

Beginning in August 2013, the Indivior Group was informed of the filing in the US of ANDAs by Par, Watson, Alvogen and Teva for generic versions of Suboxone Film. The Indivior Group filed patent infringement lawsuits against Par, Watson and Alvogen in the US District Court for the District of Delaware (and is currently assessing Teva's Paragraph IV Notice received on 20 October 2014), as a result of which, pursuant to the Hatch-Waxman Act, the FDA generally cannot approve the ANDA applicants' products until the earlier of 30 months after notice to the Indivior Group of the relevant ANDA filing or the disposition of the patent infringement proceedings in the ANDA applicants' favour. The court granted the Indivior Group's motion to dismiss without prejudice in the case against Alvogen as Alvogen had triggered the Hatch-Waxman Act litigation process (prematurely). The suit against Alvogen can be re-filed if and when Alvogen receives the requisite acknowledgement from the FDA. (The initial lawsuit against Par was dismissed without prejudice for similar reasons and then re-filed by the Indivior Group in April 2014.) These lawsuits are likely to result in significant legal costs for the Indivior Group. If any of the defendants is successful in establishing that the asserted patents are invalid or not infringed, 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. Either would 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.

### 19.6 ***BDSI patent disputes***

In July 2013, the Indivior Group was informed of the filing in the US 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 US District Court for the Eastern District of North Carolina in October 2013. That action was dismissed without prejudice on procedural grounds and could be re-filed by the Indivior Group if and when BDSI launched its competing film product.

BDSI has also filed six requests, most recently on 28 October 2014, for inter partes review with the US Patent Office of certain claims in a number of patents relating to Suboxone Film or film formulations. The US Patent Office has granted one request and is expected to make a decision on the second request in December 2014, with decisions on the more recent requests of 28 October expected around April 2015.

Following confirmation in early September 2014 that BDSI was preparing to launch its product, the Indivior Group filed a patent infringement lawsuit against BDSI in the US District Court for the District of New Jersey on 22 September 2014, asserting an MSRX-licensed patent that is not related to Suboxone Film (which is one of the patents now the subject of the most recent BDSI inter partes review requests). The 30-month stay under the Hatch-Waxman Act does not apply in this case.

In addition, 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 20 September 2014 seeking a declaratory judgment of non-infringement and invalidity of three patents relating to Suboxone Film, one of which is the subject of an inter partes review before the USPTO and two of which are related to the process of manufacturing Suboxone Film.

This litigation is likely to result in significant legal costs for the Indivior Group. If BDSI is successful in establishing that any of those particular patents 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 would 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.

#### 19.7 **China trade mark dispute**

The Indivior Group is currently involved in a number of pieces of related litigation in China with Nanchang Lijian regarding the mark 赛宝松 (“Sai Bao Song”, a transliteration of SUBOXONE) and which is owned in China by Nanchang Lijian. Nanchang Lijian has filed a trade mark infringement claim against the Indivior Group’s use of this mark which the Indivior Group is currently contesting. Related to this, a number of applications have been filed by the Indivior Group at the relevant trade mark registry seeking to cancel the Sai Bao Song registrations held by Nanchang Lijian which are the subject of the infringement claim. There is a risk that the Indivior Group may not be successful in defending the litigation and/or revoking these marks. Depending on the outcomes, the Indivior Group may be prevented from using Sai Bao Song, and similar marks, in the future together with the potential for Indivior to have to pay damages and costs to Nanchang Lijian. However, the Indivior Group owns SUBOXONE and various other trade marks in China, and while the case is still proceeding and pending the outcome, the Indivior Group will continue to use in relation to SUBOXONE the alternative Chinese character mark 舒备生 (“Shu Bei Sheng”) to which the Indivior Group owns rights in China. This alternative trade mark is not currently the subject of any infringement claim, or otherwise being challenged, by Nanchang Lijian. The Board believes that it is not possible at this stage to estimate the quantum of any damages which might be awarded.

#### 19.8 **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 recorded a provision of \$16m as of FY 2012 and was subsequently fined €0.3m in 2013 but has appealed against the ruling. A private civil claim has been brought against a competitor of the Indivior Group as a result of the finding against it, and it is therefore possible that a similar claim could be brought against the Indivior Group.

### 20. **Group financing arrangements**

#### **Term Loan B and Revolving Credit Facility**

On 15 November 2014 RBP Global Holdings Limited signed a commitment letter (the “**Commitment Letter**”) with Deutsche Bank AG New York Branch, Deutsche Bank Securities Inc. and Morgan Stanley Senior Funding, Inc. as initial lenders and arrangers (the “**Arrangers**”) relating to the terms under which Deutsche Bank AG New York Branch and Morgan Stanley Senior Funding, Inc. are prepared to initially lend, and subsequently arrange syndication in respect of, a \$750 million term “B” loan facility (the “**Term Loan B**”) and a \$50 million revolving credit facility with \$10 million swingline facility and \$25 million letter of credit facility (the “**RCF**”, together with the Term Loan B, the “**Facilities**”). Please refer to paragraph 8.4 of Part X (*Operating and Financial Review*) of this Prospectus for further details.

