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Sector call – Health

Friday, 5th October 2018

Operator: Good day and welcome to the Johnson Matthey Health Sector Conference call. At this time, I would like to turn the conference over to Mr Martin Dunwoodie. Please go ahead, sir.

Welcome

Martin Dunwoodie

Director of Investor Relations, Johnson Matthey Plc

Good morning. I am Martin Dunwoodie, the Director of Investor Relations here at Johnson Matthey and I would like to welcome you to our call today. This is the latest call in our series giving you more detail on our sectors and our strategy to deliver sustained growth and value creation. As usual, we will not be giving a trading update on the call. Today, I am pleased to be able to welcome Jason Apter, Chief Executive for our Health sector, which will be the subject today. We have about an hour and with that, I will hand over to Jason.

Health

Jason Apter

Chief Executive, Health, Johnson Matthey Plc

Thank you Martin. Hello everyone. I am Jason Apter, the Chief Executive for our Health sector, and today I want to talk about our strategy for breakout growth in Health. I am going to give you a brief introduction, provide an overview of our activities and then talk through our strategy. Finally, I will open the call to Q&A. Hopefully you can all see the slides on the webcast and you can navigate through these yourselves as I talk.

Introduction

Moving to slide 2, you can see the cautionary statement and I will move on to slide 3. I joined Johnson Matthey at the beginning of March and have not had a chance to meet many of you yet. So to give you a bit about my professional background, I have been fortunate to have had a wide-ranging professional journey leading up to my joining JM. After roles in finance, business transformation, product management and corporate strategy and development, I led businesses in China, Asia Pacific, and most recently leading a global division at MilliporeSigma, the life science business of Merck KGaA through the post-merger integration of Sigma-Aldrich and Merck Millipore.

I have worked in a number of different industry segments, including industrial manufacturing, life science tools and pharma raw materials, both on the fine chemicals side and the bioprocessing side. This has given me extensive experience in driving innovation, growth and operational effectiveness, which I am now excited to bring to JM to execute the strategy for Health.

I am inspired by the ambitions and strategy in Health to deliver breakout growth with improvements to the existing business and expansion of the product portfolio. I am excited to bring my passion for driving profitable growth to build a core growth platform for the group. I like the company's strong heritage in science and technologies and the capabilities we have in Health to support both generic and innovator customers. Additionally, the strength of leadership and culture fits with my own personal philosophies, and I'm really enjoying working with Robert, Anna and the rest of the team.

History of Our Health sector

Turning now to slide 4. Although I have only been at JM for a short time, I understand Health is not a sector that most investors are familiar with compared to other parts of our group. So before I talk about the portfolio today and the opportunities we see for breakout growth, I wanted to start by giving a brief reminder of how we have successfully developed our capabilities in Health over the past 40 years to provide value to our customers.

1970s

Our entry into Health was through pgm-based molecules, which are used in oncology and hinged on the Group's expertise in pgm chemistry.

1980s

We further expanded into controlled substances, like opiates and ADHD, which leveraged our expertise from ENR in supply chain security and high-potency manufacturing.

2001

We developed a global footprint through the acquisition of Macfarlan Smith, the world's leading manufacturer of opiate alkaloids, which increased our scale and capabilities in API manufacturing and really established us as a global leader in controlled substances.

At the same time, recognising the need to better support our customers through development and scale up of their molecules, we acquired Pharm-Eco. This acquisition provided us with a business focused on development and clinical support solutions, which enables us to help innovator customers commercialise new and novel therapies quicker. This complimented JM's existing capabilities in materials development and characterisation, which is how we work out to make a solid substance and really understand it at the atomic scale; and secondly, scale up of complex manufacturing with market-specific application support to really grow our pipeline.

These capabilities enabled JM then to start investing in the development of our generics pipeline, as we were now equipped with the ability to develop and manufacture API for both innovator and generics customers.

2015

We further expanded these capabilities with the acquisition of Pharmorphix, our solid-phase design services, which provided us with a foundational building block in particle technology for pharma customers, further enhancing our development and scale-up capability. These milestones have been key to our ability to solve complex challenges for both innovator and generics customers across the entire value chain and successfully support them in bringing their products to market.

