Generics Meet the Management

Siggi Olafsson:
Good morning and good afternoon, everyone. I'm Siggi Olafsson, the CEO of Hikma Pharmaceuticals, and today I'm delighted to be hosting the third of our series of Meet the Management events. Now we will be looking at the last of our three businesses, the U.S. Generics. As you know, this business develops, manufactures, and sells oral and other non-injectable generic medicines for the U.S. market, as well as operating a specialty business which the team will also discuss today. As before, we've decided to keep this event to a relatively short period, so only about 75 minutes of your time today. So, before we start, I'd like to remind you and refer you to the safe harbor statement in the front of this presentation, of course.

So, let's quickly review the agenda. I'll kick things off with a very brief introduction to our Generics business, Brian Hoffmann, the President of the Generics division, will give you a full overview of the business: background, where we have come from, and what the team has been doing in recent years to grow and improve the profitability of the business, as well as discussing our strategy going forward. Brian will be followed by Mike Balog, our Senior Vice President of Operations, who oversees our Columbus, Ohio facility. Mike will go into details on our operational strength and our focus on quality, and after Mike we have Kristy Ronco, our Chief Commercial Officer of the Generics business, and she can talk about our commercial approach, go to market strategy, and our customers, of course. Brian will them wrap up before we go into Q and A.

So, I'm really pleased to have the generics being here today, we have a strong business that has been transformed over the last four years. Before we get to the team, this slide sets out where the Generics business sits within the broader Hikma business. At just under a third of our revenue, and quarter of our core operating profit. It's worth pointing out that this operating profit contribution has increased significantly over the last three years, and we have the team to thank so much for this, be it from improving efficiency of the business or delivering more from the pipeline. But with that should be enough, I'll now hand it over to Brian to tell you more about the business.

Brian Hoffmann:
Thank you, Siggi, for the introduction. Good morning to everyone in the U.S., good afternoon to everyone in Europe and overseas. My name's Brian Hoffmann, I'm the President of Hikma's Generics business unit. It's really a pleasure to be with all of you here today. As Siggi mentioned, I'm going to go through an overview of our Generics business, but before I do so, I'd like to show you a short video which helps to highlight our Generics business as well as our growing specialty branded business.

[music playing]

Brian Hoffmann:

So, welcome back. I hope that video was helpful in giving you some visuals to highlight our business. So, since we last had our capital markets day in 2018, our generics business has grown significantly to today. Today, we are a top 10 generic non-injectable manufacturer in the U.S. with significant scale and market presence. Our focus is on differentiated generic products, as well as specialty brands. We believe these have higher margins and are more durable in the long term. Our aim is to be a customer and patient centric organization, and what that means is we put the customer and the patient at the forefront of all of our business decisions. That's really key toward achieving our strategic ambitions. In the next section of this presentation, Mike Balog will talk about how our operations aim to be flexible to help us with this goal. Since we completed the Roxane acquisition in 2016, our core operating profit has grown -- has grown four-fold.

Now turning to the financials, over the past six years the Generics business has gone on quite a journey. If I go back to 2015, the business was really a limited scale business, the entire portfolio was solely focused on oral solids. Then, in 2016, we acquired Roxane labs. That really transformed our business, it brought us significant portfolio scale, it brought us diversified manufacturing technologies, and it also brought us an R&D engine for growth in the future. Unfortunately for us, that acquisition also coincided with one of the most difficult periods for the generics industry, where there was significant price erosion. That impacted our business as well and it impacted particularly the profitability of our business. So, we really needed to focus on improving the business, making some significant changes to return us back to growth and also improve our profitability. We started to see those gains in 2018 and 2019, where we were able to grow the top line, and more importantly, improve the profitability into the high teens. Then, into 2020 and 2021, we started to see a significant contribution from the pipeline. This helped us to grow the top line more significantly, and even bring the bottom line into the low twenties.

So, reflecting back on the last time we had a Capital Markets Day presentation, we set out a long list of near- to medium-term priorities in order to improve the business. They included selling the Eatontown manufacturing facility, consolidating our warehousing and distribution operations, tech transferring all the products that were previous in Eatontown to both our facilities in Columbus, Ohio and Amman, Jordan. We had to optimize the workforce according to the future needs of the business, we implemented operational efficiencies all throughout the business, we clearly identified cost savings, and then put projects behind them to achieve them. And importantly, we improved our service levels to enhance our reputation and really give us the license to further grow our business.

So, as you can see here from this list, it really was all encompassing in terms of the change that we needed to implement. I'm really pleased that sitting here today, we successfully achieved what we laid out to do. So, we were able to sell our Eatontown manufacturing facility in 2018, we consolidated our distribution facilities into an operation close to our manufacturing facility in Columbus, Ohio, we did tech transfer all of the products that were previously in Eatontown, and it was quite an effort to do so. We streamlined our management layers to be more efficient, to have faster decision making, and we reduced our headcounts, so we could properly

meet that with the volume, the demand for the near term, as well as the future. This resulted in significantly increasing our production output per employee.

So today, we're operating at a higher tablet per employee than we ever have. This also resulted in significant lowering our overhead cost per unit. So we're producing more and we're producing more at a lower cost. And lastly, we achieved the metric that we set out for ourselves as being 95 percent plus service level rating. You know, particularly across our key strategic customers, who really demand us to be at that level, or even better. So sitting here today, I couldn't be more proud. And the amazing effort for our team in order to deliver these changes for the business, and to deliver the results that we have done so far.

Looking at 2021 and beyond, we have a number of long-term priorities. Quality is and will always continue to be number one. We need to operate at the highest quality standards and have that ingrained in our culture. We also can't rest on our laurels in terms of finding cost efficiencies. That has to be a part of our every day-to-day business. We'll also continue to add new technologies and capabilities that can improve our pipeline, our portfolio, and our manufacturing operations. And our Insys acquisition is a great example of that. We acquired some unit dose manufacturing technology, we brought that into our facility in Columbus, Ohio, and we've now commercialized our first product from that line. And Mike Balog will talk about that later in his presentation. Respiratory and our Hikma Specialty businesses: these are two important growth drivers for our future, so I'll talk about them in a little bit more depth today. And then we'll always look for inorganic opportunities to complement our pipeline, and these can be all across the board. They can be product licensing deals. They can be contract development and manufacturing partnerships. They can be M&A deals at the product level or the company level. We're always looking for inorganic opportunities to help complement our organic growth.