### 21. **Material contracts**

Set out below is a summary of (i) each material contract (other than a contract in the ordinary course of business) to which the Company is a party which has been entered into within the two years immediately preceding the date of this Prospectus; and (ii) any other contract (other than a contract in the ordinary course of business) entered into by any member of the Indivior Group which contains a provision under which any member of the Indivior Group has any obligation or entitlement which is material to the Indivior Group as at the date of this Prospectus.

(A) ***The Demerger Agreement***

The Demerger Agreement was entered into on 17 November 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 is conditional upon the passing of the Demerger Resolution, the approval by the Board of RB of the Demerger Dividend, RB having been entered into the register of members of RBP Global Holdings Limited as the holder of all the shares in RBP Global Holdings Limited, the UKLA having acknowledged (and such acknowledgement not having been withdrawn) that the application for Admission has been approved and, after satisfaction of any conditions to which such approval is expressed to be subject, will become effective as soon as a dealing notice has been issued, the London Stock Exchange having acknowledged (and such acknowledgement not having been withdrawn) that the Indivior Ordinary Shares will be admitted to trading on the main market and the Sponsors' Agreement not having terminated in accordance with its terms.

RB and Indivior have agreed pursuant to the Demerger Agreement that:

- (i) upon the Demerger Dividend being declared by the RB Board, RB shall transfer the entire issued share capital of RBP Global Holdings Limited to Indivior, and Indivior shall issue the Indivior Ordinary Shares to each member on the RB Share Register as at the Demerger Record Time (other than RB itself if it is a member at that time); and
- (ii) upon the transfer of the shares in RBP Global Holdings Limited to Indivior, RB shall grant Indivior a power of attorney over those shares pending registration of Indivior's holding.

The Demerger Agreement contains mutual indemnities under which Indivior indemnifies the RB Group against liabilities arising in respect of the Indivior Business and RB indemnifies the Indivior Group against liabilities arising in respect of the business carried on by the RB Group other than the Indivior 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) will be dealt with following the Demerger. In terms of the Demerger Agreement, 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 will be 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.

The Demerger Agreement will terminate if the conditions set out above have not been satisfied by 8:00 a.m. on 23 December 2014 (or such other time and date as the parties may agree). RB is entitled to terminate the Demerger Agreement at any time prior to Admission.

(B) ***Transitional Services Agreement***

The Demerger Agreement requires Reckitt Benckiser plc and RBP Global Holdings Limited to enter into a transitional services agreement in relation to the terms and conditions upon which the RB Group will provide various services to the Indivior Group after the

Demerger. The Transitional Services Agreement will be entered into immediately prior to the Demerger Effective Time.

Pursuant to the terms of the Transitional Services Agreement, Reckitt Benckiser plc (on behalf of the RB Group) has agreed to provide RBP Global Holdings Limited (on behalf of the Indivior Group) with certain services which will 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 will 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 Reckitt Benckiser plc 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 up to 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 Reckitt Benckiser plc. 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. Liability of the service provider is limited to £10 million in aggregate less any amount already claimed under the Research and Development Services Agreement. Indirect or consequential loss is excluded.

(C) **Demerger Tax Deed**

The Demerger Agreement requires RB and Indivior to enter into the Demerger Tax Deed immediately prior to the Demerger Effective Time. The Demerger Tax Deed contains indemnities relating to taxation in the UK and elsewhere (excluding the US). Subject to certain exceptions, RB indemnifies Indivior against certain tax liabilities arising as a result of the Demerger or certain pre-Demerger reorganisation steps. RB also indemnifies 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-US controlled foreign company rules applying in relation to the RB group. Subject to certain exceptions, Indivior indemnifies 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 prevents the transfer of the shares in RBP Global Holdings Limited and the issue of Indivior 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-US 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.

(D) **US Tax Matters Agreement**

The Demerger Agreement requires RB and Indivior to enter into the US Tax Matters Agreement immediately prior to the Demerger Effective Time. The US Tax Matters Agreement will govern both Indivior's and RB's rights and obligations after the Demerger with respect to US federal, state and local taxes for both pre-and post-Demerger periods. Under the US Tax Matters Agreement, the Indivior Group and the RB Group generally will be 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 will generally be 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 Prospectus), (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 US Tax Matters Agreement being incorrect or violated. RB will generally be 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 US 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 will generally be 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 this 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 jeopardise the tax-free status of the Demerger.

Though valid as between the parties, the US 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 US federal taxes relating to periods before the date of the Demerger.