Our Health Sector Today

Moving to the next page, here then is what our Health sector looks like today. Our focus is on the development and manufacture of high-quality, complex, active pharmaceutical ingredients, APIs, for both innovator and generics customers. We have five manufacturing sites across the US and Europe, as well as four development centres in the US, Europe and Asia. Around 70% of the sector sales currently comes from generics, with the rest from our innovator business. Within generics, we separate our business between controlled substance, which is about 80% of our revenue, and non-controlled substance, which is 19%. We are a market leader in controlled substances and high-potency APIs. And through our ramped-up investment in our new generic pipeline, we will grow our portfolio substantially with launches beginning of this financial year and delivering additional £100 million in operating profit by 2025.

In innovators, we separate our business between clinical development, which is 44% of sales, and this is where we work with customers through their pre-clinical and clinical development phases. The second part is our commercial API, which is 56% of sales, where we are supporting customers in the validation and subsequent commercialisation of these new therapies.

That is the current business but as I said, we have an exciting pipeline of new opportunities across both generics and innovators which is going to drive significant growth, and I will tell you about that in a few minutes.

JM Wins Through Science and Its Application

So given our journey and where we are today, why do we think Health can win? First, let me give you some context on the overall process of making a drug. There are essentially two parts to this. First is the development and manufacturing of the drug substance, which is the API. Secondly, it is turning that substance into a form that is administrable to a patient, such as a pill or an injectable solution. Our focus at JM is on the API side. We have key competences that span across the value chain from API development through to scale-up and commercial manufacturing. It is our strength from the start of the process right through to the end that really builds the relationship and adds value for the customers across both the innovator and generic product value chain.

Three key stages of the value chain

Specifically, there are three key stages of the value chain in which we play. First is the development phase where we use our world-leading materials design, development and characterisation capabilities and apply our complex chemistry to develop APIs at a lab scale. Next is our process chemistry and flexible manufacturing capability, which gives us the ability to scale up these complex chemistry processes quickly, and with the confidence to reproduce what we did in the lab at increasingly larger scales. Now this is extremely important in the overall process as the specific chemistry and particle technology is optimised as we go through scale-up. And our ability to partner with our customers to solve these challenges is what provides significant value. Finally, our process engineering and focus on operational excellence enables us to take this through to commercial scale manufacture, with higher reliability and at a quality and compliance standards that our customers and regulatory bodies expect. All of this is underpinned by our deep understanding of the needs of our customers

and our regulatory agencies, which comes from the long history in this market and our strong position in controlled and high-potency substances.

These capabilities drive success both in the innovator space and in generics, and we have a core development team that supports both. Additionally, much of this technical expertise and science is core across the whole of Johnson Matthey and we both utilise and provide expertise to the rest of the group.

In the development phase, we leverage the group's R&D capabilities to help us meet specific customer requirements, while also sharing expertise with other parts of JM. For example, some of the crystallisation techniques used to develop our leading battery cathode material, eLNO, came from Health as these techniques are used to develop the API. In scale-up and manufacturing, we utilised the Group's expertise and supply chain security and high-potency manufacturing, which are both important in ENR, with similar skills required in terms of the containment and handling of pgms to the handling of high-potent API substances.

Generics Example: Development of Dofetilide

Let me give an example of how we have utilised our strengths through the value chain to help a customer bring new product to market. In 2016, we successfully launched dofetilide with our partner, Mayne Pharma. You can see the timeline for this in the appendix. This is a generic version of a product used to prevent irregular heartbeats. We developed a thorough understanding of the patent landscape, and then utilised our capabilities to identify non-infringing chemical form and manufacturing processes that met exacting purity and particle requirements. We collaborated with our partner to minimise the development time for both the API and the drug product formulation, which allowed us to be first to market with 180 days of exclusivity. And we continued to have the only generic in the market until this summer, well after the 180-day exclusivity period because our technical advantages in development scale up in manufacturing took longer for others to achieve.

Outsourced Small Molecule API Market Is Growing At 8% P.A.

Now moving on to the market. We see the health market as attractive. It is a large market with strong growth rates and the industry trends play to our strengths and give us a competitive advantage.

