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Jazz Pharmaceuticals' footprint in France has accelerated over recent years, driven by a sharper focus on rare and complex diseases, a sequence of strategic acquisitions and a growing role in late-stage clinical development across neuroscience and oncology. In this conversation, Franck Cousserans, General Manager France and Benelux, reflects on how the affiliate is navigating innovation, policy evolution and scientific collaboration at a moment when expectations for patient access continue to rise. The exchange offers a clear view of how Jazz is shaping its next chapter in France...

How has Jazz Pharmaceuticals evolved in France since 2019, and what key milestones have shaped the affiliate's trajectory?

The period since 2019 has been marked by a steady broadening of our footprint in neuroscience and oncology, guided by a clear intent to bring meaningful innovation to patients with high unmet need. A pivotal moment came in 2021 with the acquisition of GW Pharmaceuticals, which strengthened our position in rare epilepsies. Concretely, we added the only regulatory-approved cannabidiol medicine to our portfolio. It is supported by a full clinical development programme and approved by EMA for the treatment of certain rare and severe forms of epilepsy that are resistant to conventional treatments. The medicine secured reimbursement in France at the end of 2022,

allowing us to anchor our neurology efforts around a proven and much-needed treatment option.

In oncology, our progress has followed a similar pattern of targeted expansion. The in-licensing of zanidatamab, a HER2-targeted bispecific antibody, in 2022 represented a major step. As one of the first HER2 bispecifics to reach late-stage development, it has generated strong engagement from French expert centres, and eligible patients already access it through the Early Access pathway. This has reinforced our commitment to advancing therapies in areas where options remain limited. We continued to build on this momentum in 2025 through the acquisition of Chimerix, a US-based biotech, which added dordaviprone to our pipeline. This therapy for a rare and aggressive form of brain cancer was approved by the FDA. Its arrival has further strengthened our role in rare and aggressive cancers.

Alongside these additions, we secured EU marketing authorisation in 2023 for our recombinant crisantaspase for acute lymphoblastic leukaemia and lymphoblastic lymphoma. A positive HAS Transparency Committee opinion in 2024 enabled us to introduce the medicine in France that same year, closing an important loop in our haematology portfolio. Together, these milestones reflect a coherent expansion strategy grounded in focused R&D, carefully chosen acquisitions and a continued ambition to bring new therapeutic options to patients who need them most.

In the context of Jazz's global growth, how do you see Europe's role developing, and where does France position itself within that wider strategy?

We operate across Europe – from major markets to smaller countries – as well as in Canada, Australia, and the United States, and our ambition is to develop medicines with a truly global reach. Recombinant crisantaspase, introduced in the United States, Canada and Europe, is a clear example of how we approach global brand building.

Looking forward, our priority is to continue to build on our regional contribution by expanding the reach of our existing medicines and bringing forward new assets in neuroscience and oncology. Doing this effectively requires far more than replicating what works in the United States. Ensuring that our development plans reflect local nuances is essential for giving patients timely access to innovation.

Within this broader landscape, France plays a particularly meaningful role. We invest heavily in R&D in the country, especially in oncology, where our HER2-targeted bispecific antibody is being evaluated across several international phase three studies involving leading French expert centres.

These centres contribute actively to recruitment and to local research initiatives, which strengthen our scientific presence and support earlier access for patients. Through this combination of clinical expertise, regulatory depth and strong engagement in development programmes, France contributes decisively to our momentum in Europe and to our global progress.

How did your cannabidiol treatment navigate the French regulatory pathway, and how was it perceived by clinicians once it became available?

The development pathway followed the same scientific and regulatory standards as any centrally authorised medicine. The active ingredient is plant-derived cannabidiol; the product was built on a complete clinical programme, progressing through phase one, phase two and phase three studies in well-defined rare epilepsy indications. These data supported EMA approval, after which the medicine entered the French system through a full HAS Transparency Committee review, followed by price discussions with the CEPS. Its trajectory was therefore entirely aligned with the traditional route for medicines introduced in France.

Clinicians have viewed it as a legitimate therapeutic option from the outset. The evidence base is clear, and the product's regulated status distinguishes it from less structured cannabinoid discussions. Many specialists were already familiar with the medicine through compassionate use, which allowed eligible patients to benefit before reimbursement. Since reimbursement at the end of 2022, neurologists have used it where appropriate in the approved indications, especially in situations where treatment resistance remains a persistent challenge.