(E) ***Sponsors' Agreement***

The Company and the Joint Sponsors entered into the Sponsors' Agreement on 17 November 2014. Pursuant to the terms of the Sponsors' Agreement:

- (i) the Company has confirmed its appointment of Deutsche Bank and Morgan Stanley as joint sponsors in connection with the application for Admission, and the Joint Sponsors have each confirmed their acceptance of such appointment;
- (ii) the Joint Sponsors have been granted all powers, authorities and discretions which are necessary for or incidental to the performance of their responsibilities under the Listing Rules and Prospectus Rules;
- (iii) the Company has agreed to deliver certain documents to the Joint Sponsors relating to the application for Admission and the Joint Sponsors' responsibilities under the Listing Rules and Prospectus Rules;
- (iv) the Company has given customary representations, warranties, undertakings and indemnities to the Joint Sponsors; and
- (v) the Joint Sponsors have the right to terminate the Sponsors' Agreement in certain circumstances prior to Admission. These circumstances include: (i) the Prospectus has become or is discovered to be untrue, inaccurate or misleading in a manner which is material in the context of the Demerger; (ii) the breach by the Company of any of the warranties or undertakings contained in the Sponsors' Agreement, where the effect of such breach, in the opinion of the Joint Sponsor (acting in good faith) is material in the context of the Demerger; and (iii) the application for Admission is refused by the FCA or the London Stock Exchange or where Admission will not be granted.

(F) ***Existing Supply Agreement***

RB Health and RB Pharmaceuticals Limited entered into an amended and restated Supply Agreement on 17 November 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 the day that RB Pharmaceuticals takes operational control of the FCP and therefore the manufacturing of the API) and will be replaced by the Copacker Supply Agreement (described in paragraph 21(G) of this Part XV (*Additional Information*)).

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 exclusively from RB Health. RB Health's obligations set out in the existing Supply Agreement include (i) maintaining a sufficient stock level of raw and packaging materials, (ii) permitting RB Pharmaceuticals Limited and any authorised representative to access and 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 authorising 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.

(G) ***Copacker Supply Agreement***

The Demerger Agreement requires RB and Indivior to procure that RB Health and RB Pharmaceuticals Limited enter into a supply agreement immediately prior to the Demerger Effective Time. The supply agreement will commence on 'Plant Day', being the day that RB Pharmaceuticals Limited takes operational control of the FCP (and therefore the manufacturing of the API) and RB Health will manufacture the finished products (Buprenex, Suboxone Tablet, Subutex Tablet and Temgesic), on behalf of RB Pharmaceuticals Limited pursuant to the agreement.

Pursuant to the terms of the Copacker Supply Agreement, RB Health has agreed to manufacture the finished products exclusively for RB Pharmaceuticals Limited and RB Pharmaceuticals Limited has 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 RB Pharmaceuticals Limited's obligations to each other are as set out in the Existing Supply Agreement, save that the references to the references to the manufacturing and sale of the API by RB Health to RB Pharmaceuticals Limited will not apply under the Copacker Supply Agreement and that RB Pharmaceuticals Limited shall only supply API to RB Health. There is a customary 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 RB Pharmaceuticals 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 RB Pharmaceuticals 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.

(H) ***The Lease of the FCP***

The Demerger Agreement requires RB Health to grant to RB Pharmaceuticals Limited a lease of the FCP on 1 December 2014, in return for the payment of a premium for a term of 150 years at a peppercorn rent. RB Pharmaceuticals 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 RB Pharmaceuticals 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 RB Pharmaceuticals 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 RB Pharmaceuticals Limited in the event that the landlord proposes to sell its interest in the FCP.

(I) **Research and Development Services Agreement**

The Demerger Agreement requires RB and Indivior to procure that RB Health and RB Pharmaceuticals Limited enter into an agreement immediately prior to the Demerger Effective Time in relation to the terms and conditions upon which RB Health and RB Pharmaceuticals Limited will 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 services in relation to the R&D Facilities, all of which will be provided on commercial terms and on an arms’ length basis.

The access to and use of the R&D Facilities and the related services will be provided to the same standard and level as the 12 month period preceding the Demerger and includes the use of equipment owned by RB Health, materials purchased by RB Health, quality management and quality control services, use of controlled drug licences, use of investigational medicinal product licences and a controlled drugs store. The agreement sets out services provided by RB Pharmaceuticals Limited to the RB Group to be provided for a maximum period of 12 months, while the access to and the use of the R&D Facilities and related services provided by RB Health to the Indivior Group shall be provided for a maximum period of 3 years. 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 R&D Services for a fourth year. RB Health may reasonably increase the relevant service charges in relation to such services.

RB Pharmaceuticals 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 RB Pharmaceuticals Limited is limited to £10 million in aggregate, less any amount already claimed under the Transitional Services Agreement. Indirect or consequential loss is excluded.

(J) **MSRX Agreement**

Under a commercial exploitation agreement dated 15 August 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. 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, 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, in respect of sales in the European Union.

The agreement contains certain customary warranty and indemnity provisions, and after August 2015 the contract will automatically renew 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.

