Indivior PLC (‘Indivior’ or the ‘Company’)


The Company has today posted or made available to shareholders the following documents:

▪ Annual Report & Accounts 2016;
▪ Notice of AGM; and
▪ Form of Proxy for the AGM.

In accordance with LR 9.6.1, these documents have been submitted to the National Storage Mechanism and will shortly be available for inspection at www.morningstar.co.uk/uk/NSM.

The Annual Report & Accounts 2016 and Notice of AGM can also be viewed on the Company’s website at www.indivior.com/investors/.

The AGM is scheduled to be held at 3.00pm on Wednesday, May 17, 2017 in the Wessex Ballroom, Renaissance London Heathrow, Bath Road, Hounslow, Middlesex, TW6 2AQ.

A condensed set of Indivior’s financial statements and information on important events that have occurred during the financial year ended December 31, 2016 and their impact on the financial statements were included in Indivior’s preliminary results announcement released on February 22, 2017. That information, together with the information set out in the Appendix below, which is extracted from the Annual Report & Accounts 2016, constitute the material required by Disclosure Guidance and Transparency Rule 6.3.5 which is required to be communicated to the media in full unedited text through a Regulatory Information Service. This announcement is not a substitute for reading the full Annual Report & Accounts 2016. Page numbers and cross references in the extracted information refer to page numbers and cross references in the Annual Report & Accounts 2016.

March 23, 2017
Forward-Looking Statements

The Annual Report & Accounts 2016 contains certain statements that are forward-looking and which should be considered, amongst other statutory provisions, in light of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty as they relate to events or circumstances that will or may occur in the future. Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding the Indivior Group’s financial guidance for 2017 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation. Various factors may cause differences between Indivior’s expectations and actual results, including: factors affecting sales of SUBOXONE® (buprenorphine and naloxone) Sublingual Tablets (CIII), SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII), SUBUTEX® (buprenorphine) Sublingual Tablets (CIII) and any future products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group’s drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group’s products and product candidates; risks related to legal proceedings; the Indivior Group’s ability to protect its patents and other intellectual property; the outcome of the SUBOXONE Film patent litigation relating to the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, 13 business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

Any forward-looking statements that we make in the Annual Report & Accounts 2016 speak only as of the date of the Annual Report & Accounts 2016. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of the Annual Report & Accounts 2016.

The Annual Report & Accounts 2016 does not constitute an offer to sell, or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

APPENDIX
i. Statement of Directors’ Responsibilities

The Directors are responsible for preparing the Annual Report, the Directors’ Remuneration Report and the financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare financial statements for each financial year. Under that law the Directors have prepared the Group financial statements in accordance with International Financial Reporting Standards (‘IFRS’), as adopted by the European Union, and the Parent Company financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 “Reduced Disclosure Framework”, and applicable law).

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets of the Group and Parent Company, and of the profit or loss of the Group and parent Company for that period. In preparing these financial statements, the Directors are required to:

▪ select suitable accounting policies and then apply them consistently;
▪ make judgments and accounting estimates that are reasonable and prudent;
▪ state whether IFRS as adopted by the European Union have been followed for the Group financial statements and the United Kingdom Accounting Standards, comprising FRS 101, have been followed for the Company financial statements, subject to any material departures disclosed and explained in the financial statements; and
▪ prepare the financial statements on the going concern basis, unless it is inappropriate to presume that the Group and Parent Company will continue in business.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Group’s and Parent Company’s transactions, and disclose with reasonable accuracy, at any time, the financial position of the Group and the Parent Company, and enable them to ensure that the financial statements and the Directors’ Remuneration Report comply with the Companies Act 2006 and, as regards the Group financial statements, Article 4 of the IAS Regulation. They are also responsible for safeguarding the assets of the Parent Company and the Group and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Under applicable law and regulations, the Directors are also responsible for preparing a Strategic Report, Directors’ Report, Directors’ Remuneration Report and Corporate Governance Statement that complies with that law and those regulations.

