Ipsen CEO David Loew on M&A, Rare Disease Expansion, Niche Oncology Focus & More

To be good in specialty care it is clear that the key is products, products and products!

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In a wide-ranging and exclusive interview with PharmaBoardroom, Ipsen CEO David Loew looks back on an atypical first 100 days at the helm of the iconic French mid-cap; its EUR 3 billion war chest for bolt-on acquisitions; planned expansions in rare- and ultra-rare diseases; and the niche oncology segments where Ipsen can achieve success. Loew also outlines the cultural transformation underway within Ipsen and makes a clarion call for greater collaboration across the industry to solve the most challenging global healthcare problems.

David, you left behind a very important role in big pharma, with everything this implies, to lead Ipsen. Why?

To be frank, I simply could not refuse taking on the CEO position, which was very interesting, especially for a midsized company like Ipsen, which is well-established, has great medicines that have endured over time, and has delivered great performance over the last few years in terms of growth. That means that there is a solid basis to build on and to make the company even more successful over the coming years, along with a desire to make acquisitions and/or licensing deals to continue to foster the pipeline.

David Loew, CEO Ipsen from Pharma Boardroom on Vimeo.

We also have a strong development organization that we can build on. We have defined a model more focused on external innovation, so we have a small and focused research base inhouse and the idea is to invest a lot in external innovation.

Ipsen is an extremely passionate organization with very high engagement of its employees and very strong purpose orientation. I absolutely love that. It is in the DNA of the people. They come to work every day and they want to make a difference for patients. We have great products that are very differentiated, serving very important conditions – often with niche patient populations.

New leaders often view the first hundred days as critical, but your first hundred days have been very atypical! What could and what could you not do when you started in July because of the COVID-19 pandemic? How did you begin your journey?

COVID-19 was undoubtedly a huge challenge; it completely changed the way I had to onboard because I could not fully connect with people in the organization. I am not just speaking about official meetings but also those informal chats with people in the corridors or next to the coffee machine. I could only travel within France, so I could not visit any of our other affiliates in person. We came up with some innovative solutions, for instance, like having a robot drive through our labs in the UK so that I could actually ‘travel’ through our UK labs and meet people that way!

The good thing is that COVID taught us that flying around the world at a crazy pace all the time is probably not the right thing to do. We could gain in productivity by having more digital interactions. For instance, I still have not met several members of our executive leadership team, however, we have managed to develop the trust and bond needed to succeed together. We redefined the whole strategy for Ipsen through video conferencing, which was a little awkward at first but also shows that we could do so much more digitally than we previously thought.

It allowed us to identify and prioritize the things we have to work on. For example, we potentially have some challenges now because of the potential pressure from generics. We also need to keep on improving our external innovation strategy in terms of attracting more new molecular entities across the pipeline. I think we will have to also upscale certain practices in terms of building capabilities and becoming best-in-class in our processes so that we can continue to be successful in the future.

Many pharma companies have been talking about digitalization for years now but throughout COVID, they faced the reality that their digital infrastructure and digital readiness to serve stakeholders was not up to standard. How do you evaluate Ipsen's current digital capabilities?

I see several aspects. The first is that internally, video conference and other communication tools have worked perfectly well. Our IT systems have been very stable despite the fact that everyone in the company is now using them simultaneously, which deserves some kudos.

The second aspect relates to our external interactions. That has been a big surprise for us, because, for instance, there are major providers of customer relationship management tools for healthcare practitioners (HCPs) and hospitals where everything can be linked, and it is supposed to be a seamless system, but during COVID, we found out that HCPs were not actually using these systems because there are speed deficits in different parts of the hospitals and doctors cannot go back to their offices just to link up for video conferences. Effectively, HCPs were relying on standard tools like WhatsApp or FaceTime or email to communicate. The digital transformation is much more pragmatic, in that sense.

The last is separate from COVID and it relates to the leveraging of technology like AI or machine learning to analyze the data that we have and to improve our R&D and manufacturing processes, like for Manufacturing 4.0, and so on. At Ipsen, we are working on these areas and I am excited to do this with the team.