(K) **Anti-Op Agreement**

Under a co-development and asset purchase agreement dated 10 February 2014 between AntiOp, Inc., Daniel P. Wermeling and RBP, the parties agree to jointly develop a product for the reversal of opioid overdose (the “**AntiOp Product**”). RBP agreed to pay an exclusive

development fee of \$4,000,000 and milestone payments of up to \$8,000,000 to AntiOp. RBP has an exclusive option (which has not yet been exercised) to purchase the AntiOp Product and certain other related assets on payment of \$5,000,000. The agreement contains certain customary warranty and indemnity provisions and continues until: (i) closing of the asset purchase following RBP's exercises of its exclusive option; (ii) RBP decides not to exercise its exclusive option, or (iii) RBP allows its exclusive option to lapse.

(L) ***XenoPort Agreement***

Under a licence agreement dated 14 May 2014 between XenoPort, Inc. and RBP, RBP obtained an exclusive worldwide licence for the development and commercialisation 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, 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) royalties on sales. 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.

(M) ***QLT USA Agreement***

Under a licence agreement and related asset purchase agreements dated 25 August 2008 between QLT USA, Inc. and RBP, RBP obtained an exclusive worldwide licence of QLT USA, Inc.'s sustained-release Atrigel® drug delivery technology in respect of Atrigel®-formulated products for human and veterinary use, excluding certain exceptional products (such as dental products). RBP agreed to pay an aggregate upfront payment of \$25,000,000 and certain regulatory milestone payments of up to \$5,000,000. The Atrigel®-formulation is relevant to the RBP-6000 monthly depot buprenorphine product in RBP's product pipeline.

The agreement contains certain customary warranty and indemnity provisions, and continues until the last to expire of any licensed patents, at which point RBP will be granted an exclusive licence to any licensed technology.

## **22. Environmental matters**

The Board believes that the Group has no material environmental compliance costs or environmental liabilities. An environmental study is currently being carried out on the land occupied by the FCP, with the results due on or around 1 December 2014. The Indivior Group has no further information about the environmental study at the date of this Prospectus.

## **23. Property**

The Indivior Group benefits from a lease of its head office in Richmond, Virginia, which comprises approximately 42,000 square feet of office space and terminates on 31 December 2017.

The Indivior Group also benefits from a lease of premises in Fort Collins, Colorado, which comprises approximately 23,200 square feet and terminates on 1 May 2018. The Indivior Group benefits from two options to extend the lease until 1 May 2021 and 1 May 2024, respectively.

The Indivior Group will, from 1 December 2014, benefit from a long lease of the FCP, the details of which are described in paragraph 21(H) of this Part XV (*Additional Information*).

Pursuant to the Research and Development Services Agreement, the Indivior Group will have access to and use of certain research facilities and quality control facilities, the details of which are described in paragraph 21(I) of this Part XV (*Additional Information*).

Pursuant to the Transitional Services Agreement and ancillary documents, the Indivior Group will benefit from temporary licences to occupy part of 21 different office locations in the UK, Europe and the Developing Markets, the details of which are described in paragraph 21(B) of this Part XV (*Additional Information*).

## **24. Related party transactions**

The related party transactions (which for these purposes are those set out in the standards adopted according to the Regulation (EC) No 1606/2002) of Indivior Group are set out in note 17 of Section B of Part XII (historical financial information for the three years ended 31 December 2013 and the six month period ended 30 June 2014) of this Prospectus and in note 12 of Section D of Part XII (unaudited combined condensed interim financial information) of this Prospectus. Save as disclosed in the aforementioned notes, the nature of the related party transactions of the Indivior Group has not changed since 30 September 2014 up to 13 November 2014 (being the last practicable date prior to publication of this Prospectus) and no member of the Indivior Group has entered into any other related party transactions during the period from 30 September 2014 up to 13 November 2014.

## **25. Other interests in the Indivior Group's securities**

As at 13 November (the last practicable date prior to the publication of this Prospectus):

- (A) Deutsche Bank has an economic exposure to less than 1.3% of the nominal value of the RB Ordinary Shares and it is expected that following Admission Deutsche Bank will have an economic exposure to less than 1.3% of the nominal value of the Indivior Ordinary Shares.
- (B) Morgan Stanley has an economic exposure to less than 0.1% of the nominal value of the RB Ordinary Shares and it is expected that following Admission Morgan Stanley will have an economic exposure to less than 0.1% of the nominal value of the Indivior Ordinary Shares.
- (C) Jefferies has an economic exposure to less than 0.002% of the nominal value of the RB Ordinary Shares and it is expected that following Admission Jefferies will have an economic exposure to less than 0.002% of the nominal value of the Indivior Ordinary Shares.

## **26. Consents**

PricewaterhouseCoopers LLP has given and has not withdrawn its written consent to the inclusion in this Prospectus of its reports as included in Sections A and C of Part XII (*Historical Financial Information*) of this Prospectus and its report concerning the pro forma financial information as included in Section B of Part XIII (*Unaudited Pro Forma Financial Information*) of this Prospectus in the form and context in which they appear and has authorised the contents of its reports solely for the purposes of item 5.5.3R(2)(f) of the Prospectus Rules.

