SÃ©bastien Mas â?? CEO, Skyepharma

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Skyepharma stands at a defining moment. With new shareholders, expanding high-potency and bioproduction capabilities and a sharpened focus on complex oral forms, the French CDMO is positioning itself for a new phase of growth at the intersection of innovation, sovereignty and international ambition. In this conversation, recently appointed CEO SÃ©bastien Mas reflects on where the company is today and how he intends to guide its next chapter.

How did your professional background lead you to Skyepharma, and how do you see your role as the company enters this new phase?

I have spent more than fifteen years managing industrial companies in France, across Europe and in international settings, although not directly within the pharmaceutical sector. I joined Skyepharma at a moment of significant transition, as our new shareholders, Bertrand Simon and HervÃ© Letoublon, through Oleron Pharma, acquired one hundred percent of our capital. Their arrival opens a new chapter for us, yet it also preserves the strong continuity of the existing team, which remains fully in place. My role is to support this team as we move into the next stage of our development, bringing an industrial lens that is particularly relevant to production, operational structure and overall discipline in how we deliver for our customers.

Throughout my career, I have led organisations with substantial operational demands, and I approach the CEO position as that of a team leader who aligns capable people around shared objectives rather than someone who manages every aspect alone. What I want to bring to

Skyepharma is a combination of structure, clarity and service orientation, so that we continue reinforcing the foundations that have been built and remain focused on what matters most to our partners and the patients they serve.

What makes 2025 a pivotal moment for Skyepharma, and why was this the right time for you to take on the leadership?

This year stands out for several reasons that converge to create a meaningful step forward for us. Financially, we have surpassed EUR 30 million in turnover, which marks an important milestone in our trajectory. Operationally, we have begun production in our new HPAPI facility for medicines to be handled with particular care, such as OEB4/5 class drugs. This high-potency zone is now fully operational, strengthens our capabilities in oncology and other sensitive oral medicines, and has already attracted strong interest from new projects. Together, these developments reflect the scale of investment made in recent years and the moment at which these investments become fully active.

In parallel, the change of ownership gives renewed momentum while preserving the work of the previous leadership, whose contribution was considerable. Our priority is to consolidate the progress achieved, maintain stability and prepare the organisation for the next phase of growth.

For me personally, this opportunity came at the right moment. I have led industrial operations of various sizes, including larger organisations, and I understand the demands of quality, reliability and on-time delivery that define a CDMO. While development brings its own specificities, the fundamentals of production and service are universal, and I know this environment well from the supplier side. Stepping into this role allows me to apply that experience to a company with strong potential, work closely with an operationally minded team and help position Skyepharma for the years ahead.

How would you describe Skyepharmaâ??s capabilities and how it stands out in the competitive international market?

Skyepharma is a specialist in complex oral solid forms, with expertise that ranges from early pharmaceutical development through to commercial manufacturing and packaging. Our expertise includes advanced oral technologies, such as modified-release systems designed to control drug absorption over time, targeted-release platforms, tab-in-tabs and multi-layer tablets. This niche positioning has been central to our strategy for several years, and we remain committed to high-value development rather than large-volume, commodity production.

We continue to invest in innovation that sharpens this positioning. Our teams work with academic partners and technology hubs to advance new oral delivery approaches that address the complexities our clients face. Many come to us with challenges related to delayed absorption or specific release profiles, as well as bioavailability challenges, and our role is to support them from the earliest formulation stages through to production and market supply. Today, we can manage the full development and manufacturing pathway, which is exactly the model we intend to pursue going forward.

How do you plan to sustain the growth achieved in recent years and expand across pharmaceutical development and bioproduction?

Our starting point is to remain the preferred partner for complex oral forms. Skyepharma is a one-stop-shop CDMO that supports both large and mid-sized pharmaceutical companies from early-stage development through to production and delivery, at both pilot and industrial scales. Much of our growth has come from our ability to meet a wide range of client needs while remaining agile and cost-efficient. There is a natural demand in this niche, and our regulatory track record, fully compliant with the strictest quality standards such as FDA and GMP, has reinforced this dynamic.