Global sales in API

Taking you through the key reasons, the global API market is worth $170 billion, of which we estimate $40 billion is outsourced small molecule APIs. This market is growing at around 8% per annum, driven by strong fundamentals and we target specific areas within this. We expect the growth to continue due to a number of themes.

First, our customers increasingly look to outsource parts of their value chain to reliable partners as APIs become more targeted and complex. This is where we can really add value, particularly for many small customers who might only have one drug in development and simply don't have the capabilities that we possess. Secondly, there are over 3,000 off-patent molecules today that have been either genericised or are in the process of being genericised. With the natural expiration of further patents, the pool of potential generic molecules will continue to grow. So development activities from our customers continues to increase and we are seeing more diverse customers. The market for outsourced small molecules remains

fragmented and we have the scale of a company to put the technical horsepower behind our Health platform.

An attractive segment that plays to our strengths

We also see positive trends that allow us to leverage our existing strengths to provide a differentiated customer experience. First, with more targeted medicine, there is increasingly more complex chemistry needed to solve our customers' problems, which is exactly what JM is all about. We are seeing more targeted therapies, for example, in oncology with fewer side effects, delivering much higher survival rates than 10-15 years ago.

Secondly, we continue to see an increase in the complexity of the regulatory and compliance landscape. And our expertise in the enhanced requirements of controlled substances in high potency compounds allows us to navigate this landscape and provide confidence to our customers.

Finally, the continued need to enhance bioavailability and bioequivalence remains an opportunity to create value. Let me explain this. Bioequivalence is where the generic must have the same biological profile or effect as the original branded product. Bioavailability is essentially the rate at which a drug is absorbed into the body to give the required effect. So from an API perspective, the solubility of the drug substance is a primary variable and through our particle technology focus, JM can provide our customers with a broadening array of solutions to improve in these areas.

So you can see, our business is positioned in an attractive and growing market that offers opportunities for us to use our competences to drive additional value creation for our customers.

Key Focus Areas to Deliver Breakout Growth

Let me shift now to where we are focusing. We have a lot of growth opportunities and my focus is on three areas. First is enhancing the performance of our existing business, returning that to growth and improving the overall profitability of this business. Secondly is expanding our new product pipeline to drive growth with both generics and innovators. And third is building our capabilities to better support customers for the future. I will go into each of these in more detail now.

Enhancing the Performance of Our Existing Business

New sales opportunities

Moving to the next slide, let us start with enhancing the performance of our existing business and returning it to growth. There are two main areas we are looking at here. First is new sales opportunities. We are finding that certain molecules in our existing portfolio are being expanded into new applications, such as additional therapies. So we are developing and supporting new generics filings for existing molecules, modified to meet these new requirements.

We are also working with new partners. An example of this is cannabidiol, where we have recently developed a high purity synthetic cannabis for use in pain management and multiple sclerosis. We also support sales growth through optimisation of our manufacturing footprint. We have been expanding in Annan, giving us more flexibility and efficient manufacturing, and

sufficient capacity for growth. We have accelerated our industrialisation of this facility and over the past few months, we have shipped our first commercial batches.

Operational efficiency

Secondly is our operational efficiency. There are a lot of opportunities as we globalise further to increase our operational effectiveness and achieve more throughput in our existing assets, gain higher productivity and reduce our cost base. This includes, first of all, strategic sourcing. For example, in Annan we have redesigned the process for our core codeine product to start with a different raw material which will deliver significant savings in raw material costs. And obviously the group global procurement programme will benefit us at a sector level.

Manufacturing efficiency

Second is manufacturing efficiency. We have taken a close look at our processes to identify actions we can take to improve our manufacturing efficiency. So for one product, we have improved the yield by getting the process time down from seven days to three. And culturally, as we move beyond highly valuable, restricted controlled substance space, we can make significant improvements in how we run our business.

Now this is not an exhaustive list but I wanted to give you a feel for how we are running the business better, we have plenty of sales opportunity and my focus is on making sure we convert these into profitable growth.