How is your neuroscience portfolio structured in France today, and how do you organise your teams within such a specialised field?

Our current neurology footprint in France is centred on this approved cannabidiol treatment, which remains our only marketed neuroscience asset. The strategy, however, is evolving. In August 2025, we signed a global licensing agreement with Saniona for SAN2355, a potassium channel activator in preclinical development for epilepsy and other neurological conditions. This addition strengthens the future pipeline and reinforces our long-term commitment to rare epilepsies.

The way we organise our teams reflects the nature of the diseases we address. We work with a limited number of highly specialised expert centres, which means our structure is focused rather than large. In France, we operate above the fifty-employee threshold and have a Works Council in

place, yet we maintain a deliberately compact approach suited to rare and complex conditions, where close collaboration with clinicians carries more weight than scale. Early access plays a significant role in our work, and even as a relatively lean affiliate, we invest considerable effort to ensure that patients with no alternatives can access innovation as early as possible.

How do you view the role of early access pathways in France, and what factors are influencing their evolution today?

France's Early Access and Compassionate use pathways continue to play a vital role for patients who have no time to wait for full market authorisation. These schemes enable the use of promising medicines with a favourable benefit-to-risk profile and have offered meaningful options to hundreds of patients living with severe or rare conditions. Their structured, evidence-driven nature places France among the more advanced access systems in Europe, and this is why we view them as mechanisms that deserve careful preservation.

Current discussions linked to the Social Security Financing Act (PLFSS) have created some uncertainty around how access and pricing may evolve, and we are following these developments closely. Fewer medicines are indeed accepted into early access today, yet those that are approved tend to be supported by strong data and address areas of genuine unmet need. That selectivity strengthens the credibility of the system rather than weakening it. I hope that the elements that work well are protected, because these pathways consistently provide hope and practical benefit to patients who otherwise have no therapeutic alternative.

How would you characterise Jazz Pharmaceuticals' current position in oncology, and what direction are you pursuing as the portfolio evolves?

Our oncology footprint brings together established medicines and a set of late-stage assets that reflect a sustained commitment to rigorous clinical development. Our treatment for complications following stem cell transplantation and a liposomal chemotherapy combination designed for patients with aggressive forms of acute leukaemia continues to anchor our presence in haematology. Building on this base, newer therapies, including an innovative enzyme-based therapy for certain types of acute leukaemia. and zanidatamab, our HER2-targeted bispecific antibody, are progressing through advanced trials with data strong enough to support a detailed HTA review. Ensuring that each candidate is supported by robust evidence remains central to how

we advance in oncology.

Collaboration with leading clinical centres is integral to this approach. Dordaviprone, which entered our pipeline through the Chimerix acquisition, is being investigated with the involvement of Gustave Roussy, a reference institution across multiple tumour types. Their teams are consistently open to evaluating new therapeutic options, driven by a shared objective of widening access to innovation for patients with rare or aggressive cancers. This blend of scientific depth, clinical partnership and disciplined development continues to shape the direction of our oncology efforts.

As you approach the end of the year, what are the key priorities you want to secure, and how do they set the tone for the year ahead?

Our priorities are anchored in two complementary goals. We want to ensure that the treatments already available in France reach more patients with unmet medical needs, particularly in epilepsy, where our regulated cannabidiol continues to meet a significant clinical need. At the same time, we are preparing for the next phase of growth by supporting strong recruitment across our ongoing clinical trials, including those for zanidatamab. Generating the right evidence is essential for future marketing authorisations, so advancing these studies is central to our agenda. This balance between expanding the impact of the existing portfolio and enabling the next wave of innovation will guide our work over the coming year.

The challenges ahead are tied mainly to the evolving policy environment. Discussions around the Social Security Financing Act (LFSS) may reshape the mechanics of access and pricing, and any shift in these areas influences France's attractiveness in a global context. It is important to maintain a competitive environment while safeguarding what already works well, particularly early access pathways, which remain crucial for patients with no therapeutic alternatives.

How does the recent CEO transition shape the group's direction as you move into this next phase?

Renee Gala's appointment brings continuity with a renewed sense of momentum. She joined Jazz in 2020 as Chief Financial Officer and has been closely involved in strategic development, commercial execution and financial stewardship. Her transition into the President and CEO role reinforces a clear trajectory, centred on advancing transformative medicines for patients with high unmet medical need. I expect her leadership to sharpen our focus on disciplined growth, thoughtful

portfolio expansion and sustained investment in assets that strengthen our position and serve patients.