A written consent under the Prospectus Rules is different from a consent filed with the US SEC under section 7 of the Securities Act. As the Indivior Ordinary Shares have not been, and will not be, registered under the Securities Act, PricewaterhouseCoopers LLP has not filed a consent under section 7 of the Securities Act.

## **27. Existing mandates**

The RB Shareholder Circular notifies RB Shareholders that all mandates relating to the monetary payment of dividends on RB Ordinary Shares and other instructions, including communication preferences, given to RB by RB Shareholders which are in force at the Demerger Record Time relating to their holding of RB Ordinary Shares will, unless amended or revoked,

be deemed from the Demerger Effective Time to be an effective mandate or instruction to Indivior in respect of the corresponding Indivior Ordinary Shares. RB Shareholders whose RB Ordinary Shares are held in uncertificated form and who currently participate in RB's dividend reinvestment plan will need to submit new elections through CREST on the ISIN for the Indivior Ordinary Shares in order to participate in any dividend reinvestment plan in respect of future dividends on the Indivior Ordinary Shares.

## **28. Documents available for inspection**

Copies of the following documents may be inspected at the registered office of the Company and at the offices of Slaughter and May, One Bunhill Row, London EC1Y 8YY during normal business hours on any weekday (Saturdays, Sundays and public holidays excepted) up to Admission:

- (A) the RB Shareholder Circular;
- (B) the Company's Articles of Association;
- (C) the audited historical financial information of the Indivior Group for the years ended 31 December 2011, 2012, 2013 and for the six months ended 30 June 2014 set out in Part XII (*Historical Financial Information*);
- (D) the reports from PricewaterhouseCoopers LLP set out in Sections A and C of Part XII (*Historical Financial Information*) and Section B of Part XIII (*Unaudited Pro Forma Financial Information*) of this Prospectus;
- (E) PricewaterhouseCoopers LLP's consent letter; and
- (F) a copy of this Prospectus.

For the purposes of PR 3.2.4 of the Prospectus Rules, this Prospectus will be published in printed form and made available free of charge at the registered office of the Company and at the offices of Slaughter and May, One Bunhill Row, London EC1Y 8YY. In addition this Prospectus will be published in electronic form and made available at [www.rb.com](http://www.rb.com).

## **29. Sources of information**

### **29.1 Financial information**

Unless otherwise stated, in this Prospectus financial information in relation to the Indivior Group referred to in the document has been extracted without material adjustment from the historical financial information set out in Part XII (*Historical Financial Information*) or has been extracted from those of the Indivior Group's accounting records that have been used to prepare that financial information. Information relating to gross sales and the contribution of products to net revenue has been extracted from those of the Indivior Group's accounting records that have been used to prepare the Historical Financial Information set out in Part XII (*Historical Financial Information*) and has not been audited. RB Shareholders and prospective investors should ensure that they read the whole of this Prospectus and not only rely on the key information or information summarised within them.

The PricewaterhouseCoopers LLP report on the Financial Information is set out in Section A of Part XII (*Historical Financial Information*). Unless otherwise indicated, none of the financial information relating to the Indivior Group or any operating information relating to the Indivior Group has been audited (even where such operating information includes certain financial metrics).

## 29.2 **Unaudited operating information**

Unaudited operating information in relation to the Indivior Group is derived from the following sources: (i) management accounts for the relevant accounting periods presented; and (ii) internal financial reporting systems supporting the preparation of financial statements. Operating information derived from management accounts or internal reporting systems in relation to the Indivior Group is to be found principally in Part VI (*Information on the Indivior Group and its Industry*) and Part X (*Operating and Financial Review*).

Management accounts are prepared using information derived from accounting records used in the preparation of the Indivior Group's Historical Financial Information, but may also include certain other management assumptions and analyses.

## 30. **Expenses**

The total costs and expenses of Admission (including the listing fees, printer's fees, advisers' fees and expenses and the costs of printing and distribution of documents are estimated to amount to £31 million (exclusive of VAT) and will be substantially borne by RB.

