We are ready to help patients take the first step

As the information on pages 6 to 7 shows, addiction is an epidemic not just in the US but globally. Governmental statistics suggest there are at least 145.3 million people today who are dependent on opioids or alcohol, and the numbers are likely to be significantly under-reported. The case studies in the next few pages of this report show why we believe that proper treatment transforms lives.

The growth of Indivior’s business so far has been the result of the mindset shift in countries where authorities, treatment communities, and societies have moved treatment of opioid dependence beyond special clinics expanding access to medicalized treatment in physicians’ consulting rooms. With a comprehensive treatment plan including counseling, medical intervention and Suboxone®, many opioid-addicted patients can be stabilized and returned towards normal life while they pursue their treatment goals required to address the fundamental issues of which addiction is often the symptom.

We still need to change attitudes in many other countries where treatment has not yet been normalized into mainstream medical practice, but often retains the stigma associated with supervised dosing at clinics and pharmacies. Some countries still criminalize addiction, thus preventing, or very tightly controlling, the distribution and delivery of treatment.

Since the passing of the DATA 2000 Act in the US, which first allowed the treatment of opioid addiction with schedule III, IV and V narcotics in a physician office-based practice, over 27,000 physicians have completed the training necessary to become certified to treat opioid addiction. We have supported these physicians through the initial challenges of integrating opioid dependence treatment into their practice.

Since the launch of Suboxone® Tablet in 2003 in the US, we have enabled the treatment of over five million patients with Suboxone® Tablet and Suboxone® Film.

Having said that, addiction still carries a stigma and we understand the challenges that patients face when they seek treatment. With a medical condition like addiction, the constant need to satisfy cravings, or avoid withdrawal symptoms, can be so intense that even when people want to stop, they generally only have a small window of time to pursue treatment. We are ready to help patients take that first step, empowering them to act before that moment of readiness is gone. Our objective has always been to secure better outcomes for patient and physician and it continues to be. That is why we have worked so hard to improve our product portfolio.

Case study 1

Dr Ed Johnson’s story  VP Treatment and Health Policy, Indivior

It’s not laws that shift deep-seated prejudice – it’s education. We have to demonstrate that addiction is a chronic medical condition affecting the brain, but with the positive message that treatment could help. It’s a message we must personalize because, until you believe that addiction is a medical condition that could happen to you, it’s someone else’s problem. But once you understand that it could be your child that overdoses, you are more willing to listen to the science on how treatment can help. Education is a priority.

As a patient-focused addictions company, we take the lead in promoting the understanding of patients and addiction, raising awareness and providing education on our website and through our medical affairs staff, but this is a sensitive disease space, so we work closely with the addiction societies and opinion formers. We offer educational and grant support as well as try to ensure that everyone in the treatment community – pharmacists and counselors as well as physicians – tries to be a resource for patients.

We understand that this is not a disease space where you succeed merely by selling products. We have a medical, ethical and moral responsibility to improve the safety profile of addiction medication and treatment and to do things that can help improve patients’ lives and access to treatment.
Strategic Report

Our business has been well rewarded for its success in developing our patient-focused business model of treatment in the US, in Australia and to a more limited extent in Europe. In 2014, we had net revenues of $1,115m and operating profits of $562m; this compares to less than $100m of net revenues in 2003. Despite the current market challenges in the US and Europe, with multiple generics and pricing pressures, and the consequent downward pressure on net revenue and profits, we have been able to continue to build our Company’s capabilities.

Today we have approximately 170 Clinical Liaisons working in the US alone, two-thirds of them with over five years’ experience with Indivior.

We have an R&D and Regulatory organization of 126 people working on our next generation of products.

We have a medical and compliance team ensuring we carry out our work to the highest standards of regulatory compliance, quality control and particularly patient safety. Our management team collectively has over 60 years of experience with the Company. We have developed a wonderful network of addiction experts around the world to advise us. The reputation of Indivior as the leader in opioid addiction treatment is well established, and is shown by the quality of Non-Executive Directors who have agreed to join the Board and support us in the next phase of our development.

Tony’s story

Tony’s story
Father of Damien, Australia

Damien was a sportsman. He had a full-time manager’s job, a relationship and an active social life.