Now I want to talk a little bit about the pipeline, and where I'll start off by saying is that Hikma continues to reinvest in our pipeline. As a group, we invest six to seven percent of our net sales into R&D every year. And I'm very pleased to say that, even during those more challenging times that I talked about earlier, we continued to make that investment. So Hikma has made that commitment toward reinvesting in the business, reinvesting in the portfolio so we can continue to grow. In terms of our pipeline, we continue to -- we continue to replenish it. So at any given point of time, we have products in our pipeline at all stages of development. They could be at the early stages in terms of us just selecting them or being at early formulation, all the way to the late stages of being tentatively approved or approved waiting for a launch date. In terms of the make-up of our pipeline by dosage form, we have products across a wide variety of dosage forms. And because our focus is on differentiated products, greater than 50 percent of our pipeline is in the more complex dosage forms. We also have a balance of Paragraph Four products and non-Paragraph Four products. Paragraph Four products are those where we're challenging brand patent, we're trying to challenge brand patents to get on the market before those patents expire. And it's important to have that balance of Paragraph Four and non-Paragraph Four products to balance both near and long-term growth, because the litigation process for some of these products can take longer. So we believe it's important to strike that right balance.

Now I'm going to talk a little bit in more detail about the pipeline and talk about some products. And you know, this admittedly is always a challenge for us. We know that all of you want to know more and more about our pipeline. You want to gain more and more visibility. But it is a challenge for us, because this is the -- this is the area within the company that's probably the most competitively sensitive. But

we want to give you that more visibility, so we're trying to do that here today. So what I have highlighted here is just a small snapshot of our pipeline. And it includes some of the products that are publicly disclosed, either because we're in litigation, Paragraph Four litigation, or because we've made specific press releases to announce these products. So I'll highlight a few of those here today.

So, starting off first with our specialty business. We have a few NDAs and 505(b)(2) NDAs in our pipeline. Bilastine is a product partnership that we actually just announced earlier this week with a company called Faes. It's an NDA because it would be a new chemical entity here in the U.S., but it's actually marketed today in over 100 countries. We also have some 505(b)(2) NDAs in our pipeline, which we have disclosed. These are products which are not new chemical entities but are bringing something new to the market. So in Epinephrine's case, it's a nasal spray, which would be a novel dosage form in the market today. This is a product that came alone with our Insys acquisition as well, and our R&D team is working on completing the development. Ryaltris is another product which we've partnered with Glenmark, and we're looking forward to bringing that to the market hopefully sometime next year.

Moving on to respiratory. Respiratory is an important part of our growth strategy. We're working on developing AB rated generic versions of GSK's Ellipta portfolio. And in addition, we're looking for partnership opportunities. And they could be on opportunities for devices beyond our -- is our Ellipta device, which we have the manufacturing capability in house. And we're open to partnering and being the commercial partner for other respiratory products. So we're looking forward to bringing more of those types of opportunities to the marketplace. In terms of our Paragraph Four products, I have a small snapshot of them listed here. We have a number of P-Four products in our pipeline. Some of them have first generics on the market potential. Some of them even have exclusive first to the market potential, while others may have shared first to the market potential. That really depends on the litigation status of our competition, as well as their launch readiness.

Now I want to talk a little bit about our growing specialty branded business. We're really excited about this business, and we see it as fitting quite well with our Generics business. I'll start off first by talking about Mitigare. Mitigare was our first foray into the branded specialty business and has really been a great success story. So we gained approval for this product in 2014. We market that with a dedicated sales force in a primary care space. And year over year, we've consistently grown prescription volume for that product. So it's really been a nice success story and a great contributor to our business. Recently, it has gotten more challenged, given that there have been generic entrants on the tablets.

So that's putting some pricing pressure on the product, so sales will decline. But it's been a great product for us and a great proof of concept of our ability to market branded products. Recently, or earlier this year, we announced a partnership with a company called Eyevance to be their exclusive commercial partner within the primary care and allergy, ear, nose, throat space. They're smaller products for us, but they're very strategic in that they're helping us leverage our primary care sales force, as well as extending into allergy, ear, nose, throat. We're bringing on other products into that allergy, ear, nose, throat space, so this is helping us to start to build those relationships. To start to generate that knowledge as we bring in more products into that space.

We also recently launched, in August, our Kloxxado nasal spray product that also is leveraging our primary care sales force. But we've also -- we're expanding our sales force to go into community health for that product in particular. And there's nice synergies with that product with our generic addiction therapy service products, which are also sold through the same community health channel. Kristy

Ronco will speak later in her presentation about these branded products as well. But I also want to mention that we're continuing to actively invest in our specialty branded business. So Ryaltris is another example. It's a partner -- a product that we partner with a company called Glenmark that's also a primary care and allergy ENT. Epinephrine we're developing internally. And that product actually is sold into all three channels that we're, we have a presence in today.

And then lastly, Bilastine is the most recent product that we have announced with a partnership with Faes. That's also a primary care and allergy, ear, nose, throat product. So we're really excited about this growing business. We see it as very synergistic with our Generics business. Most of all these products that you see here will also be manufactured in our facility in Columbus, Ohio that manufactures our generics products. And it's also supported by all the support functions that support our generics products, such as finance, HR, IT, et cetera. So working together hand in hand, our Generics and our specialty-branded business are helping to reduce the costs, overall, for the entire portfolio.

So, moving on to respiratory. Respiratory is an important part of our growth strategy, moving forward. We're really pleased to have gained approval for our generic Advair Diskus product, which we launched in April of 2021. We're steadily gaining market share for that product, so we're glad to have our first respiratory product on the market. We're also -- we've extended our collaboration with Vectura to develop AB-rated versions of GSK's Ellipta portfolio. This leverages the dry powder inhaler development expertise, all the learnings that we've gained through our experience with generic Advair, and also leverages the significant manufacturing infrastructure that we have within our operation in Columbus, Ohio.

The Ellipta franchise is a significant opportunity today, and it's expected to continue to grow quite significantly into the future.

In terms of respiratory, we're also looking at complementary initiatives. We want to leverage that significant infrastructure we have in-house with dry powder inhalers. We'd be very interested in working with partners for contract development and manufacturing opportunities. We're very interested in out-licensing our products to Ex-U.S. markets and we're very interested in in-licensing other respiratory products, even if it's not in the devices that we have in-house today.

So, my last slide, I just want to conclude a bit on our strategy. So, our strategy is really the same as it was when we talked to you three years ago.