## PART XVI — GLOSSARY

<b>340B Programme</b>	a programme that requires drug manufacturers to provide outpatient drugs to eligible healthcare organisations and covered entities at significantly reduced prices;
<b>505(b)(2) NDA</b>	an NDA under FFDCA section 505(b)(2) for a drug product that has some differences from an already-approved drug product;
<b>Affordable Care Act</b>	the US Patient Protection and Affordable Care Act, as amended by the US Health Care and Education Reconciliation Act of 2010;
<b>Alvogen</b>	Alvogen Pine Brook, Inc.;
<b>analgesics</b>	any member of the group of drugs used for pain relief;
<b>ANDA</b>	abbreviated new drug application;
<b>API</b>	active pharmaceutical ingredients;
<b>AUD</b>	alcohol use disorders;
<b>BDSI</b>	BioDelivery Sciences International Inc.;
<b>BLA</b>	biologics licence application;
<b>Buprenex</b>	injection used primarily for the relief of moderate to severe pain in the US;
<b>buprenorphine</b>	a semi-synthetic partial opioid agonist that is used to treat opioid dependence;
<b>CBP</b>	the US Bureau of Customs and Border Protection;
<b>cGMP</b>	current good manufacturing practice issued by the FDA and other regulatory authorities;
<b>CMS</b>	Centres for Medicare and Medicaid services;
<b>CSA</b>	the US Controlled Substances Act of 1970;
<b>DATA 2000</b>	the US Drug Addiction Treatment Act of 2000;
<b>DEA</b>	the US Drug Enforcement Administration;
<b>EMA</b>	the European Medicines Agency;
<b>FCP</b>	Fine Chemicals Plant;
<b>FDA</b>	the US Food and Drug Administration;
<b>FFDCA</b>	the US Federal Food, Drug and Cosmetic Act of 1938, as amended;
<b>FSS</b>	Federal Supply Schedule;
<b>GCP</b>	good clinical practice;
<b>Hatch-Waxman Act</b>	the US Drug Price Competition and Patent Term Restoration Act of 1984;

<b>HHS</b>	the US Department of Health & Human Services;
<b>HRSA</b>	Health Resources and Services Administration;
<b>INCB</b>	International Narcotics Control Board;
<b>Induction Phase</b>	the medically monitored start-up of buprenorphine and naloxone therapy;
<b>Maintenance Phase</b>	phase reached when a patient is responding well to a steady dose of buprenorphine and naloxone;
<b>Medicaid</b>	a joint US federal and state programme that assists with medical costs for those with limited income and resources;
<b>Medicare</b>	a US federal health insurance programme for people who are 65 or older, certain younger people with disabilities and people with permanent kidney failure;
<b>MHRA</b>	the UK Medicines and Healthcare products Regulatory Agency;
<b>MSRX</b>	MonoSol Rx, LLC
<b>MSTAs</b>	Indivior Group's Medical Science Treatment Advisors;
<b>naloxone</b>	a competitive opioid antagonist that can temporarily reverse the effect of an opioid by removing it from the delta receptors;
<b>Nanchang Lijian</b>	Nanchang Lijian Pharmaceutical Co. Ltd;
<b>NDA</b>	new drug application;
<b>NIDA</b>	the US National Institute on Drug Abuse;
<b>Non-FAMP</b>	a weighted average non-federal average manufacturer's price;
<b>OTC</b>	over the counter;
<b>Par</b>	Par Pharmaceutical Companies, Inc;
<b>REMS</b>	risk evaluation and mitigation strategy;
<b>RLD</b>	reference listed drug;
<b>Suboxone Tablet</b>	a buprenorphine and naloxone-based sublingual tablet for the treatment of opioid dependence;
<b>Suboxone Film</b>	a buprenorphine and naloxone-based sublingual film for the treatment of opioid dependence;
<b>Subutex Tablet</b>	a buprenorphine-based sublingual tablet for the treatment of opioid dependence;
<b>Temgesic</b>	sublingual tablet and injection for the treatment of moderate to severe pain outside the US;
<b>USAO-NJ</b>	US Attorney's Office for the District of New Jersey;
<b>USAO-VAW</b>	US Attorney's Office for the Western District of Virginia;

**USPTO**

the US Patent and Trade mark Office;

**VA**

US Department of Veterans Affairs; and

**Watson**

Watson Laboratories, Inc.

## PART XVII

### DEFINITIONS

The following definitions apply throughout this Prospectus unless the context requires otherwise:

<b>2010 PD Amending Directive</b>	Directive 2010/73/EU;
<b>Admission</b>	admission of the Indivior Ordinary Shares to the premium listing segment of the Official List and to trading on the main market for listed securities of the London Stock Exchange becoming effective in accordance with LR 3.2.7G of the Listing Rules and paragraph 2.1 of the Admission and Disclosure Standards published by the London Stock Exchange;
<b>ADR</b>	American Depositary Receipts;
<b>ADS</b>	American Depositary Share;
<b>Articles</b>	the articles of association of the Company;
<b>Audit Committee</b>	the audit committee of the Company;
<b>Board</b>	the directors of the Company as at the date of this Prospectus;
<b>Bribery Act</b>	the UK Bribery Act 2010, as amended;
<b>CEO</b>	chief executive officer;
<b>CFO</b>	chief financial officer;
<b>City Code</b>	the City Code on Takeovers and Mergers;
<b>Code</b>	the US Internal Revenue Code of 1986, as amended;
<b>Companies Act</b>	the UK Companies Act 2006, as amended;
<b>Company</b>	Indivior;
<b>CREST</b>	the electronic transfer and settlement system for the paperless settlement of trades in listed securities operated by Euroclear UK & Ireland Limited;
<b>Demerger</b>	the proposed demerger of the Indivior Group from RB to be effected by way of an indirect dividend demerger on the terms and subject to the conditions set out in the Demerger Agreement;
<b>Demerger Agreement</b>	the agreement relating to the demerger of the Indivior Group from RB entered into between RB and Indivior on 17 November 2014, a summary of the principal terms of which is set out in paragraph 21 of Part XV ( <i>Additional Information</i> );
<b>Demerger Dividend</b>	the proposed dividend in specie to be declared by RB, which shall be equal to the book value of RB's interest in