But once he started using heroin, his friends fell by the wayside. He was taking time off and owed a lot of money – enough to support a $300 a day heroin habit. The crisis hit Damien when he lost his job, girlfriend and flat, all in one week. So he came and just blurted it all out to me.

I grabbed him by the collar and said “We’re going to beat this”. But I ran into problems immediately. Places that were supposed to help just told me to check online.

So Damien went to my daughter’s house and did nine days’ cold turkey. It must have been horrendous. But he managed to withdraw from the heroin. I thought, wow, we’ve fixed it – until, gradually, I realized it wasn’t over. Damien started drinking heavily, couldn’t get a job and felt like he’d let everyone down.

The day he died started normally for him. He and his girlfriend went shopping, then to the pub. But after an argument, she left and he kept drinking. He went off to King’s Cross, Sydney’s heroin center, then to a pharmacy for clean needles. At 10:15 pm, Damien went to a back alley stairwell in a disused hospital, where he used for the last time.

Case study 2

Tony’s story
Father of Damien, Australia

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I thought, wow, we’ve fixed it – until, gradually, I realized it wasn’t over
I wasn’t eating or sleeping – days just blended in
Our first objective ➤ Expand access to treatment and strengthen our leadership position

Building resilience of our existing franchise
We will do this mainly by expanding the treatment of opioid addiction to more patients, and by continuing to educate patients, physicians and payors on the chronic disease of addiction, the role Suboxone® plays in treatment and the importance of expanding treatment access. The population of patients in treatment is growing and we believe that there are strong grounds this will continue.

• In the US, there are estimated to be at least 2.4 million opioid-dependent people today, of whom more than half are not in treatment of any kind.

• In Europe there are estimated to be 1.3 million heroin users, of whom perhaps 0.7 million are in treatment. There is an emerging patient population of opioid analgesic dependent patients who are currently under-diagnosed. Conservative estimates suggest that there are over 300,000 of these individuals in the UK, France, Germany, Spain, Italy and the Nordic countries.

We know the very clear economic argument for treatment: it is estimated that every $1 spent on a patient in treatment may save up to $12 in healthcare and other societal costs.

By continuing to expand access to treatment, and working with physicians and payors to improve the patient outcome, we expect to continue to help even more patients by addressing the needs of the market.

We will continue to work to demonstrate to payors, commercial or governmental, the real value that Suboxone® delivers. We have a growing patent portfolio to support our existing business. Suboxone® Film in the US is covered by three Orange Book-listed formulation patents, and by six process patents providing protection to 2022, with further protection pending.

We have a further 11 patent applications pending. We will defend our intellectual property, which we have worked so hard to establish and grow, on behalf of Shareholders. While the IP of the Suboxone® Film is being challenged, we have a plan in place to defend it vigorously.

Case study 3

Mark’s story  Patient, US

I was an avid racketball player. I needed surgery on a shoulder injury and was given opioids. I took them as directed, but then started to look forward to them. It started to preoccupy me.

I’d go through a monthly prescription in two days and needed several doctors to keep me in supply. It became a full-time job. I was moody, distant and demanding. But I didn’t care. I didn’t even go to work. I just blamed my shoulder.

I wasn’t eating or sleeping – days just blended in. It was all about the pills. I’d probably be dead, but everything came to a head: divorce, the thought of losing my kids and my job.

I remember the day I said “this has got to stop – I need help”. That’s when I started my recovery. It’s vital that you find the right physician and realize what took you down this path.

I’ve been on Suboxone® Film for two years. I’ve not relapsed once, even when my son was given opioids for a broken arm. I poured them into my hand and sat and looked at them. Then I put them back. Two years ago, I’d have taken the whole bottle.

The morning is my time now. I get up real early, make coffee, read the paper and I love it. It’s one of life’s simple pleasures.
Our third objective ►
Expand access to addiction treatment for patients around the world

Capitalise on international growth opportunities
There are an estimated ten million opioid-dependent individuals in the countries in which Indivior has a commercial presence, only 30% of whom are currently receiving treatment. Geographic expansion of our footprint to countries currently underserved by existing therapies and treatment options brings a further ten million opioid-dependent individuals within our commercial reach. Expansion of our business to the treatment of alcohol addiction in all markets offers an opportunity to access an estimated total of 145.3 million potential patients, illustrating significant international growth opportunities for us.