So, we need to continue to stay focused on maintaining and enhancing our foundation. So, focusing on our cost of goods sold, our capacity utilization, our service levels -- it's at the core of what we do. We need to do that really well. We also need to continue to invest in our portfolio. We need to continue to enhance our organic R&D efforts, complement that with external initiatives, partnerships, and/or acquisitions. And lastly, we need to continue to invest in our people. Our people are our greatest asset. They are the ones who are delivering the growth that we're seeking.

So, with that being my last slide, I'm going to hand it over to Mike Balog, who is our senior vice

president of operations.

Mike Balog:
Thank you, Brian. Hello. My name is Mike Balog, senior vice president of Columbus Generics Operations, responsible for the Columbus, Ohio production facilities, as well as our U.S. distribution operation, supporting both the Generics and Injectables Divisions. I've been with Hikma for over four years now, with greater than 10 years in general manager equivalent roles, previously with Teva, and then a small start-up, Aprecia Pharmaceuticals. Prior to that, a proud military veteran. I served on nuclear submarines in the U.S. Navy.

So, from the left side of the slide, you can see the diverse technologies that we cover in our generics division, covering the full spectrum from active pharmaceutical ingredient -- API -- production at our Hikma Chemical Facility in Jordan, R&D development in both Jordan and Columbus, a wide range of solid-dosage and differentiated technologies all the way through our own distribution operation.

With approximately 95 percent of the volume in sales of the Generics division running through Columbus, let me put some focus on this location. This premier site was acquired from Boehringer Ingelheim in 2016.

I used to open discussions of this sort by saying, "A generics site like no other." While generics are still the core of our business, I probably need to alter the opening a bit, as we continue to add more specialty and branded items to our portfolio. In 2021 alone -- and Kristy will provide some greater detail -- we added generic Advair, our specialty dry powder inhaler -- DPI -- and Kloxxado, our branded Naloxone 8 milligram-unit dose nasal.

Both of these additions are direct examples of us continuing our shift to more differentiated technologies, where there are fewer competitive players. That is what this site is best suited for: hold our own on more common technologies and absorption vehicles, all the while utilizing this outstanding facility to produce smaller quantities of more unique and higher-margin technologies. Having this balance in our operation has supported this year-over-year steady improvement in margins for the Generics division since the acquisition of the site.

This approach is in direct contrast to the recent trend of much of the industry off-shoring generic production to lower-cost centers overseas. In addition to our own products, to maximize utilization of the facility, we also do some contract manufacturing for around a dozen partners. Our 1,200 employees in Columbus, across production and distribution, make this happen. I've seen many generics facilities in my pharmaceutical career. This site is, far and away, the most quality oriented and capable operation that I have seen to date. I feel very fortunate to be the steward of this tremendous asset for Hikma that we are leveraging to our strategic advantage.

Diving a little more in the specifics, the Columbus operation will approach 6 billion equivalent tablets this year, an increase from 4.5 billion at the time of the acquisition, thus continuing to

increase the utilization and efficiency of this high-capacity facility.

Obviously, we do plenty of the more routine technologies: immediate and extended-release tablets and capsules in both blistered and bottled presentations; also liquids and suspensions. But it's the differentiated technologies that truly sets this site apart. From cytotoxic and potent products to responsibly-produced controlled substances -- Schedule 2 through 5 -- to being the generics leader in nasal production, to respiratory dry powder inhalers -- to master this broad base of technologies in one campus is not typical.

With that being said, we continue to add technologies, such as equipment to support us on the second generation of DPI products. Currently, our generic Advair competes with the Diskus device. The next generation of DPI products that we have in development will be competing with the Ellipta portfolio. Additionally, hot-melt extrusion, sachet technologies give our group additional targets to develop.

I acknowledge that many make the claim that safety and quality are a top priority. I believe that our track record is impressive. On the safety front, having endured the COVID pandemic for greater than 18 months now, I would be remiss if I did not quickly address our performance in this regard. During the entirety of the pandemic, we have maintained greater than 90 percent staffing at all times, and actually increased our production output during this period. We quickly established a safe work envelope for the 700 employees that were required to be physically present to produce our needed products, including being the lead producer of a COVID front-line therapy, Dexamethasone, a corticosteroid reducing inflammation in severe COVID cases.

Obviously, it's hard to produce pharmaceutical products remotely. For the remaining employees linked to our site, we leveraged technology to support remote work schedules, keeping the overall risk the lowest possible among our entire workforce. It has been very important that we kept the envelope of our facility as safe as possible from a spreader event, especially with 700 individuals directly supporting production.

With regards to quality, I'll cover that on the next slide.

Customer service and reliability became paramount during the pandemic. We quickly increased safety stock and active ingredient inventories to our key products, continuing to qualify alternate suppliers of active ingredients -- not just for ongoing cost of goods improvements, but also for business continuity considerations. This has served us well in being able to rapidly respond with our domestic-based operation, a strategic advantage in this instance over many of our peers.

Despite the diverse technologies that we support, this is a world-class, efficient operation as well, as we measure by our key performance indicators, such as conversion costs per tablet, output per employee, and right-the-first-time metrics. We acknowledge that, with a higher U.S. base labor cost, we have to be very efficient to remain competitive. We've notably improved

our overall efficiencies over the last few years, but this is a never-ending journey in our continuous pursuit of operational excellence.

Jumping back to quality, approved by 10 international regulatory agencies around the world -- including the FDA and DEA domestically -- this site has successfully completed greater than 60 inspections over the past decade, with zero critical observations, quite the accomplishment that confirms our commitment to quality and compliance.

It should be noted that we are currently a designated training partner with the FDA, assisting them with the training of new inspectors at a non-sterile facility -- an incredible honor to be held in this high regard. Over the last two years, we've hosted close to 80 newly-qualifying field inspectors, training them on what a well-run, quality-minded, non-sterile facility looks like. They've already booked us again for 2022. We fully support this collaborative effort with the FDA.

Shifting a little bit to distribution, following the acquisition of the Columbus production facility, a new distribution center had to be established to process the higher volume of the larger organization, including Generics and Injectables. Strategically, Columbus was chosen for three reasons. First, same city as the largest facility in the network. Also located in Columbus, our purpose-built distribution center went live in 2017 and is just 20 minutes away from the operations we just discussed.

Second, central to the core population of the United States. Geographically, Columbus is within a day drive of approximately 60 percent of the U.S. population, as you can see on the graph, a smart selection for a distribution center. And, finally, proximity to key wholesalers. Amerisource Bergen, Cardinal, and McKesson represent a large portion of our distribution volume. Two of those three, Amerisource Bergen and Cardinal, have their national distribution centers within two miles of our location. The third, McKesson, is within this one-day drive in Olive Branch, Mississippi. Having these key partners very close to us has stabilized our delivery patterns and response times, improving our partnering with these groups that have resulted in improved ratings on their scorecards. For the remainder of less than a truckload in individual shipments, our geographic location keeps us timely and efficient.