	RBP Global Holdings Limited, as set out in the Demerger Resolution;
<b>Demerger Effective Time</b>	the time at which the Demerger becomes effective, expected to be 8.00 a.m. on 23 December 2014;
<b>Demerger Record Time</b>	6.00 p.m. on 22 December 2014;
<b>Demerger Resolution</b>	the resolution numbered 1 as set out in the notice of the RB General Meeting;
<b>Demerger Tax Deed</b>	the deed of tax covenant containing indemnities relating to taxation of the United Kingdom and elsewhere (excluding the US) to be entered into by RB and Indivior, a summary of the principal terms of which is set out in paragraph 21 of Part XV ( <i>Additional Information</i> );
<b>Developing Markets or DvM</b>	all the markets outside North America and Europe in which the Indivior Group sells its products. Sub-regions in DvM include Africa/Middle East/Turkey; Israel; South East Asia (Indonesia and Malaysia); Greater China/Taiwan; and Australia/New Zealand;
<b>Directors</b>	the directors of the Company as at the date of this Prospectus;
<b>Deutsche Bank</b>	Deutsche Bank AG, acting through its London Branch at Winchester House, 1 Great Winchester Street, London EC2N 2DB;
<b>DOJ</b>	the US Department of Justice;
<b>European Economic Area or EEA</b>	the European Union, Iceland, Norway and Liechtenstein;
<b>European Union or EU</b>	an economic and political union of 28 Member States which are located primarily in Europe;
<b>Eurozone</b>	the Member States of the European Union that have adopted the euro as their common currency and sole legal tender;
<b>Exchange Act</b>	the US Securities Exchange Act of 1934, as amended;
<b>FCA</b>	the UK Financial Conduct Authority;
<b>FCA Handbook</b>	the FCA's Handbook of Rules and Guidance;
<b>FCPA</b>	the US Foreign Corrupt Practices Act of 1977, as amended;
<b>FSMA</b>	the UK Financial Services and Markets Act 2000, as amended;
<b>FTC</b>	the US Federal Trade Commission;
<b>H1 and H2</b>	the six months ended, respectively, 30 June and 31 December;
<b>HMRC</b>	HM Revenue & Customs in the UK;
<b>IFRS</b>	International Financial Reporting Standards as adopted by the European Commission for use in the European Union;

<b>Indivior</b>	Indivior PLC, a public limited liability company incorporated under the laws of England and Wales with registered number 9237894;
<b>Indivior ADS</b>	an Indivior American Depositary Share, each of which will represent an ownership interest in Indivior Ordinary Shares and a pro rata share of any other securities, cash or other property that may be held by the depositary under the terms of the deposit agreement to be entered into between the Company, the depositary and the registered holders of Indivior ADSs from time to time;
<b>Indivior Business</b>	the pharmaceutical business which is currently carried on within the RB Group by RBP Global Holdings Limited and its subsidiary undertakings and which is proposed to be demerged in accordance with the Demerger Agreement and will be owned by Indivior following the Demerger Effective Time;
<b>Indivior Group</b>	the Indivior Business from time to time which will from the Demerger Effective Time include Indivior and its subsidiaries and subsidiary undertakings;
<b>Indivior Ordinary Shares</b>	ordinary shares of \$2.00 each in the Company;
<b>Initial Lenders</b>	as defined in paragraph 8.4 of Part X ( <i>Operating and Financial Review</i> );
<b>IRS</b>	the US Internal Revenue Service;
<b>ISIN</b>	International Securities Identification Number;
<b>Jefferies</b>	Jefferies International Limited;
<b>Joint Sponsors</b>	each of Morgan Stanley and Deutsche Bank AG, London Branch;
<b>LIBOR</b>	the London Interbank Offered Rate;
<b>Listing Rules</b>	the listing rules made by the UK Listing Authority under Part VI of FSMA (as set out in the FCA Handbook), as amended;
<b>London Stock Exchange or LSE</b>	London Stock Exchange plc;
<b>LTIP</b>	the long-term incentive plan previously adopted by Indivior for members of the Indivior Group's management team;
<b>Member State</b>	member state of the European Economic Area;
<b>Model Code</b>	the model code published in Annex I to Rule 9 of the Listing Rules;
<b>Morgan Stanley</b>	Morgan Stanley & Co. International PLC;
<b>Nomination Committee</b>	the nomination committee of the Company;
<b>Official List</b>	the Official List maintained by the UKLA;
<b>Overseas Shareholders</b>	Shareholders who are resident in, ordinarily reside in, or are citizens of, jurisdictions outside the United Kingdom;