The Directors are responsible for the maintenance and integrity of the Group and Parent Company’s website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Responsibility statement of the Directors in respect of the Annual Report

The Directors consider that the Annual Report and Accounts, taken as a whole, are fair, balanced and understandable, and provide the information necessary for shareholders to assess the Group and Parent Company’s position and performance, business model and strategy.
Each of the Directors, whose names and functions are listed on page 58, confirm that, to the best of their knowledge:

- the Parent Company financial statements, which have been prepared in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 “Reduced Disclosure Framework”, and applicable law) give a true and fair view of the assets, liabilities, financial positions and profit of the Company;
- the Group financial statements, which have been prepared in accordance with IFRSs as adopted by the European Union, give a true and fair view of the assets, liabilities, financial position and profit of the Group; and
- the Directors’ Report and Strategic Report, includes a fair review of the development and performance of the business and the position of the Group and Parent Company, together with a description of the principal risks and uncertainties that it faces.

ii. Risk Factors and Risk Management

The Board of Directors have carried out a robust assessment to ensure that the principal risks, including those that would threaten the Group’s business model, future performance, solvency or liquidity are effectively managed and/or mitigated to help ensure the Group is viable. While the Group aims to identify and manage such risks, no risk management strategy can provide absolute assurance against loss.

Set out below are what the Group considers to be the principal risks that could cause the Group’s business model, future performance and solvency or liquidity to differ materially from expected and historical results, and how the risks relate to the Group’s strategic priorities. Additional risks, not listed here, that the Group cannot presently identify or does not believe to be equally significant, may materially and adversely affect the business, results of operations and financial position. The principal risk factors and uncertainties are not listed in order of significance.

Principal risks

Business operations and business continuity

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

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- Dependence on single product line.
- Approval and launch of generic or branded products that compete with our products.
- Generic manufacturers seeking approval to launch competing products prior to expiry of existing patents.
- Launch of branded products that compete with our products.
- Claims that our products infringe third-party patents.
- Inability to deliver continuous supply of compliant finished product.
- Inability to retain or attract high-performing and high-potential staff could adversely impact achievement of Group objectives.
- Significant disruptions of information technology systems or breaches of data security could disable critical systems and cause loss of sensitive data.
- Failure to protect and restrict access to critical or sensitive computer systems or information.

- Continue to expand the market by expanding access to treatment and working with physicians and payors to improve patient outcomes.
- Capitalize on international growth opportunities, continued development of our pipeline and disciplined acquisitions to enable diversification.
- Obtain and enforce product patents and other IP rights, and develop and implement strategies, including new product(s), to face both generic competition, if the outcome of patent litigation is unfavorable, and new and existing branded competitors.
- Develop and implement strategies to ensure freedom to operate. Explore settlement opportunities.
- Continuity planning for certain black swan events to secure business continuity in worst case scenarios.
- Establish and closely monitor stock levels.
- Ongoing partnerships with manufacturers and packagers to optimize manufacturing and Quality Assurance (QA) processes.
- Continuously review talent retention program with focus on identifying key roles and successors.
- IT disaster recovery plans in place to support overall business continuity. Systems in place to protect data and devices.
- Various IT policies, processes and systems in place to provide access control and security management for Indivior-used or owned infrastructure.

- Hinder patient access to treatment.
- Loss of market share.
- Loss of revenue and profits, which in worst case scenarios may require business restructure and recapitalization.
- Damage to reputation.
- Exposure to litigation and significant legal costs.

- Build resilience of our franchise.
- Business development.
and applications, now operating independently from RB. Completed initial and continuing ongoing End User Cyber Security Awareness training.
Product liability, regulation and litigation

- As an innovative pharmaceutical company, the Group seeks to obtain appropriate intellectual property protection for its products. Its ability to obtain and enforce patents and other proprietary rights particularly for its products, drug formulation and delivery technologies and associated manufacturing processes is critical to business strategy and success. Specifically see disclosures on pages 44 to 45 referring to the current status of ANDA litigation and to the going concern statement on page 95 contained within the Statement of Directors’ Responsibilities, which discusses the risks associated with current ANDA litigation, and the contingent liabilities disclosures in Note 20 of the financial statements on page 126.

- The manufacture of the Group’s products is highly exacting and complex, due in part to strict regulatory and manufacturing requirements. Active Pharmaceutical Ingredients (API) in many of the Group’s products and product candidates are controlled substances that are subject to extensive regulation in all the countries in which the Group markets its products.

- The testing, manufacturing, marketing, and sale of pharmaceutical products are highly regulated and entail a risk of product liability claims, product recalls, litigation, government investigations and enforcement action, and associated adverse publicity, each of which could have a material adverse impact on the business, prospects, results of operations and financial condition. Specifically, see disclosure on page 44 referring to the current status of the DOJ investigation and other investigative and antitrust litigation matters, and the contingent liabilities disclosures in Note 20 of the financial statement on page 125.