Finally, let me close with a very tangible example of the great work that we do in Columbus: our recent launch in August, Kloxxado. In a very short 24 months, we went from the acquisition of this product, naloxone 8-milligram nasal spray, to the launch of this life-saving drug, adding another weapon to the battle against the devastating impact of this national opioid crisis. We are all aware of how slow this industry can move at times. In this relatively short period of time, we extracted all production and laboratory equipment out of a Texas facility, relocated, installed, and qualified this equipment for this new, challenging combination product. Similar to generic Advair combination product is a medical device combined with a drug product. We then produced registration batches, filed with the FDA, gained a first-pass approval, and now have recently launched. The Columbus team stepped up to the challenge of this project, bringing this critical drug to market produced here in Ohio, a state that has been hit especially

hard by this opioid crisis. Thank you for your attention. I will now pass to our chief commercial officer, Kristy Ronco.

Kristy Ronco:
Thanks, Mike. Such a great success. And I will certainly talk more about Kloxxado later in the deck. Hello, everyone. I'm Kristy Ronco, chief commercial officer for U.S. Generics and Hikma specialty. I also lead our shared service teams, which support our U.S. Injectable and Generic business. I come to Hikma with nearly 25 years' experience in life science across brand and generic pharmaceuticals. Prior to joining Hikma, I spent over a decade establishing and growing Zydus Pharmaceuticals in the U.S. and in various sales and marketing roles with various organizations including Teva, Sandoz, and Johnson & Johnson prior to that.

Three years ago I stood in front of you and presented at our last Capital Markets Day after less than three months with the organization. Since then, we have transformed and strengthened Hikma Generics' commercial operations and culture. To improve customer service and maximize our opportunities, we created two commercial verticals: one focused on the generics category and our key trade customers and the other focused on building and expanding our specialty brand business. The left-hand side of this slide highlights the four buying groups and their associated key stakeholders. Similar to their footprint three years ago, these buying consortium represent greater than 90 percent of the total U.S. generic purchases. The remaining 10 percent is comprised of smaller customers across various classes of trade, including regional chains, distributors, managed care, PBMs. We have strong relationships with each strategic customer and focus on individual formularies while balancing opportunity and risk across the entire market. We have created the infrastructure both internally and externally to support our growing verticals in the changing market landscape.

On the right, I have outlined our commercial structure. In addition to a dedicated sales and marketing team, we gain additional benefits from leveraging our shared services such as contract negotiations, trade operations, and market access. Generics is supported by four national account directors under the guidance and leadership of a dedicated vice president of sales. On the specialty side of the business, we have a comprehensive commercial team of more than 100 full-time employees, including a dedicated head of sales, seven regional managers, over 70 field sales representatives, government liaisons, and medical experts. We utilize call-point synergies across primary care and allergists, community health, and government to maximize our sales potential and product portfolio.

As Brian mentioned earlier, we have been focused on fixing the foundation. We continue to focus on efficiencies and operational improvements in the business. A key part of our margin expansion is our ability to drive these efficiencies and accountability in commercial strategy and operations through people, process, and systems. We have dedicated the last three years to deconstructing existing process and methodologies, challenging the status quo, and rebuilding the teams. We have established a new commercial structure and collaborative culture while elevating expectations and empowering our people. This foundational improvement has led to operational benefits that will continue to facilitate our growth and ongoing success. We have

solidified ourselves in the market, enhancing our reputation, and customer relationships. On a daily basis, it is a well-orchestrated series of events that leads to flawless execution.

As Mike mentioned, as a result of our preparation, flexibility, and process improvements, we are viewed as a trusted and reliable manufacturer. This transformation was critical during a volatile time for our industry, and we continue to challenge ourselves to think outside the box and ensure patient needs are met. As Mike mentioned earlier, safety and quality are our top priority, and we uphold the highest quality standards while executing year-over-year COGS improvement, contributing to our product sustainability. Our investment in systems and people will carry forward and support our strategic growth initiatives. I feel strongly that we have a firm foundation and an infrastructure to support our growth potential and deliver strong results. The work that we have done was critical to our launch success in '20 and 2021.

Now, I would like to share a few examples of the strength of our team and our ability to execute and capture market opportunities. As you heard earlier, we are investing in an expanding respiratory pipeline and other products which maximize our manufacturing capabilities and technology. Examples of key products falling into these categories are everolimus, icosapent, and fluticasone salmeterol, better known as generic Advair. Everolimus, specifically generic Zortress, has been an important product for us. Generic Zortress is a paragraph IV success and highlights the importance of being first to market with seamless execution. As an unexpected exclusive supplier, we utilize our core competencies to meet the market needs.

Next, icosapent. Icosapent demonstrates the team's litigation capabilities and strength of our procurement teams. Icosapent is differentiated based on API sourcing complexities and limitations. We continue to work on our supply of API while delivering on our 2021 commitments to our customers. We do have a multipronged approach, leaving no stone unturned, and are working diligently and aggressively to increase access to additional API and finished goods. Third, our strategic alliance -- through our strategic alliance with Vectura, we successfully launched generic Advair in April of this year. This critical product demonstrates our R&D strength and is the foundation of our future respiratory franchise. Although slow to start, we are gaining momentum and beginning to see consistent customer pull-through from our secured customer base.

Another differentiated product and the genesis of our community health platform is Kloxxado, our branded 8-milligram naloxone. Kloxxado is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose and is intended for immediate administration as emergency therapy in settings where opioids may be present. Kloxxado is a lifeline to support ongoing treatment and recovery through risk of relapse. Our community health organization focuses on education and support while providing a holistic approach to this -- to this crisis. The statistics are astonishing. As you can see here, in 2020 more than 93,000 Americans died from a known drug overdose. This is an increase of 32 percent from 2019. Most opioid overdose deaths are attributed to fentanyl, fentanyl derivatives, or synthetic opioids.

In 2015, synthetic opioids were only involved in 18 percent of all overdose death, however fast forward to 2020 and it appears this number grew to more than 60 percent. Because of this, more than 30 percent of opioid reversals involved two or more doses of four milligram intranasal Naloxone, creating a national need for this product. It is imperative that we meet the growing necessity and provide an important new treatment option in addressing the opioid epidemic.