Case study 4

Dr Rubinstein's story  Medical Director and Treatment Advocate, US

When the American Psychiatric Association first invited me to get waivered to start prescribing Suboxone® Tablet, I declined. I had an Internal Medicine practice in an upper middle class suburb of Chicago and thought that having addicts in the waiting room would make my patients uncomfortable.

After the third invitation, I thought I’d just go and see what it was about. At the training, something in me lit up. I thought “I can do this” and I loved the idea of helping people in ways I couldn’t before. So I got waivered.

Quickly, my thinking shifted: these people were no different from the patients I already had.

They weren’t bad people who’d disrupt my practice; in my waiting room, you can’t tell who is there for addiction to pain pills and whoever else is there. I realized that patients with addictions are everywhere – in every medical practice and Emergency Department.

I can’t usually say “I made a difference to someone’s life today”, but treating these patients, I really can. Not only am I helping them, but their families and employers.

I say to doctors that, if they want to get the spark back, and the satisfaction that made them get into healthcare, get waivered. It’s not hard to do.
Strategic Report

Our fourth objective
Grow our business through targeted acquisitions that align to our vision

Expanding by license and acquisition

We are clear that our core business is addiction and that will remain our main focus. We continue to search for products and technologies that will help us improve the delivery of buprenorphine in opioid addiction treatment.

Even within broader addiction, we will continue to look for medical compounds that have demonstrated potential for treatment in areas where we are not present today, such as cannabis, cocaine, methamphetamine and alcohol.

We believe that being an independent company, with a sole focus on our core business, we are much more strongly positioned to attract partners in the field of addiction. We can also look at expanding our business into areas of co-morbidity where we can leverage our existing strengths and business model.

Conclusion

Indivior has a long-term, sustainable business built on a unique patient-focused model. We are the leading opioid addiction treatment company in the world. We have a sustainable franchise in opioid addiction, built on the strength of our existing marketed products, sustained relationships we have across stakeholders and our intimate understanding of the patient journey.

We are actively pursuing future growth platforms, with an exciting pipeline of new opportunities in development. We have a highly committed and experienced management team.

2015 will be a year of transition for Indivior. Suboxone® Film will be affected by pressure on market share and pricing in the US with greater competition from four generic and two branded entrants. In Europe, government austerity measures continue to put pressure on pricing. However, we believe the business will prove to be resilient and will continue to outperform industry norms. The promise of our exceptional organization and our exciting pipeline give me great confidence in our long-term future.

Case study 5

Karrie’s story Patient, US

At 18, I was all ready for college. In fact, it was the start of a decade-long addiction that changed my life. I began taking prescription painkillers to fit in with my peers and soon developed an all-consuming addiction. My only priority was to feed that dependence.

Through the next ten years of addiction, I still managed to hold a steady job. But when I was asked to relocate, I decided I’d rather lose my job than move away from my drug connections. Unemployed, and estranged from my family and friends, I spent two months living in my car. My friends and family tried to help, but I was afraid of withdrawal – and giving up the person I had become under the influence of drugs.

My boyfriend struggled with the same addiction and decided to seek help. When he started working with his doctor, I noticed positive changes in him and wanted to improve too. I recognized that, as an addict, I would never achieve what I wanted in life.

Through support groups and daily treatment with Suboxone® Film, I began to turn my life around, so I could be the person I wanted to be. Now, I feel I have healthy relationships and a purpose in life.

Our priorities for 2015

1. Build resilience of our franchise
   Preserve leadership position in US against four generic and two branded competitors

2. Develop our pipeline
   • Lifecycle products for Suboxone®
   • Treatments for other addictions and overdose rescue

3. Expand global treatment
   • Expand access to treatment in US
   • Expand treatment for opioid painkiller dependence in Europe
   • Expand to underserved countries outside our footprint

4. Business development
   Expand business and diversify business risk through targeted business development
I began to turn my life around, so I could be the person I wanted to be