At your recent Capital Markets Day investor presentation, you sent a clear message that Ipsen is reinforcing its specialty care positioning with a focus on oncology, rare diseases, and neuroscience. What are the key ingredients for the success of this strategy?

In my view, to be good in specialty care it is clear that the key is products, products and products! You need to have a portfolio with great assets. We have to really be the best at making the most out of the products we currently have on the market. We have shown that we can be very competitive; for instance, we have number one positions in several areas where we are active.

Somatuline® is number one in most markets, even when we are in competition against Big Pharma like Novartis. I think Ipsen probably has not made enough noise about the success of our products, which really has been fairly impressive.

But there is still much more that what we can do. With a really differentiated product like Dysport®, which is indicated for the treatment of spasticity, we can also focus on growing the market. Currently, only 20 percent of those patients actually receive a neurotoxin treatment. That is a disaster for the other 80 percent because now they are at home but cannot move correctly because their brains are sending the wrong signals to their muscles. This impedes their daily lives and it is very painful. We have to play a role so that more patients can receive this treatment. If we talk about patient-centricity, it is not just about empathizing with patients but to actually generate deep insights about the patient journey. Where are these patients getting lost within the system? Why are they not taken care of as they should be? Then we need to work with stakeholders to find and deploy solutions to ensure that these 80 percent of patients receive the treatments they need. This helps the patients and the healthcare system.

We need to also build a sustainable long-term pipeline and that means we want to accelerate our internal pipeline development, for instance, with assets like long-acting neurotoxins or pain compounds. At the same time, we want to become even better at external innovation, which means licensing in more products of high quality. We need to learn from our experiences to structure deals differently for success.

The third consideration is that we are entering a period where we might not experience the same exponential growth we have had for several years. We will still grow, of course, but this means we have to become more disciplined at focusing our resources and spending. We need to find efficiencies that will allow us to invest more in our pipeline and to launch new assets like Cabometyx® in promising indications.

Fourthly, we also want to boost our culture of collaboration and excellence. For instance, this means establishing global brand or core asset teams. These are best-in-class behaviors within the industry. That is something that we are currently changing within Ipsen. We have started to implement core asset teams where the team leader is the CEO of that brand, and they are backed by a highly empowered team that will consider the entire lifecycle management of the drug and develop proposals on investments for new indications.

This also means that we have to be extremely open to collective intelligence, to learning from each other. I often say to people, if only Ipsen knows what *Ipsen* knows, we will all be much smarter –

because someone somewhere in the organization has the knowledge we need but we do not always find that person in time. We need to lift these people up and help them disseminate the knowledge and share these best practices. We have actually embarked on a collective intelligence exercise within medical affairs, and we will also start a new one within global brand management.

Oncology, one of Ipsen's priority areas, is extremely competitive, with some segments starting to be overcrowded. How do you define Ipsen's value proposition in this segment, for payers and for patients?

I do not necessarily agree that all areas in oncology are overcrowded. Where Ipsen has been laser-focused are segments where we know we can be successful. We want to be focused on niche tumors and, if we go into larger tumors like breast cancer or lung cancer, we want to have clear biomarker-driven hypotheses that represent between one to five percent of patients. We are not talking about, say, HER2-positivity, which is around 15 to 20 percent in some cancers. We are looking at one to five percent prevalence, and the reason is that that roughly equates to peak drug sales of between USD 300-800 million, which is typically the territory of a midsized company, not a large multinational (MNC). Big MNCs are looking for targets that hit broadly across many cancer types to develop potential blockbusters, that is their model. Our model is to find our niches and be very active and successful in there.

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In these spaces, there are also not that many truly globally active competitors. Sure, almost every Big Pharma MNC is in oncology but that is not the case for midsized companies. If we stop hunting in the same woods as the large MNCs, we actually see a lot less competition.

What about rare diseases, another priority area, how do you evaluate the challenges and opportunities here, especially in terms of liaising with regulators and HTA bodies?