<b>PD Regulation</b>	the Prospectus Directive Regulation (2004/809/EC);
<b>PFIC</b>	passive foreign investment company;
<b>PRA</b>	the UK Prudential Regulation Authority;
<b>Premium Listing</b>	the premium listing segment of the Official List;
<b>Prospectus</b>	this document;
<b>Prospectus Directive</b>	Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State;
<b>Prospectus Rules</b>	the prospectus rules made by the UK Listing Authority under Part VI of FSMA (as set out in the FCA Handbook), as amended;
<b>Q1, Q2, Q3 and Q4</b>	the three months ended, respectively, 31 March, 30 June, 30 September and 31 December;
<b>RB</b>	Reckitt Benckiser Group PLC, a public limited company incorporated under the laws of England and Wales with registered number 06270876;
<b>RB General Meeting</b>	the general meeting of RB to be held on 11 December 2014 pursuant to the notice of meeting set out in the RB Shareholder Circular and any adjourned meeting thereof;
<b>RB Group</b>	in respect of any time prior to the Demerger Effective Time, RB and its subsidiaries and subsidiary undertakings including those companies which form part of the Indivior Group and, in respect of any period following the Demerger Effective Time, RB and its subsidiaries and subsidiary undertakings excluding those companies which form part of the Indivior Group;
<b>RB Health</b>	Reckitt Benckiser Healthcare (UK) Ltd;
<b>RB Ordinary Shares</b>	ordinary shares of 10 pence each in RB;
<b>RB Overseas Shareholder</b>	RB Shareholders who are resident in, ordinarily reside in, or are citizens of, jurisdictions outside the United Kingdom as at the date of this Prospectus;
<b>RB Shareholder</b>	any shareholder of RB Ordinary Shares (excluding treasury shares);
<b>RB Shareholder Circular</b>	the circular to RB Shareholders dated 17 November 2014 containing, among other things, details of the Demerger;
<b>RBP</b>	Reckitt Benckiser Pharmaceuticals, Inc.;
<b>Reduction of Capital</b>	has the meaning given to it in paragraph 4 of Part XV ( <i>Additional Information</i> );
<b>Registrar</b>	Computershare Investor Services PLC;
<b>Regulation S</b>	Regulation S under the Securities Act;

<b>Relevant Member State</b>	each Member State that has implemented the Prospectus Directive;
<b>Remuneration Committee</b>	the remuneration committee of the Company;
<b>Restricted Securities</b>	securities within the meaning of Rule 144;
<b>Rule 144A</b>	Rule 144A under the Securities Act;
<b>SDRT</b>	stamp duty reserve tax;
<b>Securities Act</b>	the US Securities Act of 1933, as amended;
<b>Senior Managers</b>	those persons whose names are set out in paragraph 2 of Part VIII ( <i>Directors and Corporate Governance</i> );
<b>Sherman Act</b>	the US Sherman Antitrust Act of 1890;
<b>Shareholder</b>	a holder of Indivior Ordinary Shares;
<b>SID</b>	the senior independent director;
<b>Sponsors' Agreement</b>	the agreement dated 17 November 2014 entered into between Indivior and each of the Joint Sponsors, as further described in paragraph 21 of Part XV ( <i>Additional Information</i> );
<b>Takeover Panel</b>	the UK Panel on Takeovers and Mergers;
<b>Transitional Services Agreement</b>	the transitional services agreement to be entered into by RB and Indivior, a summary of the principal terms of which is set out in Part XV ( <i>Additional Information</i> );
<b>Treaty</b>	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 on capital gains;
<b>UK</b>	the United Kingdom of Great Britain and Northern Ireland;
<b>UK Corporate Governance Code</b>	the UK Corporate Governance Code dated September 2014 issued by the Financial Reporting Council;
<b>UK Listing Authority or UKLA</b>	the FCA acting in its capacity as the competent authority for the purposes of Part VI of FSMA;
<b>United States or US</b>	the United States of America, its territories and possessions, any state of the United States of America and the District of Columbia;
<b>US Holder</b>	a beneficial owner of Indivior Ordinary Shares or RB Ordinary Shares that is: (i) a citizen of or an individual resident of the US, as determined for US federal income tax purposes; (ii) a corporation (or other entity treated as a corporation for US federal income tax purposes) created or organised under the laws of the US or any state thereof or the District of Columbia; (iii) an estate the income of which is subject to US federal income taxation regardless of its source; or (iv) a trust (A) if a court within the US is able to exercise primary jurisdiction over its administration and

one or more US persons have authority to control all substantial decisions of the trust or (B) that has a valid election in effect under applicable US Treasury regulations to be treated as a US person;

**US Tax Matters Agreement**

the agreement relating to certain arrangements in respect of taxation in the US entered into by RB and Indivior, a summary of the principal terms of which is set out in section 21 of Part XV (*Additional Information*);

**US Treasury**

the US Department of the Treasury;

**US SEC**

the US Securities and Exchange Commission; and

**VAT**

value added tax.



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*indivior.com*