Expanding Our New Product Pipeline and Portfolio

Slide 10 is the second area I'm focusing on and it's expanding our product portfolio. This is important as we will see fall off in our existing generics products because of natural attrition and where certain products are in their life cycle. For context, we look at our business in two market-facing business units, innovators and generics. To expand our portfolio, we essentially follow two regulated paths with our customers. The first are new drug approvals, NDAs, which are how our innovator customers introduce new and novel therapies to market, and can take as long as 10 to 15 years due to the need of regulatory approval after demonstrating success through clinical trials where they test the effectiveness of the treatment to a large sample population and monitor response. The second route is abbreviated new drug approvals, ANDAs, which are a much quicker route to market and how our generics customers introduce new versions of existing drugs to the market, driving more competition to create better access and better affordability.

Looking at our pipelines, the capabilities required for generics and innovators are very similar, so I consider the pipeline holistically. Both use the same resources and skills and provides a balanced approach to the timing of our investments, as generics will deliver near-term profits whereas the innovator pipeline by its nature is longer term.

Generics

Taking each of these in turn and starting with the generics. In generics, not all are equal. We focus on molecules with more complexity where our strengths really add value for our customers. You are not going to see us involved in the stereotypical low-cost, high-volume, high-competition products where margins are low. The overall pool and potential generic candidates is greater than 3,000, which continues to grow with patent expirations. And we

have screened hundreds of compounds to narrow our focus to a small subset of molecules, less than 20% of the total, where we believe JM can provide value. We subsequently screened these molecules for strategic fit and technical feasibility and selected an initial 40-50 API products that we felt confident to develop and work with partners to bring to market.

Partners also come to us with good ideas and of course, we are always looking to add more to that pipeline. We have a very strong and diverse pipeline that I am confident will deliver the £100 million incremental operating profit per annum by 2025 that we have spoken about before. As mentioned, we have 40-50 products, so we are not reliant on any one particular product or even focussed on a particular indication, so it is broad and diverse. We expect 20-25 of these to launch over the next three to four years. We can model the £100 million of additional operating profit from the pipeline with a great degree of confidence.

We know the size of the branded market, approximately how many new generic launches there will be and also the expected timing of the launches based on the patent expiry. Years of industry data shows the sales profile for each newly launched generic in markets of a similar size and with similar generic competition, which gives us a great deal of confidence in what our pipeline will deliver. We are also conservative with our assumptions for the pipeline and do not assume that we will be first to market for the vast majority of our products. There are a number of variables outside of our control, though, which means the overall earnings of the pipeline can be lumpy until we reach scale. This is why we are building a diverse and large portfolio with over 40 products in various stages of development.

Innovators

Shifting to innovators, the innovator side of things is something I was positively surprised by. It is only 30% of our Health sales at the moment but I do see significant potential here. As targets become more specific, drug design is getting more and more complicated. And that complexity demands better capabilities in material characterisation and particle technology, which moves into our sweet spot. In the innovator business, our model is to partner with our customers early on as they are developing their product. We work in a fee-per-service model that allows us to generate value during the long development time, as we help develop the API. And then subsequently support our customers to scale up through various stages of clinical testing and ensure they have the product they need to support their clinical trials. This customer intimacy allows us to continue as their partner through the commercial scale if the drug is eventually approved. It is a great business because we are with our customers from the very early stages all the way through to delivering a therapy to the patient. The commercial business is very sustainable because of the high barrier to entry due to the regulatory approval.

The key risk we need to manage in innovators are attritions of drugs that fail in clinical trials; hence a larger and more diverse pipeline will help with that portfolio effect. Our innovator business has been successful in the past four years with a doubling of sales, but we have a lot of potential going forward with currently around 20 projects in pre-clinical, clinical trials and late stage commercialisation.

Building our Capabilities to Better Support Customers for Future Growth

The third area I am focusing on is building our capabilities to better support our customers and cement our position as the technology partner of choice. Customers choose to work with

JM today due to our strong capabilities we have across the value chain, but there are specific areas we can continue to build on. Innovators today is largely driven in the US and we are working to globalise our development capacities, for example, with solid form sciences in Cambridge, UK. Particle technology is also important and used in generics to work around patents and in innovators to improve functionality and efficacy. So we are building our capabilities in that area too.

We are also working to improve our understanding of formulations and the technical challenges with excipients so that we can be a better technical partner. Most of this work will be through an organic investment. But once we have improved our base business and are well on the way to delivering our pipeline of new products, then we can consider selective value-creative M&A to enhance our capabilities and add new technologies.