We are in a unique position to leverage the synergies between our generic and specialty portfolio and bridge rescue to recovery while meeting a critical need and combating opioid overdose. As outlined earlier, our dedicated community health team is focused on national distribution and awareness of this lifesaving product, and other substance use disorder treatments, both in the private and public sector. Kloxxado is the first naloxone spray to offer a savings card and bring value-based pricing and copay assistance to consumers. We have received positive feedback from advocacy groups, physicians, and pharmacists, and will continue to do our part to address this epidemic. With that, let me hand it back to Brian.

Brian Hoffmann:
Thank you, Kristy, and thank you, Mike. So, I'd like to conclude on a little bit on our strategy as well as our priorities before we then open it up for Q and A. So, first with our strategy, in terms of operations, we're focused on the highest quality standards and best in class operations. As Kristy highlighted about our commercial organization, we're focused on excellent execution, partnering with our customers, and delivering the best service levels in the industry. We're continually focused on adding and enhancing our pipeline through both our organic efforts and our inorganic. We're focused on specialty and differentiated generics, as well as niche brands, and we're also interested when developing our pipeline, with external inorganic efforts as well.

Our people are so important to us, it's so important to develop and retain the best talent in the industry, that's who's really going to drive us forward. In terms of our priorities, we have very clear priorities. We want to continue year over year, top- and bottom-line growth. In order to achieve that, we need to consistently deliver 10 percent of our revenue every year from new -- for new launches, and we're also striking a balance between solidifying and maintaining a growing base generics business with a growing specialty business. So, with that, we'll conclude and start the Q and A session.

Operator:
Okay, and now we can start the Q and A session, so if you have a question, please use the raise your hand option at the bottom of your screen. Or if you'd like to pop in your question in the Q and A panel also at the bottom of your screen, please go ahead and I can read out your question to the team. And with that, we have our first question, from Pete Verdault. Pete, please go ahead and ask your question.

Pete Verdault:
Yeah, thanks everyone. Pete Verdault here from Citi. Thanks for the presentation. Three

questions, two are very quick, one's a bit more general. Brian, just on slide 10, the pipeline slide, appreciate it's very difficult to give any sort of granularity, but appreciate you trying. Just in terms of the comments you made about first to market, or where you could have exclusivity, can we -- could I just ask you to tease out which products they were. Question number two, the Bilastine deal looks very interesting. Just timelines as to what might be the earliest you get to market there.

And then one maybe for Siggi, conceptually about next year, when we think about U.S. generics, or Brian, for that matter. You know, we've got a four-year contribution and hopefully a big step up in Advair, but all the investments to support your specialty strategy, we've got a likely Xyrem windfall, given your exclusivity and you've got your ongoing R&D commitment. I mean, if we put that all together and you execute, it just seems inconceivable to us that there won't be a large step up in profitability. So, I realize this is not the forum for giving 2022 guidance but at least let us know where we're thinking about 2022 correctly or incorrectly. So, there are my three questions, thank you.

Brian Hoffmann:
All right, thanks Peter. You cut out a little bit on your first question, I got the other -- the other two.
Pete Verdault:
I'm glad -- I'm glad you didn't cut out on the last question, because I think I'd be boring everyone on the call.

[laughter]

Okay, the first -- the first question, simply you talked about the pipeline, you talked about some where you had first or exclusive to market.

Brian Hoffmann:
Right, okay. I got it.

Pete Verdault:
Can you tease out what those products were?

Brian Hoffmann:
Okay. Well, first, Pete, thanks for joining and great questions. I'll start off and if -- Siggi, if you'd like to jump in on the last one, please feel free.

So, first about the pipeline. You know, as I mentioned in the presentations, and always are -- it's always our greatest challenge of giving you that visibility, talking about it, without disclosing competitively sensitive information. Though I can't disclose which exact products on that list are exclusive, and which ones aren't, some of it depends on litigation, some also depends on whether our competitors are ready to come to the market or not. So, I can't comment that -- on that specifically.

With regards to Bilastine, we're really excited about that partnership, we're really excited about that product opportunity. So, it's very early days, we just announced that the partnership early this week. We've had very good discussions with Faes through diligence about how that product has been performing in international markets, so it's improved in over 100 different countries and some countries it's number one or number two, second generation antihistamine. So, markets such as Japan, Canada, France, and Spain, the product is doing very well. And so, we're excited now that we've concluded the agreement. We'll work collaboratively with Faes and with the FDA to get that approved as soon as possible. We have a lot of data that we can leverage through their experience with other markets, and we'll get that on the market as soon as we can. We can't communicate timing at this point.

Pete Verdault:
Fair enough, thank you.

Siggi Olafsson:
So, maybe I jump in on the growth in 2022, and yes, Pete, as you rightly said, we can't guide you, we will guide you in February like we do every year. But let me be clear that this team has done amazing things and how I think about it, without giving you any details, there're like four building blocks to Generics you need to think about next year, and how that goes in and out. First of all, it's the base business, and the base business we have -- we have approximately 90 products on the market. Depending on the price erosion, competition, challenges to our products where we have a -- you know, maybe a good position today, that depends on how the base business will do, like every year. This is the same story; we look at the base business and evaluate that.

The second items are the new product launches, and we don't know exactly today, it's a bit too early to say we haven't guided on generic Xyrem , I know Jazz has commented on that. But those kinds of things we need to look into and the rest of the pipeline, what will come through on the generic pipeline. On our -- I think I call it, like, the specialty generics, which is the -- maybe generic Advair and Icosapent, generic Advair, we are excited about the opportunity, but also keep in mind that there might be others, that two other companies that have filed, but we're excited about the growth of the business and the markets here we are getting today. But we probably know more the closer we get to the end, and on Icosapent, we are very excited. As Kristy mentioned, we are leaving no stone unturned to increase the supply of this product, we have to see how that will go into next year.

And the last piece of this, the fourth building block to this business, is the specialty business, Kloxxado launched in August. It's too early to say how big that product will be as both Kristy and Brian mentioned, that's been a really good feedback from the doctors and the community about this product, the need for this product. But that has to be turned into prescriptions. So, I feel we have a growing business, no doubt in my mind, but how it will grow, I think we have to wait for the February guidance to get there. But really, a strong business, growing business, and this team has executed flawlessly over the last four or five years.

Pete Verdault:
Thank you.

Operator:
All right. Next question is from James Vane-Tempest [spelled phonetically]. James, please go ahead and ask your question.