We want to expand indeed in rare and ultra-rare diseases. The question I have in my head now – because Ipsen is aiming to launch a drug for an ultrarare disease very soon, which has perhaps

9,000 patients across the world and only around 1,000 identified patients in Western markets – relates to ultrarare diseases and their therapies. Pricing is important here because if companies cannot receive good prices for ultrarare indications, they do not have the incentive to develop solutions for ultrarare indications. The mathematics are very simple: the fewer the patients, the higher the price because the costs for infrastructure, R&D, logistics, etc. remain. Companies need to be able to square the numbers.

Some payers may say, look, ultrarare diseases are just not a priority. But I think as a society we will eventually have to have very difficult discussions about the ethics surrounding the allocation of resources. Children with genetic diseases are born with those through no fault of their own. Can we say to them, 'well, there are only very few of you so it is difficult to pay for your treatment because it is so expensive'? This is a conversation to be had as a society.

You also highlighted Ipsen's need to improve the structuring and execution of its external/open innovation deals. What are some of the key principles that you have in mind?

Very simply, we have to be careful how we evaluate the business cases of these external innovations and should not place too much money upfront at risk. Drug development is very tricky and so much can go wrong. Ideally, we want to structure deals so that we pay a certain amount upfront and then pay for subsequent milestones achieved. That seems evident but it also relates to the assessment of potential assets.

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Ipsen is going to look more at in-licensing opportunities in the future, instead of acquisitions where we have to pay much more upfront. We are looking at in-licensing opportunities across the entire pipeline and across all our key therapeutic areas. We want to look at some Phase II and III assets to launch in the US, and we also want to look at pre-clinical Phase I and II early-stage assets globally.

We expect to continue to build up great firepower – EUR 3 billion – as we are generating a good amount of cash so we are able to do these bolt-on in-licensing deals. But it is also important to be very disciplined in such searches. There is an abundance of opportunity in the global scientific hubs

in, say, Boston and San Francisco, certainly, but there is also great science across Europe and also in China.

In addition, there are many biotechs, for instance, that thought they could launch their products themselves but then experienced challenges during the commercial stage. At that point, I think they understand the importance of having the right capabilities and experience in global development and commercialization that companies like Ipsen can provide. It is very difficult for a one-drug company to build a commercial organization and to hire talent. We are speaking to a few companies like that right now regarding co-promotion deals, which is another way to do external innovation.

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Of course, as a midsized company as well, we are able to dedicate the A-team to the assets we in-license. Big MNCs often cannot and will not do that for assets that they acquire because they want to focus on their own internal pipeline.

Ipsen has a good commercial team, which is reflected in strong commercial growth numbers in 2019, with nearly 15 percent growth in sales. How will the commercial organization be impacted by the new strategy?

Ipsen can be very proud of what we have delivered in the past. We have seen very strong growth rates. Looking forward, we expect to see challenges for Somatuline® with the entrance of generics, but we are also looking to strike a balance between investing in R&D and investing in commercialization. There is a trade off because investing too much on commercialization means less firepower for rebuilding the pipeline and investing too much in R&D means that the commercial activities can run out of steam. We need to continue to make smart spending decisions, to focus on investments that really move the needle, and to gain an in-depth understanding of the levers that we need to push to achieve commercial success for our assets.

Ipsen has been good at this but we can still get better. We have a new strategy, which is '*Focus. Together. For patients & society'*. This means we need to focus on doing fewer things but doing them better so that we can have a strong impact on patients and society. This also means freeing

up money to invest in more external innovation. Where can we trim in R&D? How can we slim down our overheads? Where can we gain the efficiencies to refuel our external innovation efforts and to accelerate our pipeline development?

You highlighted cultural transformation as a priority too, pointing out that Ipsen already had a great patient-centric culture and focus. What are you looking to improve on? What are the new values you would like to instill within the organization?

Certainly, the patient-centricity is real. I can really feel that at Ipsen people are truly driven by our purpose, they are very altruistic, and they love what they do.

What I want to do is to move this empathy and desire to do good into the generation of an even larger impact. I want to amplify the positive benefits from this attitude. This means becoming more analytical, gaining better and deep insights into the patient journey and how they interact with the healthcare system, and understanding how the healthcare system actually delivers care. These are questions we need to ask ourselves to really move the needle on delivering much bigger impact for patients, which, of course, will also generate commercial success for Ipsen. That, in turn, helps us develop more drugs and innovations to then bring even more positive benefits to more patients.