A significant part of our future growth will also come from bioproduction. We launched the Skyehub Bioproduction model with MaaT Pharma in 2022, our first biotech resident, for whom we built a dedicated and fully equipped cGMP facility on our site, reputed to be the largest facility entirely dedicated to microbiota-based therapies. Their teams work independently while relying on our industrial and quality systems, which allows us to collaborate closely on how their microbiome science is translated into reliable oral products. This set-up remains unique in the CDMO space and has generated strong interest from other biotechs and some non-biotech companies looking for a tailor-made, dedicated facility. Here at Saint-Quentin-Fallavier, we still have space and capacity to welcome new partners and offer them a facility where they can focus on their know-how while we secure the industrialisation and production steps.

This combination of deep expertise in complex oral forms and a unique European bioproduction business model gives us a solid base to continue expanding. It is also a model that biotechs value, and MaaTâ??s successful experience illustrates how effective this approach can be.

What opportunities do you see for complex oral forms versus injectables, and how is innovation reshaping this field today?

I do not see a limit to the potential of complex oral forms. Injectables are expanding quickly, yet they still present challenges for patients, whether due to discomfort, the need for administration or the simple fact that they are less convenient for long-term treatment. When people are given a choice between a daily tablet and a recurring injection, the preference for an oral option is clear. In several countries, particularly in Eastern Europe, patient preference carries even greater weight, which reinforces the value of oral technologies.

We continuously invest in innovation to overcome the solubility and bioavailability issues of oral solids, as well as the challenges of precise targeting and controlled release of the API in the human and animal body â?? the challenges faced by many oral solid-form treatments. In this context, the recent advances have also broadened what oral delivery can achieve. Sophisticated formulations can sustain the release of active ingredient over twelve hours or more, enabling profiles that, in some cases, approach the effect of an injection while offering a far more practical option for patients.

A good illustration is MucoTabS, a gastro-retentive platform we have recently submitted for patenting. Designed to adhere to the stomach or upper intestinal wall, it allows controlled diffusion of the active ingredient and builds on our long-standing expertise in multi-layer and modified-release technologies. Our innovation leader works closely with the University of Lyon, Lille and Bordeaux and several innovation hubs to ensure that we remain ahead of emerging possibilities in oral delivery.

Our aim is to bring forward solutions that help partners address their most complex formulation challenges, often by proposing approaches they may not have considered. This is how we see the next phase of innovation in complex oral forms, and it is a direction we intend to pursue with discipline and focus.

How has Skyepharmaâ??s business model evolved in the global context where CDMOs take on a more strategic role in development?

Our way of working combines a strong responsiveness to client needs with a deliberate effort to contribute ideas early in the process. Many partners come to us with specific challenges in complex oral forms that must meet cGMP requirements in markets such as the United States or Japan. In these situations, we become involved from the outset, take time to understand the problem they are trying to solve and draw on our experience to propose options that support the development path they are pursuing.

At the same time, we often suggest innovative ways to approach the existing development challenges thanks to our advances in the field of innovation. It is a constructive way of helping them consider alternatives they may not yet have examined. This combination of early technical input and forward-looking dialogue reflects how the CDMO landscape has changed. Clients now look for partners who can bring insight as well as capacity, and we shape our collaborations with that in mind.

How do you adapt your model to support both biotech start-ups and big pharma players?

Our starting point is always the same. We uphold the highest GMP standards and ensure that the quality of what we deliver is never in question. From that foundation, the way we work adapts to the profile of the partner. The partnership with MaaT Pharma is a clear example. They approached us with a very specific need, and within twelve months, we designed and constructed a dedicated facility, validated it and moved straight into operations. That ability to mobilise quickly and stay tightly aligned with a project is one of our strengths.