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<td>◆ Failure to obtain, maintain, and protect patents and other proprietary rights, including potential invalidity or non-infringement findings in the current US Federal Court or US Patent and Trademark Office proceedings. Legal proceedings related to product liability claims, antitrust, government enforcement and/or private litigation associated with the testing, manufacturing, marketing and sale of our products. Potential liability and/or additional expenses associated with ongoing regulatory obligations and oversight.</td>
<td>◆ Obtain and enforce patents and other proprietary rights. Suboxone® Film in the US is covered by three Orange Book-listed formulation patents and two process patents, having terms that run from 2022 to 2030, which are currently in litigation in the US Federal Court and/or US Patent and Trademark Office. ◆ Develop and implement strategies, including new product(s), to prepare for generic competition in the event of adverse outcomes in these proceedings. ◆ Quality, product safety and compliance are embedded in the Group’s processes and culture and monitor and oversee the Company’s activities. Develop and implement strategies to defend against and pursue</td>
<td>◆ Loss of revenue and profits. ◆ Adverse impact on the Group’s ability to raise funds necessary to continue its operations.</td>
<td>◆ Build resilience of our franchise.</td>
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appropriate resolution of these claims.
- The Group has instituted policies, systems, and training programs to ensure adherence to regulations governing product quality, patient safety and business standards.

Product development

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

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<td>Failure to receive regulatory approval to successfully commercialize a pipeline product.</td>
<td>Increased R&amp;D investment to enhance clinical capabilities and support the development of pipeline products.</td>
<td>Potential delays or inability to develop new products.</td>
<td>Develop our pipeline.</td>
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<td>Failure of third-party Clinical Research Organizations to properly/successfully perform their legal, regulatory, and contractual obligations.</td>
<td>Thorough contract review process in place to ensure that third-party vendors are properly vetted, inherent risks are identified and mitigated, and deliverables and obligations are clearly defined before contracts are finalized.</td>
<td>Hinder patient access to treatment.</td>
<td>Expand global treatment.</td>
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<td>Inability of product candidates, if approved, to achieve expected market acceptance.</td>
<td>Ongoing monitoring of the third-parties’ activity and performance to ensure that good clinical practices (‘GCP’) are being followed and milestones are met.</td>
<td>Loss of revenue and profits, which in worst case scenarios may require business restructure and recapitalization.</td>
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<td>Financial models and external support in place to provide market valuation and due diligence support.</td>
<td>Damage to reputation.</td>
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<td>Adverse impact to long-term growth.</td>
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<td>Adverse impact on the Group’s ability to raise funds necessary to continue its operations.</td>
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Commercial and governmental payor account, pricing and reimbursement pressure
- The Group’s revenues are partly dependent on the availability and level of coverage provided to the Group by private insurance companies and governmental reimbursement schemes for pharmaceutical products, such as Medicare and Medicaid in the US.
- Changes to governmental policy or practices could adversely affect the Group’s revenues, financial condition and results of operations. In addition, the reimbursement of treatment established by healthcare providers, private health insurers and other organizations may be reduced.

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<td>Increased competition</td>
<td>Continue to work with payors, commercial or governmental, to ensure access to and coverage of our products. Establishment of health economic business case to justify existing pricing.</td>
<td>Loss of revenue and profits. Hinder patient access to treatment.</td>
<td>Build resilience of our franchise. Expand global treatment.</td>
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<td>Increased competition</td>
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<td>Reduced reimbursement</td>
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Compliance with law and ethical behavior

- Business practices in the pharmaceutical industry are subject to increasing scrutiny by government authorities. Failure to comply with applicable laws and rules and regulations in any jurisdiction may result in fines, civil and/or criminal legal proceedings, each of which could have a material adverse impact on the business, prospects, results of operations and financial condition. Specifically see disclosure on page 44 referring to the current status of the DOJ investigation and other investigative and antitrust litigation matters, and the contingent liabilities disclosures in Note 20 of the financial statements on page 125.

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Non-compliance with anti-corruption, healthcare, data privacy, or local laws could result in business interruption or restructuring, fines, loss of reimbursement, damage to reputation and criminal penalties.

Failure to comply with payment and reporting obligations under the US Medicaid Drug Rebate program or other governmental pricing programs.

Restrictions on Group’s ability to sell products or product candidates in certain markets/countries due to controlled substance legislation, regulation, and/or classification.

Government investigations of the Group’s business activities alleged to be improper.

The Group has enhanced, and continues to enhance, its compliance program and compliance capabilities.

All employees required to complete a comprehensive compliance training program annually.

Reviews and controls put in place over government pricing and reporting.