Health Sector to Deliver Breakout Growth

So moving to the last page and to conclude, I am delighted to have joined the Johnson Matthey team. It is an exciting time to have joined with our clear strategy, combined with investment in recent years, positioning us well to deliver strong growth in the medium to long term. We do expect this year to be a year of transition, with operating profit down, as we have already guided to, particularly in the first half as the business rebases. However, I am looking forward to delivering the strategy we outlined at the Capital Markets Day and have confidence that our existing generics product pipeline will add £100 million per annum to operating profit by 2025. The sector as a whole will show double digit operating profit growth beginning in 2019 to 2020 and margins reaching the high-20s there afterwards.

So I will now open it up to Q&A.

Q&A

Operator: Thank you. If you would like to ask a question, please signal by pressing *1 on your telephone keypad. If you're using a speakerphone, please make sure your mute function is switched off to allow your signal to reach our equipment. Again, press *1 to ask a question. We will take our first question from Tom Wrigglesworth from Citibank. Please go ahead, sir.

Tom Wrigglesworth (Citibank): Hi there. Thanks very much, Jason, for the presentation. Couple of questions, if I may. Firstly, in terms of the – is there a margin difference between generics and the innovators' sales performance. Secondly, obviously you were talking about the – if your portfolio was running today, how long would that portfolio run to until revenues were zero. I.e., what's the natural decline rate in the portfolio as you kind of – as the generic drugs kind of drop off or come to end of life? Can you give us some kind of sense, and then how that would relate to that £100 million? What would be that £100 million net or some guidance around that? Then third question, how do you win business? What is it that JMAT's USP is? Can you help differentiate that? Because a lot of your pitch I understand from a high level but if I sit down with Lonza, they have exactly the same kind of pitch, so I just want to know what you think you're seen in the market as doing better than your competitors. Thank you.

Jason Apter: Thanks Tom. So let me start with the first question. When you look at our business model between innovators and generics, from an innovators' perspective, we're

generating value throughout the development cycle as a fee-for-service and then obviously working towards the late stage commercialisation. And then on the generics side, what we're working with is on the development of the molecule and then partnering with partners to help with the formulations. So we have an interesting model where we take a profit share on the drug product as we've helped our partners create that. So really, when you look at the profitably of the two businesses, because of the two different models, they are very similar.

I will move to the second question that you had, which is the run rate of the portfolio. So when we talk about decline – and I think it's interesting on the generics side, drugs are not necessarily going away, right? So the attrition is more that either they're genericised so there's more competition, which creates penetration shifts and that in the market. But the other decline that we have is that profit shares eventually expire, and hence the reason why we've got the new pipeline. And we don't necessarily have a rate for that, per se, but we always look to take those existing model fields and even go into new applications.

Then Tom, if you wouldn't mind, I didn't quite catch the last question. You said JMAT USP but essentially were you asking about our value proposition?

Tom Wrigglesworth: Yeah, and how that's different from your customer base. So, sorry, customer base – how you're different from your competition because from – without any expertise in this area, really, it's hard to differentiate what it is. I mean, obviously I get that you do these – that you've got the security measures to do these opiate drugs and the cannabis, etc., but beyond that on the technical side, what is it that JMAT offers above and beyond the competition?

Jason Apter: I think it's very clear. So I think the first area that provides us competitive advantage is our focus. And so we have stayed very focused on what our core is all about and that comes into complex chemistry. And so I think that – and as I spoke about in the three areas of the value chain, so we talk about development, scale-up and manufacture. We have chemistry expertise in all three areas. And then I think the platform foundation of our expertise in particle technology and the materials characterisation, the depth of expertise we have in this area provides us an advantage. And again, as I talked about with focus, we are not distracted with other areas and we have very deep expertise in our selected niche.

Tom Wrigglesworth: Okay. Thanks very much. Yeah, that's helpful. Thank you.

Operator: If you find that your question has been answered, you may remove yourself from the queue by pressing *2. We will take our next question from Ben Gorman from UBS. Please go ahead, sir.

