Chief Executive Officer’s statement

Many journeys, one destination

"I firmly believe we are the company – working in partnership with other experts – best positioned to tackle the growing global addiction crisis. Our vision, patient focus, guiding principles, and pursuit of innovation will continue to drive Indivior’s success in delivering value for shareholders and meeting the unmet needs of patients.”

Shaun Thaxter
Chief Executive Officer

The year in review

In 2017, Indivior delivered against its strategic priorities. Our execution drove progress toward our vision that all patients will have access to evidence-based treatment for the chronic conditions and co-occurring disorders of addiction. We created greater certainty for Indivior, most significantly by extending our leadership position in developing and advancing global addiction treatment with the US FDA approval of monthly SUBLOCADE for moderate to severe opioid use disorder (OUD). At the same time we grew Indivior’s capabilities and resources to enable us to invest in developing promising future treatments focused on unmet patient needs in addiction and its co-occurring disorders.

Our strong execution in 2017 translated into improved top- and bottom-line results for Indivior. Sales grew by 3% to $1,093 and net income grew by 6% to $270m, on an adjusted basis.

Our results are even more notable considering the multiple forces we faced during the year: an intensifying competitive landscape for our market-leading SUBOXONE Film treatment in the US, continued healthcare austerity in Europe and the investments required to successfully develop and commercialize our key pipeline assets in the US in 2018: SUBLOCADE and, if approved by FDA, RBP-7000 (monthly risperidone injection).

In relation to the various litigation and investigational matters, the Board agreed with the Executive Committee that it was prudent to increase the provision related to these matters to $438 million to reflect collectively their current status. Since these matters are ongoing we cannot provide any guarantee in terms of when these matters may be settled and what the ultimate impact to Indivior will be. We continue to cooperate fully with the various parties and are hopeful for resolution in a timely manner.

Below are the strategic priorities the Board and management team set for the Group, understanding that these have the greatest impact on our business, and that building upon them best positions Indivior to generate long-term shareholder value.

1. Building the resilience of our franchise by continuing to expand access to treatment and maintaining a leadership position;
2. Developing our innovative pipeline to help improve patient outcomes;
3. Expanding global treatment by capitalizing on international growth opportunities; and
4. Preparing for our future by creating a robust growth infrastructure and effectively managing business risks.

I’ll now expand on each of the strategic priorities, looking at the progress made against each in 2017, and our plan for leveraging our achievements moving forward.

1. Building the resilience of our franchise by continuing to expand access to addiction treatment and maintaining a leadership position

According to new data released by the US Centers for Disease Control and Prevention (CDC), there were more than 63,600 total drug overdose deaths in 2016, or 174 drug overdose
deaths per day. This number is up 21% in just one year – from 144 a day in 2015. Furthermore, the US healthcare system is struggling to keep pace with the addiction crisis, and many patients are unable to access the evidence-based treatment and care they require. In fact, despite extensive evidence of the personal and societal benefits of medication-assisted treatment (MAT), only a small minority of OUD patients receive it, and OUD diagnoses are currently outpacing MAT prescriptions at an alarming rate of nearly eight to one.

In 2017, Indivior continued efforts to support patient access to care. Treatment capacity expanded to a record number of physicians and other qualified treatment providers in the US, ending the year at about 48,480 providers, a 25% increase over 2016. The increase in the patient treatment cap from 100 patients to 275 patients, and the ability of nurse practitioner’s (NPs) and Physician Assistants (PAs) to prescribe added to treatment capacity and market growth.

As a result, total market growth accelerated to low double-digit levels in 2017, from high single-digit levels the previous year.

Against this backdrop in the US, our SUBOXONE Film franchise maintained its leading position in its largest market, with an average share of 57% of the buprenorphine medication-assisted treatment (BMAT) market in 2017. The resilience of our franchise is a testament to our patient-focused platform. We are well-positioned to support the launch of SUBLOCADE, which we believe may become a new standard of care for the treatment of moderate to severe OUD.

2. Developing our innovative pipeline to help improve patient outcomes

“SUBLOCADE™ is now available to US patients and their treatment providers.”

US SUBOXONE® Film share has been resilient

Source: Symphony Health Retail & Non-Retail TRx MG (IDV) ending Dec 2017

Notes:
- Suboxone® is a licensed trademark of Orexo US, Inc.
- Bunavail® is a registered trademark of BioDelivery Sciences International, Inc.

$1.1 Bil
formulation approved to treat moderate to severe OUD. A significant scientific innovation, SUBLOCADE represents a new treatment option to help patients attain more illicit opioid-free weeks during their treatment program.

SUBLOCADE is the first therapy that, at steady state, delivers buprenorphine at a sustained rate of at least 2 ng/mL over a one-month period. These sustained plasma levels of buprenorphine translate into high mu-opioid receptor occupancy in the brain, which blocks the drug-liking effects of opioids.

In addition, SUBLOCADE is disseminated through a restricted distribution system, which is intended to prevent direct distribution to the patient, thereby minimizing the risk of serious harm or death through intravenous self-administration. This approach is also intended to help reduce the risk of diversion, misuse and abuse.