James Vane-Tempest:
Hi. Good afternoon, James Vane-Tempest from Jefferies. Thanks for taking my questions. Three if I can, please. There's a helpful slide up front, talking about the changes which were made from 2018 to where we are today. So, I remember when you took over, you sort of were saying doing judge me over what I do for the next couple of years, let me make the changes and then the business will be in a position to grow forward. Just wondering if you can sort of remind us some of the key hires which you've made over the past years, and what changes, you know, have been made to put the business on a much more sustainable footing going forward? My second question is -- I think the first half results -- I sort of wondered by the time we get to this point in the year, whether you'd have enough visibility on pricing between now and the end of the year. Because I know you've reiterated the five to seven percent pricing. What you're seeing in your business between now and year end? And also, visibility on Xyrem into next year; whether that could be first half or second half or if you can comment on 22 at all. And then, my final question is, you talk about maintaining the generics business with the growing specialty business. Just to give us a feel if, you know, the pipeline opportunities come through as they could do. What proportion of the business do you think could be the specialty products in five years? Thank you.

Siggi Olafsson:
Maybe I'll kick it off, and then I'll hand it over to Brian on the changes. Really what the transformation of the generic business has been the execution of the team. As Brian highlighted, we simplified the organization. Many of the team members on with you today have been relatively short with the company. Great experience. Kristy joined just before we had our meeting in 2018. She has brought a great team. Mike, the same. He joined in 2017. So, it's a relatively young and energetic team that has done amazing things. In a way, it's gone further than I excepted, James, when we met in 2018. I had just joined. But maybe one way of thinking about it would be to think about the gross margin. How we changed that from 36 percent, which we had in 2017, into the mid to high forties that we delivered midyear. Maybe Mike, you could go a little bit through that. What you have seen as the transformation, and what has played into the transformation of the gross margin?

Mike Balog:
Thanks, Siggi. You know, I think there's several significant levers that we've executed over these few years. The first one, obviously, was consolidation. I think taking the Eatontown facility and making a smooth transition into Columbus and Jordan and doing that efficiently as Brian described. That was a big lever. Ongoing alternate API programs. We know that that's

necessary to continue to improve our cost profile. Obviously, we made headcount adjustments. Right-sizing the operation relative to the work that we needed to do. We're a dogged pursuer of operational excellence. That's built into our program and everything that we do. Those are probably the bigger ones that have improved the margins as you describe, over the last few years.

Siggi Olafsson:
Maybe, Brian, if you pick up the other questions.

Brian Hoffmann:
Yeah, sure. I'm happy to pick up the other questions as well, so. I think the next question was around pricing. So, we -- I'm sorry?

James Vane-Tempest:
Yes, yeah. Pricing and Xyrem. So, time for next year.

Brian Hoffmann:
Pricing and Xyrem. So, you know, pricing, we -- last year, I think we guided toward mid-single digits. This year, we're seeing slightly higher price erosion on, you know, higher mid to single digits this year. I think, certainly, last year during the pandemic, there was a lot more focus on supply continuity, given the challenges with the pandemic for manufacturers to respond to. So, now there's been a little bit more pricing activity and more activity from our customers. So, we're seeing slightly higher pricing erosion this year. And in terms of Xyrem, you know, we have a settlement agreement with Jazz. We have a date certain launch of January 1st, 2023. However, we do have accelerators, if the market shifts. So, I think we're watching that carefully. We're watching the growth of Xywav. You know, there's a possibility that our launch could be accelerated into 2022. And with that being said, I'll just say that if it does, you know, we'll be ready.

So, we don't know exactly when or if we could get accelerated, but we'll be ready with supply on an AG to go into the marketplace. I guess, you know, I'll just also add to Siggi's comments about changes to the organization. You know, certainly some of the bigger changes with manufacturing and distribution consolidation; we achieved a significant reduction in our overhead costs. But we also brought in, you know, new talent throughout the organization, to help us get to the next level. And I think I'd like to give Kristy the opportunity to talk to some of the changes that we've made commercially as well.

Kristy Ronco:
Sure. Absolutely, thanks, Brian. We have made a tremendous amount of changes over the last three years. Initially, came on board and took the moment to kind of assess and see how the business was functioning. And where there were some gaps. And so, through some commercial changes, internally and externally, with the sales teams, we, like I said, laid out those verticals. We have a new head of sales on the generic side of the business, and a team that has a broad-based experience, both on the wholesale and retail side of the business.

They've sat on the manufacturing side, as well as the customer side, and have a really great understanding of what our customer needs.

Internally, we've had a dedicated focus on every area, from order to cash, to revenue management, forecasting allocation, offer development, contracts, etcetera. So, our operational efficiencies are key, and we rebuilt the organization in those key areas.

Siggi Olafsson:
That last question, James, was about the ratio between generics and specialty. It's, like, you can't ask me which of my kids I love more. You know, we love them both a lot. I think as you saw from the pipeline on the specialty, there are exciting products in the pipeline. But, if and when they come to market, we are excited about those opportunities. But obviously, it's a little bit more long-term. So, in the meantime, we continue to grow our generic business. That's really good. But also, with Bilastine that we signed this week, the opportunity of Epinephrine nasal spray and Ryaltris coming to the market, hopefully next year, as Brian mentioned. I think the proportional growth on the specialty side could be very good over the next few years.

So, we are excited about both parts of the business. We want to continue to grow both of them. But by having two business, this derisks the business. And this is the point I wanted to make. So, I'm sure there will be more questions about price erosion. But even when we come to a serious -- if there would be a really bad year, in terms of price erosion going forward, we would see something we saw in 2016, and 2017. We are better prepared today, both with the infrastructure, the cost of goods, and the manufacturing that we are doing with Mike and the team in Columbus. But also, in point of having more in the specialty which is not affected to the same amount. So, by building up the two businesses, that helps us, even if we see a tough year in the generic pricing environment. So, that's the reason why we want to continue on both tracks to grow the business.

James Vane-Tempest:
That's great, thank you.

Operator:
Our next question is from Jo Walton. Jo, please go ahead and ask your question.

Jo Walton:
Thank you. Just a few please. Firstly, can you tell us a little bit about the barriers to generic Advair adoption? Like, when you have a traditional pharmaceutical simple tablet, you get a very quick switch to generics. These more complex devices appear to have much greater patient loyalty, or payer loyalty. Do you think -- well, what's the barrier to you getting even faster adoption of your generic advair? Which, having seen the video, you know, looks almost identical to the originator product. So, I'm just looking at the barriers there. And if you could talk about, perhaps more generally, on the Ellipta portfolio, when you think the first product could roll off the line for you? And we just knew how long it took from the end of the traditional portfolio to when we had generics. I'm assuming that it's going to be faster when

you have the Ellipta.