Ben Gorman (UBS): Hi. Thanks very much. Just two quick ones from me. In terms of the molecules that you don't currently operate in – you mentioned something like 20% or less than 20% that you do operate in, the remainder of the market, can you just give a bit more of a clear idea in terms of why you don't operate there? You mentioned that you can see your ability to add value proposition. Is that because there's not much value in that part of the market or is that because your capabilities don't match that? Is that something you could move into?

And then just in terms of the £100 million, can you give a bit of an idea about any upside to that? Do you think that that's really giving a fair example of the potential in either the

generics or the innovation side? I'm just wondering whether you actually see that as a cautious estimate in innovation, given you really don't know whether half of the drugs you're working with customers on, are going to get approved or not. So actually that number could jump one way or the other based on the innovation side quite a lot.

Jason Apter: Okay. Thanks Ben. Let me address both of those. So first, let's first of all talk about where we're not playing. Then so – I think this is, again – the core foundation of what we're doing is we're very focused on where there's complexity and where it's tough, which naturally means there'll be fewer players in that space because not everyone has the capabilities that we've got and the abilities to work through some of the complex molecules.

So as an example, we are not going to work on aspirin, and things like that that are – and not that there's not a lot of value there. They are very high volume and that, but there tends to be more players in there and it tends to be less complex than what we'd like to work on. So hopefully that gives you a flavour of how – of the things that we are working on but specifically of things that we just wouldn't work on.

Now let me talk about the £100 million. So again, just to be clear, the £100 million we spoke of is from our generic pipeline. And so as we've said, the certainty that those molecules will or are genericised is there. So we do have a lot of certainty on the market. These are currently either branded drugs or even genericised drugs. So they're existing molecules. So it is not a matter of if, it's a matter of when. And that's really where we've been guiding towards and the innovator side we have not spoken about because of that fact. I think the fact that you mentioned is there is attrition rate and so that's why we built a fee-for-service model so that we're not taking a risk in the development of something that may not come to market.

Ben Gorman: Great. Thanks very much. Cheers.

Operator: We will take our next question from Chetan Udeshi from JP Morgan. Please go ahead sir.

Chetan Udeshi (JP Morgan): Yeah, hi. Thanks. You mentioned the new pipeline of 40 products. Is there any one or two key products which clearly drives the bulk of that £100 million, or is it equally spread across most of those 40 different products, pipeline products?

Second question, just to ask it a different way than a few of my colleagues tried to ask previously, is – your current profit is say roughly £40-45 million, so are we to add £100 million to it to get to 2025 number? Or this £100 million is to some extent going to replace some of the natural attrition in the existing pool? Just to be clear on that.

And last question is, you mentioned something about excipient and I didn't quite catch what your strategy there was. Thanks.

Jason Apter: Thanks Chetan. So let me address the first one. So, on the pipeline of 40 products, no, we're not dependent on any one or two products. It's largely spread across all of the pipeline. And keep in mind we continue to add products to this pipeline as we're working through things. So again, there's a – as I mentioned earlier, there's very low dependency on a particular product.

Let me move to the third question on excipients for a second. So to dumb it down, the pharmaceutical formulation is the point where you have a pre-formulation which starts to look

at the interaction between the API and the excipient. And then subsequently the formulation is turning that pre-formulation into a product that's administrable to a patient. And so, our ability to understand the interaction amongst that allows us to develop the API, the crystal form and even co-crystallisation forms with excipients better. So it's our understanding of how the interaction works amongst those three things, which is what we continue to build our understanding of, so that, again, we can create more efficient solutions from an API perspective. Does that make sense?

Chetan Udeshi: So are you saying that in the future you might try to do excipients yourself as well? I don't know if you do already, but is that the next sort of route to your growth strategy as well? Maybe take some of the excipient development within JM?

Jason Apter: Our growth strategy is really to focus on where we can apply our complex chemistry, particle technology and our flexible cGMP capacity. So that's really our focus and we're not necessarily focusing on excipients or other parts but really where we can add value through the capabilities.

Chetan Udeshi: Understood.

Jason Apter: Now from a profitability perspective, again, when we talked about – the £100 million is for our generics pipeline and obviously as we grow the pipeline, as we explain, there will be some natural attrition. I'm not going to tell you how to do the maths but that's kind of how it works. And again, we also have our innovator business that we have continued to grow.