SUBLOCADE represents an evidence-based, paradigm shift from how we approach treatment of moderate to severe opioid use disorder today. Its development is testament to Indivior’s depth of expertise in receptor pharmacology and pharmacokinetic understanding. It also demonstrates our focus and ability to listen and partner with our stakeholders, including the US FDA, the treatment community and patient advocates, to find and develop another evidence-based option that meets patients’ needs.

I am pleased to report that SUBLOCADE is now available to US patients and our confidence in its potential is reinforced by our peak annual net revenue expectations of at least $1,000 million.

**RBP-7000**

Our patient focus and desire to deliver on unmet patient needs extends to the co-occurring disorders of addiction. In 2017, we made excellent progress with RBP-7000, an investigational once-monthly injectable risperidone in the ATRIGEL® delivery system for the treatment of schizophrenia. In December 2017, the FDA accepted our New Drug Application (NDA) for RBP-7000, which is a significant milestone for Indivior as we expand our treatment portfolio.

RBP-7000 leverages much of the science and capabilities we established with the ATRIGEL technology platform. In much the same way that SUBLOCADE delivers on unmet patient needs with buprenorphine, we believe RBP-7000, if approved, will meet key patient needs with risperidone: principally a rapid onset of action with consistent plasma levels of risperidone over the entire monthly dosing interval. We have spent time with prescribing psychiatrists and, while they like risperidone’s established efficacy profile – it is still the most prescribed anti-psychotic – they don’t yet have a monthly risperidone option that they would consider a ‘breakthrough’ treatment.

To ensure RBP-7000’s anticipated success, we have established a new Behavioural Health Business Unit, which has required an investment in new sales and marketing capabilities. This includes recruiting new talent with expertise in this disease space to enable the successful launch of RBP-7000 and to leverage our significant R&D capabilities to develop life-cycle management opportunities.

RBP-7000’s PDUFA date is July 28, 2018 and, assuming a favorable approval decision from the FDA, we anticipate a Q4 launch and project delivering peak annual net revenues of $200 to $300 million.

**Addex**

To further build upon our leadership position in addiction, we entered into a strategic collaboration with Addex Therapeutics to license and accelerate the development of GABA, positive allosteric modulators (PAMs), which have demonstrated preclinical activity and tolerability in animal models for alcohol use disorder (AUD) and cocaine use disorder (CUD).

We are particularly excited about the potential of the lead compound, ADX71441. The US National Institute on Drug Abuse (NIDA) recently awarded a $5 million grant to support the development of ADX71441 in CUD. In 2018, we will be working with Addex to define the key activities that will support the development of ADX71441 as well as the research program that will be dedicated to the identification of new GABA, PAMs.

### 3. Expanding global treatment by capitalizing on international growth opportunities

In 2017, we continued to make good progress with our SUBOXONE Film and Tablet franchise outside the US.

In Australia, SUBOXONE Film continues to gain share against legacy treatment approaches as the treatment community grows more familiar with Indivior. In Canada, where per capita addiction (or overdose) rates are greater than the US, SUBOXONE Film was added to the List of Drugs for an Urgent Public Health Need in British Columbia. In Canada, overall, our SUBOXONE Tablet share position continues to grow. Our early successes in Australia and Canada demonstrate our ability to identify opportunities to address the unmet needs of patients and differentiate from other buprenorphine options and quickly flex our organization to gain meaningful market entry.

Our European business, which constitutes our largest market outside the US, also continued to grow despite the focus on funding austerity in key European markets. We have continued to provide buprenorphine medication-assisted treatment (BMAT) for OUD in Europe and have expanded our portfolio in the region. In July 2017, the French regulatory agency, l’Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM), approved a Marketing Authorisation (MA) in France for Indivior’s NALSCUE® (naloxone hydrochloride) nasal spray for the emergency treatment of suspected opioid overdose.
Delivering on our strategy

Our strategic priorities

Building the resilience of our franchise

- Maintained SUBOXONE Film’s leading share position at an average of 57% (2016: 61%) in our largest market, the US, despite competition from lower priced generic options
- SUBOXONE Film’s resilience demonstrates the strength of Indivior’s brand and our focus on patient needs
- Treatment capacity expanded to a record number of physicians and other qualified treatment providers in the US, ending the year at about 48,480 providers, a 25% increase over 2016

Developing our innovative pipeline

- SUBLOCADE – FDA approved on November 30th the first and only once-monthly treatment for moderate to severe OUD; SUBLOCADE now available to patients nationwide in the US
- RBP-7000 (monthly risperidone injection) – FDA accepted submission of the NDA and established a PDUFA date of July 28, 2018; Q4 2018 launch expected, if approved
- Arbaclofen Placarbil – Phase 1 Bioavailability Clinical Study Protocol (INDV-AP-102) completed; planning to meet with FDA to share our plans and agree on next development stages
- Addex Therapeutics Strategic Collaboration – Exploring the potential of GABA_PAMs in addiction treatment; US NIDA recently awarded a $5.3 million grant to Addex to support the development of ADX71441 for cocaine use disorder (CUD)