Increased oversight and monitoring of controls and procedures in emerging markets.

The Group has enhanced, and continues to enhance, its compliance program and compliance capabilities. Continued cooperation with the authorities on ongoing investigations, utilizing external counsel as needed.

Loss of revenue and profits, which in worst case scenario may require business restructure and recapitalization.

Fines and/or penalties.

Hinder patient access to treatment.

Build resilience of our franchise.

Expand global treatment.

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### Acquisitions and business development

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

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<td>Inability to identify, acquire, close or integrate acquisition targets successfully.</td>
<td>Board of Directors reviews all significant transactions. Best Practice Management Tools for Diligence and Integration Planning and Execution have been developed. Acquisition Governance Model agreed, along with identification of SME required for Acquisition Integration team. Internal and external resources in place to ensure rigorous due diligence and integration of acquisitions and/or new product initiatives. Ongoing regular appraisal of debt and equity capital markets advisors and counterparties.</td>
<td>Adverse impact on Group’s ability to raise funds necessary to continue its operations. Loss of revenue and profits. Damage to reputation.</td>
<td>Build resilience of our franchise. Business development. Expand global treatment. Develop our pipeline.</td>
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Product safety

- The pharmacovigilance process has been established to monitor the safety of the Group’s products in a comprehensive and thorough manner. This includes capturing safety-related data from multiple sources (e.g. Medical Information Unit (MIU), market research, literature search and clinical trials) and entering all adverse events received into a safety database. The Company reports to health authorities across the globe within the required and mandatory timelines and identifies safety signals with an assessment of changes to benefit/risk profile and determines actions needed to optimize the safe and effective use of our products, including communicating any relevant changes to key stakeholders.

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<td>Change in benefit-risk profile based on cumulative evidence internally (from all Indivior cross-functional departments) and externally.</td>
<td>Quarterly reviews performed by Global Signal detection team of all potential safety sources across Indivior organization and externally.</td>
<td>Product recall.</td>
<td>Build resilience of our franchise.</td>
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<td>Recommended actions (e.g. Labelling changes, Risk Management Plan update, Dear Dr. Letters, Post- Authorization Safety Studies) approved by the Global Signal management team to optimize the safe and effective use of all Indivior products.</td>
<td>Hinder patient access of treatment.</td>
<td>Expand global treatment.</td>
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<td>Significant legal cost.</td>
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Risk management

To achieve our objective of being the leading pharmaceutical company focused on the treatment of addiction, we recognize that we must have a good understanding of the risks we face, those inherent in our strategy and operations, and those presented by external conditions. We take a systematic and robust approach, which aims to continuously monitor those risks and internal control systems accordingly.

Our approach

Our systematic risk management approach is designed to identify risks that would threaten the Group’s business model, future performance, solvency or liquidity. Effective risk management is fundamental to our ability to meet our operational and strategic objectives. The competitive market in which we operate has industry-specific risks, particularly those relating to new product development, intellectual property enforcement and legal proceedings, and compliance with laws and regulations. This requires effective decision-making to ensure that the risks the business takes are assessed and appropriately measured, whilst ensuring that there is overall resilience to risks the business has limited control over through disaster recovery and business continuity procedures. Our overall risk management approach remains to foster and embed a culture of risk management that is responsive, forward-looking, consistent and accountable.
The Executive Committee helps to establish the risk agenda, for the reporting and ongoing management of risks and for the stewardship of the risk management approach. The Executive Committee reviews the risk register on a quarterly basis and identifies and assesses Indivior’s principal risks on an ongoing basis.

Risk control assurance
The Board has overall responsibility for the Group’s risk management framework. The Board reviews the Group’s principal risks with focus on the key risk areas framework. The Board’s Committees regularly review risks relevant to their area of focus; this includes, but is not limited to, risks relating to legal, financial and compliance matters. Assurance on risk controls is provided by internal management information, internal audits, external audits and Board oversight. There is also an externally supported whistleblowing reporting system in place.

iii. Related party transactions

Subsequent to the demerger from former parent, RB, on December 23, 2014, Indivior continues to receive certain services like office space rental and other operational services on commercial terms and on an arm’s length basis. Adrian Hennah, the RB CFO, served on the Indivior PLC Board of Directors until the AGM on May 11, 2016. The amount included within SD&A in respect of these services is $4m (2015: $9m).

Key management compensation is disclosed in Note 6a.

The subsidiary undertakings included in the consolidated Financial Statements at December 31, 2016 are disclosed in Note 2 to the Parent Company Fin