Chetan Udeshi: Thank you.

Jason Apter: Cheers.

Operator: We will take our next question from Adam Collins from Liberum. Please go ahead, sir.

Adam Collins (Liberum): Hi. Good late morning. I had a couple of questions, please, Jason. Just to start with, just to follow up on last set of question, when you said you'd let us do the maths, but just going back to the issues around the so-called legacy business, the generic for controlled substance, which as far as I can tell is about 55% of the revenue base, so it really does matter. Would you mind spending a minute or two just talking us through what that looks like today, what are the areas that are threatened in particular by the issues in relation to US authority concerns about the misuse of controlled substances, recreational misuse of controlled substances? To what degree is that area related to areas that we need to worry about and to what extent isn't it?

And then on a slightly less difficult basis, second question is on the guidance for increased margins longer term. I understand that this is to some degree driven by the fact that some of those new product areas relate to profit shares, as opposed to, if you like, toll[?] manufacturing. Would you be able to give us a sense as to the exposure to profit share in that portfolio, and what you think are the main drivers as to why margins will go back to where they used to be in the division?

Jason Apter: Great questions, Adam. And so first, let me start with the controlled substance. So yeah, controlled substance is a material part of our business and actually, when you look at it, it's a very nice niche. It's highly regulated, even further through whether

it's DEA or home office regulations because of the controlled aspects to it. So it's got less competition and it's got extremely high barriers to entry, so it's a great business. And in that business, you mentioned the US opioid crisis and it's important to point out that we do not – not all controlled substance products are created equal. And in the US we are not positioned in what we call bulk opiates, which is where the primary concern has been. So our exposure to – from a product perspective is very limited in the US to what the overall crisis is today. And in fact, what I find exciting about the controlled substances portfolio is in fact we also have a specialist opiates line, which contains a few molecules which are used in anti-addiction therapies before[?] this. So I think some of these trends will actually play well to our controlled substance portfolio because of where we positioned it.

I'll move on to the second question, which is on the increased margins and you asked specifically. So a large portion of our pipeline is targeted – because of the value we can bring, because of the capabilities that we have, a large portion of that is targeted towards a profit share style of model because we're working very collaboratively with our partners and they value the capabilities that we have in the background. And I think it's upwards of 80% of that pipeline and of that £100 million is in the form of profit share, so that obviously has a positive impact to our margins.

The second piece of the margin expansion is really what I spoke about in really improving how we're running the business and making operational improvements. As I've said, we've been – controlled substances has been a great area, it's a great niche and it's highly high-barriers-to-entry and we've had lower competition. But because of that, it's also created – when you have low competition, you're spoiled by being protected a bit. And I think there's some opportunities for us to really improve it and operate in a more competitive fashion, which will obviously enhance the margins for us as well.

Adam Collins: Thank you for that. May I just ask one other thing? I know there's a lot going on in the UK business in terms of reallocating production between the two factories. Would you be able to say a bit about what the programme involves?

Jason Apter: I'd love to. It's – I spoke about – it really links, actually Adam, to both of your questions. So our optimisation of our footprint in the UK is – the underlying driver behind that is capacity. Today, we have limitations on capacity in certain specialist opiate products and so the focus of the programme is really to optimise the capacity utilisation. I mean, I'll give you an example of a product that we have, which is called buprenorphine. And again, that product is used within a number of anti-addiction therapies. But the complexity of the manufacture, again core to our strengths, we go through roughly eight-stage manufacturing process. And as you can imagine, it's a five to six month manufacturing time to make that product through various stages. And so the programme in the UK – it's very complex. So the programme in the UK, it's really to take the complexity of that manufacturing and optimise the capacity so we can meet existing demand. Makes sense?

Adam Collins: Okay. Yes it does, yeah. Okay. So basically, one plant is going to be more complex than the other and you're directing product towards it? Just going to deal with the more complex molecules.

Jason Apter: [Inaudible]. I think we have complex manufacturing at both sites and the Annan facility provides us capacity to, again, address increasing demand and allows us to modulate between the two sites.

Adam Collins: Okay. Thank you very much.

Operator: We will now take our next question from Charlie Webb from Morgan Stanley. Please go ahead.