My second question would be, going back to the importance of having product being made onshore in the U.S. Whether that's -- you know, we've talked about some of the really tough times when you had lots of price erosion. Is now a good time, where people are very keen to source from you, because you're one of the few people who are able to source from the U.S.? Just wondering how important that is. What extra capacity you might have to do, contract manufacturing or whatever, to take advantage of this? We want to have stuff bought locally. And my final question, just to understand your Kloxxado product. You talked about having copay cards there. Do people -- I'm obviously not understanding this at all. I can't imagine an addict thinking they might take an overdose, and buying one of these, and using a copay card. So, can you just explain who the people are? And, you know, how you do the contracting around that product, please? Thank you.

Brian Hoffman:
Okay, thanks, Jo, great question. So I'm going to start off addressing Ellipta. Michael, I'll ask you to also talk about our U.S. manufacturing base, and Kristy, I'll ask you to also to talk about GxA adoption and Kloxxado. So first on Ellipta. We're excited to work on these products with our partner, Vectura. We think we've gained a lot of experience through our generic Advair experience, which will certainly help us with Ellipta as well as our in-house infrastructure. We have the manufacturing technology set up in Columbus, so we feel that with the experience we have that we can move quicker. But these are very challenging products to develop. Their complex drug and device combinations. They also require clinical studies. So it will take us some time to bring the first one to market. We're not yet ready to guide timing for our first Ellipta products, but we do think we can leverage our experience to be quicker this time around.

Siggi Olafsson:
And maybe on that, Brian, we could mention here that, you know, if you look into the Orange Book -- this is just general, I'm not guiding you when it comes, but the first Orange Book patent expire in 2027. So there is still significant time until we see the first Orange Book patent expiry on the Ellipta portfolio. But there are the patents, of course, that need to be overcome to bring these products to the market. But just so you have a little bit of concept of the timing until Ellipta comes. Sorry, Brian.

Brian Hoffmann:
No, that's a great point. There's patent challenges as well. So why don't we -- since we're speaking about respiratory, why don't we turn to generic Advair. As you may have seen, 50 percent of the market is still with the brand and they're aggressively defending that. So that is a challenge that as a generic we need to overcome. So why don't I hand it over to you, Kristy to talk about generic Advair and then Kloxxado.

Kristy Ronco:
Sure. As you said, Brian, 50 percent of the market still remains with the brand. And a lot of our

opportunity depends on how GSK does in the market. However, we did launch in April. We have had successful customer negotiations. We have had some right of first refusals that have definitely fallen our way. We secured a strategic base across multiple classes of trade. So we're diversified in our customer base. It has been slow. We are seeing the lag in IQVIA. That's for many reasons. As you said, there is a slower brand to generic conversion. It is not the same as a standard multi source generic -- that is for many reasons, including some GSK strategies that we're seeing but not privy to, obviously. And we're taking generic market share and growing over the course of the rest of this year. And we feel that we'll be in a good position in Q1 of '22 with a stable share on Advair, generic Advair. We did see some larger buy ins. Just as a footnote, we did see some larger by ins of the incumbent product and that product and material had to be depleted before our formulary positions were firmed up. And we were seeing the dispense that was equal to the stocking. And we're starting to see that now.

Mike Balog:
Kristy, I don't know if you want to cover the Kloxxado copay card and then I'll get into the U.S. based operations.

Kristy Ronco:
You got it. Yeah. So that's a great question. And we certainly understand that there are many individuals that we are speaking to that should carry Kloxxado, right. So the family, the caregivers, the mom, dad, the spouse, those are the individuals that certainly should have Kloxxado on hand and the copay would be there for their support. In addition to those that are a known abuser, it's those individuals that are receiving opioids from their physician. And we're looking at co-prescribing those individuals that are receiving opioids that have a known respiratory issue. Those are the individuals that should be carrying Kloxxado. And the copay is there for them to have a support in order to kind of facilitate that co-prescribing and dispensing of Kloxxado.

Mike Balog:
Let me cover the U.S. based operation for a little bit. There are many layers to this. I touched on a little bit, the dexamethasone. We were the leading producer dexamethasone before COVID hit. When the U.K. study was published sometime mid last year we were able to immediately respond. I mean, the business went up by multiples and our ability to deliver on short notice to this immediate need, directly helping on the COVID front is a testament to the benefit of the U.S. based operation. But I would say even beyond the COVID specifics, and obviously I won't go into that -- our injectables division, our portfolio supported COVID significantly. We have greater than 90 products in our Generics portfolio. And many of those did experience upsets because there's longer shipment time. I think the workforce disruptions overseas were greater, et cetera. Combine that with the close proximity to the large wholesalers. When they had a need, we were able to respond quickly. And I do think many of our buyers are leaning a little bit more towards the quality, reliability of supply versus the unbelievable forces that were just driving prices down. Price is always going to be important. I talk about us needing to be efficient and competitive, but I do think reliability of supply is favoring us more than previously.

Brian Hoffmann:
And I think I'll build on what Mike said and in terms of, you know, U.S. government opportunities and our CMO opportunities. So, you know, we're in a nice position in terms of our capacity utilization in Columbus, where we're about 65 to 70 percent utilized. But if there is more of an opportunity, we can certainly respond. So if there's a concerted effort from the U.S. government to buy more from U.S. manufacturing sites, you know, we have the ability to scale up and meet that demand. And I'll also say from a branded CMO perspective, we have gotten more inquiries and more activity from branding companies of finding a U.S. based CMO partner. And we welcome those opportunities. We have the capacity to take that on. And that's very healthy business for us from a margin standpoint.

Operator:
Our next question is from Max Hermann. Max, please go ahead and ask your question.

Max Hermann:
All right, thanks very much. I've got just a couple of questions you might have been asked already. So one was just, I think, during the presentation you made quite significant comments about the views of the market on Hikma and how that had changed over the last few years. And obviously, your scale has changed dramatically since the Roxane acquisition. So I wonder what sort of measures you're taking on that and some examples of how that has maybe positively impacted the business. And then secondly, just on Bilastine -- kind of interested in the second generation antihistamines. I wondered how you see the differential of that product coming to market in the U.S. with obviously the historical Zyrtecs and such in the market.