Larger pharmaceutical companies operate within a different rhythm. Tech transfers and scale-up phases can extend over several years, and they look for partners who can manage that progression while maintaining precision and flexibility. Thanks to our expertise in complex oral forms, we can begin with modest volumes, expand as the market grows and plan investments together when future demand becomes clearer. This blend of technical depth, operational stability and measured agility is what both types of partners value. It enables us to move at the pace required, respond to evolving needs and support them throughout the lifecycle of their programmes.

How are you strengthening Skyepharmaâ??s capabilities in high-potency and oncology manufacturing?

We have recently opened a new 450 mÂ² high-potency zone dedicated to medicines to be handled with particular care. It is a fully contained and segregated cGMP environment designed for highly potent oral drugs, including oncology treatments, and is equipped to handle OEB 4 and 5 substances that require a very strict level of protection and operational control. The facility was completed at the end of 2024 and has been fully operational since early 2025.

This investment aligns with the wider France 2030 objective to reinforce domestic production of strategic medicines. It has already generated strong interest. Several oncology partnerships are in place, and there is still capacity for new projects. We also designed the zone so it can be extended rapidly as demand grows, which enables us to scale capacity while maintaining a competitive and

efficient cost structure for our partners.

How do you view Franceâ??s renewed emphasis on domestic manufacturing, and where does Skyepharma position itself within this national effort?

France 2030 has placed a strong focus on health sovereignty, including the relocation or reinforcement of production for around fifty essential medicines where dependence on imports remains high. The initiative also extends to biomedicines and other complex therapies. We are closely aligned with this agenda. Skyepharma was selected under the France 2030 relocalisation programme for essential medicines and received EUR 1.6 million in public support to strengthen our manufacturing capacity, which confirms the contribution we can make to this national priority.

Our site operates under full GMP certification, and we work in close coordination with the ANSM to maintain the highest French and international standards. That regulatory foundation enables us to support partners through development, approval and production of complex oral medicines.

Our positioning is clear. We do support sovereignty by producing in France for the French market, while continuing to serve our clients internationally.

How would you describe Skyepharmaâ??s international footprint today, and what ambitions guide your global outlook?

Skyepharma has a strong reputation in the international market. We hold cGMP certification from the FDA in the United States, ANSM acknowledged by the European market and from ANVISA in Brazil, which effectively positions us to supply more than 160 markets. We also have experience with other major jurisdictions, including Japan. At Skyepharma, we only move once we are certain that our compliance and operational readiness meet the expectations of those authorities.

For now, we operate from a single site in France, and that choice is intentional. The facility offers considerable room for expansion, which is one of the reasons we were able to build the Skyehub unit for MaaT Pharma in just twelve months. Keeping our operations concentrated maintains a disciplined cost base and reduces supply-chain complexity while still giving us the flexibility to address a broad international market. Further developments may become relevant over the coming years, depending on how global conditions evolve, including the tariff environment in the United States. At this stage, we can serve all our existing markets from France, supported by a team with a diverse international profile and a strong global perspective.

How do you envision Skyepharmaâ??s position in the next three to five years, and what message would you share with an international audience?

I have been in the role for only a short time, so we are still shaping the strategic plan that will guide us over the coming years. Even so, a few priorities are already well defined. We want to continue advancing the programmes of clients who have trusted us for more than a decade, while deepening our involvement in the scale-up of biotech projects and other innovative players, where our ability to move quickly gives us a genuine advantage. We also intend to consolidate our position in oncology, which is a clear pillar of our future direction. If, in three to five years, we can say that we have delivered meaningfully on these fronts, we will have taken an important step forward.

More broadly, I would tell the international audience that Skyepharma remains a flexible and reliable partner for complex oral forms. Our cost structure allows us to respond quickly, and the interest we saw at the last CPHI confirmed the relevance of what we do. Many new companies reached out, and we were able to offer tangible solutions in a short timeframe. I would encourage any organisation working in advanced oral technologies to connect with our team. Our capabilities are strong, our innovation programs are ambitious, and our quality environment is impeccable, which shows the significant value we can provide to partners.

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