Charlie Webb (Morgan Stanley): Hi Jason. Just a few questions on the pipeline. First off, what proportion of the pipeline do you forecast exclusivity? I know you said not many but how many of the 40 – or 40-50 are you thinking that exclusivity is likely or at least the probability is likely? How many of the 40-50 generics do you have in that pipeline? How many are they targeting patents that might expire in the next 24 months? And then maybe circling back to – because I don't think it was mentioned, just around the blue sky value of that pipeline, I understand obviously you need to risk adjust it, we won't see that blue sky outcome. But just trying to understand between the best outcome possible and the worst outcome possible, where does that base case £100 million currently sit? So if you could give us some sort of range in 2025, I know that's very difficult, but based upon your model, that would be helpful as well.

Jason Apter: Right, so let me address those – so first of all, from an exclusivity perspective, again, I think as I said before, we tried to keep the assumptions in our pipeline conservative. And we do model the number of competitors and we are not modelling any exclusivity deals in that pipeline. We are assuming competition that's going to be there and we're assuming certain market penetrations but we're not assuming best case scenario in any of our assumptions, which I think is an important thing. As far as the number of molecules that are coming off patent, of the 40, I roughly say – probably a good majority of those are a coming up patent in 24-36 months, I would say.

Then on the range, I would actually probably reference you guys back to the CMD where we actually showed the range of the portfolio. And there's a really nice chart that you can reference that kind of shows where our ambitions lie within that range.

Charlie Webb: And that range still stands? Nothing's changed to it?

Jason Apter: Yeah, I don't think there's any material reason to change that.

Charlie Webb: Okay. And just one last question, on the 20 API products in the innovator pipeline, clearly, I guess there's far more variation in terms of what's going to get to get to market, what will not – what will be successful, what will not. But again, is it possible to tempt you to give us a sense of what that could be worth further out, or is it just too difficult to say?

Jason Apter: It's really difficult to say because obviously, again, the business model is we're supporting our customers, fee per service, though, through the development and it's really up to the approvals of those. But we do have some that are in later stages and we're monitoring those and partnering with our partners closely.

Charlie Webb: Okay, thank you very much.

Operator: Once again, if you would like to ask a question, please press *1. We'll now take a follow-up question from Tom Wrigglesworth from Citi. Please go ahead.

Tom Wrigglesworth: Yeah, thanks Jason. Just a follow-up question about helping me to understand capital intensity and as you've alluded to with the restructuring of the UK, what you're limitations are in terms of capacity. Is there business that you have to turn away because it's going to be too high volume? And how do you think about the investment around capacity, given the growth of the underlying markets that you indicate?

Jason Apter: Good question. So I think – the capacity question, so we have been investing in the past few years in that capacity and that's part of my comments of where I'm excited to have joined the business. It was a great time because we've started to make the investments in the pipeline. We've also been making the investments in the capacity. I will say that we have been limited and had to allocate on certain molecules, and that's been a limiting factor because of that in the past. And what we're excited about is to really open that up through what we're doing. And our target is, through this year, to really have that capacity in Annan fully capable and ready.

Tom Wrigglesworth: Sorry, I guess the underlying question was how long can you keep going at these kind of growth rates without needing the next stage of investment?

Jason Apter: Understood. So, if you look at our capacity model today, we do have a healthy balance between what we're using and then open capacity. Again, as we bring the Annan investment on board, that will open up. Then keep in mind, we also have available room in various centres to make those investments. So, I think we will be continuing to invest and grow our capacity, as we would do in normal course of business, throughout. And for generics, because again, we know what we want to make on the generics pipeline. And again, the nice thing about the innovator model is we're working collaboratively with our customers all the way through, so it gives us good visibility of when they need capacity, we can put it in for them, with them.

Tom Wrigglesworth: Okay. Thank you very much.

Operator: It appears there are no further questions at this time. I would like to hand the conference back over for any additional or closing remarks.

Martin Dunwoodie: It's Martin Dunwoodie back again. Thank you very much everyone for joining the call today. If you have any further questions, then please contact us at Investor Relations. Goodbye and thank you for joining.

Operator: This concludes today's call. Thank you for your participation. You may now disconnect.

[END OF TRANSCRIPT]