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I also want people to work better together. People at Ipsen are already very collaborative, imaginative and enthusiastic. I think we can still improve thanks to a dialogue as a company about becoming better and more disciplined at planning and organizing such collaborations. We need to focus on where we can have the most impact. For that reason, I think the establishment of core asset teams with CEOs that are accountable for their brands and have the ability to take fast and agile decisions is really going to transform the way we work as a company.

Very concretely, we will also see more internal promotion. Ipsen has had a lot of external appointments in the past because it had to build up its oncology team and expertise but now that we have accomplished that, we want to develop and promote more from within and also foster

more diversity within the organization.

Putting into practice all these aspects, as well as the leveraging of our collective intelligence, will help us move mountains. I have personally experienced the energy and fun that these types of processes release, as well as the pride and sense of accomplishment, and I think this will start a virtuous cycle that will help Ipsen become better and better.

We are really living in transformational times, especially this year. Looking more broadly across the industry, what do you think leaders like yourself need to champion in order to drive the industry's advancement?

In our industry; there is no secret that drug development has become even more challenging. For me, personally, I think we need to redefine how the industry deals with the data within drug development. Currently, the system is pretty inefficient. For clinical trials, we have to write a case report form that the doctor or study nurse fills in and then we enter the information in our database. But there are already databases with that information within the healthcare system, so there is a redundancy there.

One of the root causes is that these databases are not harmonized. There are perhaps three huge global providers that are offering individual hospitals a lot of customization options. That is obviously a great business model for them but it creates fundamental incongruence across datasets, not even globally but within countries and states and cities. We had a discussion with a health insurance provider in the US, and they said their servers for the north of the country cannot even communicate to the servers for the south of the country, even though the servers are next to each other in the same server room. The databases are all configured differently. This forces the pharma industry to establish our own databases, which is highly inefficient.

We need a future where electronic medical records (EMRs) are harmonized within countries and then across healthcare systems. That would help us develop drugs at much lower costs, because companies will not need to reinvent the wheel every time we do a clinical trial. I have hopes that we will observe this happening in the next ten to 15 years but the process will be slow and painful because every institution and hospital is attached to their own database system. I think we will need to see some coordination and leadership from health ministers on this topic. They need to broker agreements between healthcare institutions and the industry to help us leverage EMR data for drug development.

When we spoke to Dr. Janet Woodcock, director of the US FDA Center for Drug Evaluation and Research (CDER), she said that Europe has a huge advantage on EMRs because of the single-payer public healthcare systems within most countries. Do you concur?

I would not celebrate too early. To be very humble here, I think in theory, Europe should have a head start because in many countries there are socialised healthcare systems. However, in practice, when these systems are imposed top-down, they are often not very efficient in their set-up and organization. On the contrary, the US may have seen a mushrooming of different systems, many of which are private, but due to cost pressures, many are now consolidating. Many large organizations like the Mayo Clinic, Kaiser Permanente and so on have now started a process of vertical integration. The US is also passing laws regarding data harmonization, which could really spark future development in this area.

In that sense, I think Europe needs to be very careful not to lose the advantage that we theoretically enjoy. We need the willingness of national leaders to say, we want to harmonize our healthcare databases across the continent. That is very difficult. We have had discussions with them but the response typically is, I would be happy just to harmonize the systems within my country, much less across the European Union. We have to see how this will play out in the longer term.

A final message to our international audience?

I really think the industry has to find a way to work together. We are all too siloed and everyone is thinking about solving their own problems and areas of focus. But governments are facing increasing cost pressures and the COVID-19 crisis is only going to exacerbate them. The positive side is that we are going to become more and more compelled to work together and to work together better. Otherwise, we will not get there as an industry. We can always point fingers and say, well, drug prices are too high, and payers do not want to pay, and taxes are too high, etc. but ultimately, all stakeholders need to square the equation better – and we need to do it together. I am confident we'll make it happen.

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