What are the key pricing considerations you believe deserve clearer understanding, particularly as France reassesses its health-policy framework?

One point that is often overlooked is the weight of the French price beyond France itself. The country sits at the centre of several external reference pricing systems, so a non-viable price in France does not remain contained within the national market. For any organisation operating globally, this creates a tangible downstream risk. If a medicine is priced too low in France, its long-term availability can be affected not only domestically but also in other reference countries.

This is why the debates surrounding the LFSS matter. At their core, they raise a simple but fundamental question: do we want tomorrow's innovations to reach French patients? If prices are set below a level that reflects the value delivered to both patients and society, companies may not be able to launch, and access to important therapies could be compromised. The challenge is to maintain a system that remains internationally competitive while preserving the conditions necessary for meaningful innovation to reach the market.

The French pricing environment can appear complex from the outside, particularly because patients rarely know the price of the medicines they receive. Yet pricing decisions result from structured negotiations with the CEPS, which applies clear mechanisms to safeguard the sustainability of the social security budget. It is a rigorous process, led by experts whose responsibility is to balance financial stewardship with patient access. Trusting that framework and ensuring that debate remains proportionate and grounded in value is essential if France is to continue attracting and sustaining medical innovation.

After a decade with Jazz Pharmaceuticals, what continues to anchor you in the organisation, and which values shape the way you lead the affiliate in France?

These ten years have been defined by a steady progression in both our portfolio and our role within the French ecosystem. Entering epilepsy was a major step for us as an affiliate, and the succession of launches that followed has kept the work both demanding and rewarding. What keeps me motivated here is the ability to bring therapies with real clinical value to patients who often have limited options, and to see that work translate into meaningful change in specialist centres. That

sense of purpose remains a strong driver.

Leadership, for me, is tied to the environment we create for our teams. I try to lead in a way that reflects the values we expect from one another: clarity, openness, collaboration and a strong sense of responsibility for the quality of our work. We spend time reinforcing the behaviours that support a high-performing organisation, whether that is encouraging people to speak up, giving constructive feedback or helping teams develop a more structured approach to prioritisation. These are simple concepts, but they matter when you operate in rare and complex diseases.

The organisation itself is built on a diverse range of profiles. The team brings together multiple generations, from those just starting their careers to colleagues with decades of expertise. That variety creates a balanced dynamic, bringing fresh perspectives together with deep therapeutic and operational experience. It makes for a culture that is both grounded and forward-looking, and it is one of the reasons I am confident in what we can achieve in the coming years.

When it comes to values driven by diversity and inclusion, those are also key components of Jazz Pharmaceuticals France's DNA. We signed a charter with *L'Autre Cercle*, the leading French non-profit organisation for LGBTQIA+ inclusion in the workplace in France.

How is France's new framework for cannabis-based medicines shaping expectations, and what distinctions matter for clinicians working in rare epilepsies?

France is preparing to introduce a dedicated national framework for cannabis-based medicines through the 2024 Social Security Financing Act (LFSS). This new status will allow the ANSM to grant temporary authorisations of up to five years, supported by more flexible conditions on manufacturing and distribution. These products will not follow the traditional route involving a full clinical development plan or a centralised European marketing authorisation. The implementing decree is still pending, and the HAS is expected to assess the first dossiers early next year, so the practical contours of the framework are still being defined. For some patients with no remaining alternatives, it may open an additional pathway to treatment.

Currently, the situation is confusing: on one hand, we have regulatory-approved pharmaceutical specialities, including those containing cannabinoids; on the other hand, we have cannabis-based medicines. These two product types, however, fall into fundamentally different regulatory categories. Our therapy is a centrally authorised neurology medicine built on a complete phase one to phase three clinical trial programme and reviewed both by the EMA and the French HTA bodies. It carries robust evidence on efficacy, safety and tolerability in the rare epilepsies for which it is

approved. We are not offering a cannabis-based medicine, which would be restricted to the latest lines of therapies when all approved options have been used. We are offering an EMA-approved speciality pharmaceutical product supported by extensive clinical data. Maintaining that distinction is essential for clinicians and patients. Clear communication on these differences is vital to avoid confusion.

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