Siggi Olafsson:
So maybe I'll jump in, Brian, on the view of Hikma and our positioning, I think, Max, we are in a totally different situation than four years ago, both on our Injectable business where we, by the way, in the latest IQVIA, we are now the second biggest injectable company in the U.S. by volume; we just overtook Fresenius in terms of volume, but also on our Generics side. And to become a top 10 company is something that when Westward was, a few years back with $100 million business, was not in sight. So I think that changed. But really what changed in my mind, and you know what Kristy was explaining is the perception of Hikma as a reliable and a high-quality company. We have always had high quality, but sometimes service level, when we didn't have the plant in Columbus, when we didn't have transformed -- when we hadn't moved the products over there, when we didn't have the focus on all these issues, our scorecards from our customers were not always great. And over the last, especially last two years, this has improved significantly for us. So the reputation this team has built is outstanding in terms of that. I always say to people, you know, that's the reputation today. You cannot make a mistake tomorrow because it's only worth what you do. You build up your reputation. And if you take a misstep that can affect you, of course, going forward. This is why we are emphasizing the quality, the service level on this team is outstanding in that: in manufacturing, in the customer service, in the relationship with the customers, how we can help them. I think that's really the perception that Hikma has built also both on the U.S. Generic and on the

Injectable side. Brian, sorry

Brian Hoffmann:
No, thanks very much for that, Siggi. I think that's spot on. I just add a couple quick points. I think first, in terms of customers, our reputation certainly has increased. And where that's helpful is our customers will go to us if they're looking for supply on a certain product or we're bidding on an RFP, they have greater reliability on us. So that's really important for us. It's really the foundation for us to work with our customers and grow our business. And then I'll also say from an external partnership standpoint, now that we have a much larger business, we're seen as a much more significant business. And potential partners have seen what we can do, how we can execute on both the generic as well as the specialty brand front. We're seeing more inbound inquiries, more opportunities are being presented to us. So that's exciting from a partnership standpoint as well. I think your second question was around Bilastine and it's early stages here to go into details about our marketing strategy. But I'll make a couple of quick comments. Then, Kristy, if you want to add to it. You know, we think the product has performed very well on a number of international markets. It does have some unique characteristics that we think that will help us with selling the product. So we're really excited to have it in our portfolio. Kristy, do you want to make some additional comments?

Kristy Ronco:
Yeah, just to talk about customer relationships and reputation. So I was able to understand a bit about Hikma's reputation as a competitor before I joined, obviously, and getting the feedback today from our customers and how that has changed. And it is not necessarily how you perform when everything goes right. The customers care about what kind of partner you are and how you perform when things are not going right, right. In the -- during the pandemic and COVID, the feedback that I received is you guys came through when you were concerned you were transparent, you gave us notice, you delivered more times than not, and you can be counted on. That puts us in a different perspective. And we're in a different box than maybe where we were four or five years ago. The communication, the collaboration with the customer is definitely something that we do more of today. And sometimes we do have to deliver bad news. It's making sure that we are transparent and working with them so that we then become that reliable supplier. And I think that's significantly different than maybe where we were several years back. And we're seeing that in the scorecards, not only on time, in full scorecards, but how you hit every other area. Our customers are watching every move we make, right. Are they getting enough notice? Are we being transparent? Do we have enough touch points? Those are the areas that they're looking at and we are delivering and we're taking their feedback to heart and we're trying to improve every day.

Max Hermann:
Thanks, guys.

Operator:
We have time for one more question. We have Rosie, who has a question. Rosie, please go ahead and ask your question.

Rosie Turner:
Good afternoon. Thank you very much for taking my question. I actually had two. Firstly, just to follow up on Jo's question on Kloxxado. Who are the majority of contracts with those? Is it with the ambulance companies, with specific doctors? How does that work? And we have discussed it before, but it would be good just to get a bit more detail there. And then secondly, on the Vascepa you obviously discussed the kind of API issues. Just wondering if you're seeing any impacts of Dr. Reddy's coming to the market yet. And also, I think HSS has announced -- HHS has announced some additional funding for API. And I think it was more kind of new policy just in the last couple of weeks or so. I'm just wondering if that is actually having any impact or if we're still to see any positives coming from that. Thank you.

Brian Hoffmann:
Thank you, Rosie. So why don't I first start off with generic icosapent. Dr. Reddy's has launched. I think they've communicated externally that they've launched in somewhat limited supply. So we haven't yet seen any significant impact from Dr. Reddy's launch in terms of what we're doing, we're trying to continue to gain additional supply. Our market share is increasing over time, and that's really what we're focused on. In terms of Kloxxado, you're absolutely right, Rosie. There's a retail component as well as there is a community health component. So it is unique in that way. And that's why we're expanding our sales force to help us in that community health space. And maybe, Kristy, if I can hand it over to you to talk a little bit more about how we're how we're growing that part of our infrastructure.

Kristy Ronco:
Sure, absolutely. As you said, Brian, we established a dedicated sales force for Kloxxado under the community health umbrella. And that existing sales force is focused on calling on the retail sector or primary care physicians. We are looking at high prescribers of opioids, of naloxone and other addiction medicine. So that is how we've dedicated that branch of the sales team. And then second, we do have a focus in the government area. And as you stated, the city and state buy in, we are working with each state and each group right now to see where we fit in for their '22 budgets. They're making decisions today that would impact those programs in 2022. And we have a seat at the table and we're pretty excited about being able to come through and partner with these city and state groups, whether it be the EMS, police, fire and other organizations that are in the public sector.

Brian Hoffmann:
And I think your third question, Rosie, around U.S. based API. I think the, you know, the pandemic is certainly put a spotlight on the supply chain and particularly API and our reliance on ex-U.S. markets, including India and China. So there could be policies coming out of the U.S. government, HHS and other arms about encouraging manufacturers to supply API from the U.S. We're not a big API supplier today. That's not a big part of our strategy to do that. However, we would welcome the presence of more API suppliers for us to work with for our finished goods. So that's probably more the opportunity for us than us going into and being a significant API manufacturer.

Rosie Turner:
Great, thank you very much. Thank you, Brian. Thank you, Kristy.

Siggi Olafsson:
So I think the time is up. Seventy five minutes are up. So I just want to thank you all for joining us today and listening to all the three of our Meet the Management events that have been held over the last six months. We really hope these sessions have been helpful in a way to understand more about the businesses and seeing also the leadership behind each of the three businesses. We, of course, will continue, in some way or form, and we will update you in the near term what we will do in in 2022. So have a good rest of the day and I hope to see you face to face soon. Thanks a lot.

Kristy Ronco:
Thank you.

Brian Hoffmann:
Thanks, everyone.

[end of transcript]