Expanding our global treatment

- Maintained leading share of BMAT market in Europe, Indivior’s largest market outside the US
- Preparing regulatory submission for SUBLOCADE approval in key Western European markets in 2018
- NALSCUE for the emergency treatment of characterized or suspected opioid overdose received regulatory approval in France
- Australia and Canada continued to generate share with strong sales growth; SUBLOCADE regulatory submissions being prepared for both Australia and Canada

Developing the business

- Completed extension of Indivior R&D facilities in Fort Collins (CO, USA) (18,500 sq ft) and new R&D Center of Excellence in Hull (UK) (54,000 sq ft)
- Initiated the appeals process against Dr. Reddy’s after the Court validated Indivior’s patents, but found non-infringement; appeal is progressing in the Federal Circuit Court of Appeals
- Entered a settlement agreement with Mylan resolving patent litigation related to SUBOXONE Film, including termination of their inter partes review (IPR) action
- Continued to assert Intellectual Property, including SUBOXONE Film Orange Book listed patents
- Entered a settlement agreement with Amneal related to antitrust litigation
- Replaced US and Euro denominated term loans with new facilities that carry more favorable durations and terms, thereby significantly improving Indivior’s overall financial flexibility
NALSCUE has been provided in France under a Temporary Authorisation for Use (Autorisation Temporaires d’Utilisation or ATU) since July 2016. Our solid growth in Australia and Canada, along with steady performance in Europe, drove overall Rest of World sales to $216 million in 2017, a 7% increase. We continue to work with European treatment leaders to destigmatize addiction and to raise awareness among policy makers about drug-related deaths and the ways to help reduce them with buprenorphine-based OUD treatments. We believe the potential for SUBLOCADE is substantial in Western Europe, and over the course of 2018 we will be working with key European agencies to seek approval for use. In the near term, the environment is expected to remain challenging, but we continue to eye Europe as a future growth market for SUBLOCADE.

4. Prepare for our future by creating a robust growth infrastructure and effectively managing business risks

In 2017, we continued to build our capabilities and financial strength to ensure Indivior is optimally positioned to endure both seen and unforeseen challenges. We have expanded our talent base across the organization, including investments in compliance, R&D, future medicines development and finance. In 2017, our compliance group doubled in size which reinforces our commitment to operating a compliance-focused culture. Our R&D investments are aimed at solidifying our commitment to focus on life-cycle management of SUBLOCADE. After launch, we will monitor patient outcomes, the efficacy and safety of this important medicine and monitor patient experiences to learn how we can further enhance treatment options.

Indivior’s global presence

*SUBLOCADE™ received US FDA approval in November 2017, but had no net revenue impact in the year.*
I am particularly proud of the world-class manufacturing and R&D capabilities we have established in Hull (UK) and Fort Collins (US). These investments will help us lead the science of addiction and its co-occurring disorders and develop new treatment options for patients around the world.

Late in the year, we further secured our future by favorably amending and extending credit terms with lenders. As a result, we gained the financial flexibility to allow us to invest in Indivior’s key growth initiatives and consider business development opportunities.

We have also continued to assert and defend appropriately the intellectual property surrounding SUBOXONE Film. In September 2017, we experienced a setback in our infringement lawsuit against Dr. Reddy’s, with the US District Court of Delaware ruling that while our patents were valid, Dr. Reddy’s did not infringe on them. We have since filed an appeal against the Dr. Reddy’s decision and intend to continue vigorously defending our intellectual property, including asserting two important new Orange Book listed patents (‘454 and ‘221). Unfortunately, the Court’s timing and ultimate decisions are out of our control. I can, however, say for certain that Indivior’s position is much improved with the availability of SUBLOCADE in the US, our strong cash position and improved overall financial flexibility.

**The Indivior culture**

At the heart of Indivior is a shared passion and commitment to help support the patient journey to treatment and recovery, remove the barrier of stigma, enable access to evidence-based treatment, and provide education, new scientific understanding and knowledge to the treatment community. Indeed, a rigorous and unwavering focus on patient needs informs everything we do. Based on a clearly-defined set of principles and behaviors, our culture is a key competitive advantage. All of our guiding principles, but particularly our capacity to demonstrate honesty and integrity at all times, support a culture that strives to adhere to the highest ethical principles at all times. In 2017, this culture continued to drive our performance, enabling us to create not only a business that will prosper and grow, but an organization that will create lasting social value by helping to address one of the most urgent epidemics of our time.

Looking ahead, our priority is to increase Indivior’s value by enhancing our leadership in the treatment of addiction and its co-occurring disorders, maintaining our focus on the patient and engaging and learning from our stakeholders. As a company, we will continue to educate, enable and convene with the aim of progressing our understanding of the broader addiction disease space and delivering better treatment solutions. I firmly believe we are the company – working in partnership with other experts – best positioned to tackle the growing global addiction crisis, and its co-occurring disorders. And, while change occurs at pace in the world around us, our vision, patient focus, guiding principles and pursuit of innovation remain resolutely unchanged. These are the key ingredients that we believe will continue to drive Indivior’s success and long-term value for shareholders. We therefore face the future with great confidence, knowing that our bedrock foundation is strong.

**Shaun Thaxter**

Chief Executive Officer