A New Vision for Progressing Advanced Therapies

Over the past year, ReciBioPharm has emerged as a formidable player in the biopharmaceutical sector, having strategically expanded its capabilities through the acquisition of companies specializing in niche biologics and advanced therapies. These acquisitions, including Arranta Bio, Vibalogics, and GenIbet, have equipped ReciBioPharm with a diverse portfolio ranging from nucleic acid and protein therapies to microbial and viral work.

With a host of unique capabilities and differentiating expertise the company has focused its efforts on becoming a leader in nucleic acid manufacturing, supported by substantial industry feedback and advancements in technology. This strategic amalgamation of diverse technological strengths underpins ReciBioPharm's vision to not only lead in innovation but also to foster a unified, flexible corporate culture that resonates with dynamic market demands and client needs with the goal of realizing the future of advanced therapies.

In this Q&A, ReciBioPharm's Vice President of Business Strategy and Program Management Nathaniel Youndt discusses the company's evolving strategy and how it is strategizing to help drive the future of these diverse sectors, with *Pharma's Almanac* Editor in Chief David Alvaro, Ph.D.

Nathaniel Youndt
Vice President of Business Strategy and Program Management, ReciBioPharm

David Alvaro (DA): ReciBioPharm has grown through strategic acquisitions in key biotech sectors. Could you describe how you have integrated these diverse operations to align with ReciBioPharm's overarching vision and strategic focus?

Nathaniel Youndt (NY): ReciBioPharm emerged from Recipharm's interest in expanding into new territories within the biologics and advanced therapies sectors. The company targeted acquisitions that were uniquely positioned in these areas: Arranta Bio, originally a microbiome and plasmid DNA operation, which adapted during the pandemic to also handle plasmid, mRNA, and lipid nanoparticle (LNP) services; Vibalogics, with its legacy in oncolytic viruses in Germany and a newer venture into viral vectors in the United States; and GenIbet Biopharmaceuticals, which emerged as the GMP arm of a research institute with a diverse portfolio ranging from recombinant proteins to a variety of viral, microbial, and nucleic acid products.

These acquisitions allowed Recipharm to significantly broaden its capabilities to include microbial, viral, nucleic, and protein work. Once they were completed, the challenge was to brand this diverse set of capabilities under a unified vision. We ultimately decided to focus our strategy on becoming a leader in nucleic acid manufacturing, supported by positive market feedback and substantial grants for advancing our technology.

The markets for some of our other services, like oncolytic viruses and viral vectors, can be quite niche or are dominated by a handful of major players. Thus, we positioned these as robust platforms, and we hope to grow into a leading presence in these sectors through specific points of differentiation currently under development. The microbiome market has contracted in the last year or two, but our broad capabilities allow us to continue supporting this area strategically and to stay poised for future growth.

Overall, our approach has been to leverage our diverse strengths without forcing integration where it doesn't naturally benefit the markets we serve. We aim to balance being present in essential markets while maintaining the unique strengths of each acquired company.

DA: Given the differences between the sectors where ReciBioPharm and the parent company Recipharm are focused, do you see your character and culture evolving along different lines?

NY: Recipharm has a longstanding reputation as a trusted stalwart in small molecule and large-scale commercial operations. At ReciBioPharm, we are targeting an earlier-phase clinical market in new modalities and feel that our long-term success hinges on harnessing that legacy while offering an even greater level of nimbleness and responsiveness that suits the dynamics of these evolving sectors. Our ethos is about rapid adaptation to meet changing customer needs, whether that involves shifting technologies or operational strategies.

We have defined ourselves by synthesizing the rigor and reliability of Recipharm with an even greater level of adaptability that suits the dynamics of the advanced therapies sector. Our team operates almost like a skunkworks project — highly agile and always ready to tackle the next challenge, no matter how daunting it might seem. Whether we are accelerating timelines to meet urgent needs, providing regulatory support, or integrating next-generation technologies into our platforms, we're committed to pushing the boundaries to advance our clients' projects.

Our culture thrives on flexibility and a lack of ego, allowing every level of our team to dive deep into projects to ensure they advance exactly as needed. This approach not only sets us apart from our competition but also makes us a pivotal force in driving emerging modalities from concept to clinic.

DA: You mentioned the importance of not forcing integration absent clear benefits, but have you seen novel synergies result from bringing these diverse companies and capabilities together within one organization?

NY: The synergy across our operations manifests in two main ways. First, we actively share best practices across sites. If one facility excels in implementing new equipment, executing efficiently, or using valuable program management tools, we adopt these practices across all locations, elevating everyone to the best standard.

Second, we specialize in high-value, complex processes that are sometimes unique to specific sites. For instance, unit dose lyophilization is exclusively handled at our Cuxhaven site, while bulk lyophilization occurs in Watertown. Similarly, if automated sterile filling is required, we can route that work to our sites in Massachusetts or Germany that have the necessary equipment, even if the drug substance originates elsewhere.

Operationally, we aim to reduce complexity by maintaining minimal movement of products across sites. We prefer to handle entire projects at one center of excellence to streamline processes and reduce logistical challenges. This approach helps us cater to smaller and medium-sized companies in the advanced therapies sector, who favor working closely with one cohesive team. Additionally, we strategically plan redundancies, like being able to offer mRNA/LNP production in both the United States and Europe, providing flexibility to our clients based on their strategic needs.

This integrated yet flexible approach allows each part of ReciBioPharm to function both independently and as part of a larger whole, maximizing efficiency and expertise without compromising on the agility required to respond to customer needs.

DA: How has ReciBioPharm integrated the teams from its various acquisitions to blend the legacy expertise with new leadership dynamics?

NY: We've been committed to retaining core members from each acquired company because their deep expertise in specific modalities and therapeutic areas is invaluable. These individuals are true subject matter experts (SMEs), and their presence ensures that we offer genuine, in-depth knowledge to our clients, which is critical because our customers can discern the difference between generalist knowledge and specialized expertise.

In addition to preserving this essential knowledge base, we have been strategically enhancing our organizational capabilities by incorporating new skills that are essential for our growth and integration. For instance, we've brought in professionals with robust manufacturing operations backgrounds to unify our sites, ensuring that they operate cohesively. Our marketing team is focused on sharing the story that encapsulates the unique value of combining these diverse companies, which is vital for communicating our integrated capabilities both internally and externally. And our sales team is equipped with specific knowledge from the niche markets we serve, enabling them to effectively convey our value proposition to the market and feedback valuable insights into the company.

Integrating cultures from different organizations is itself a significant challenge, and it's an ongoing process. Initially, we had three distinct company cultures, each with its own identity and operational style. Currently, we are in the midst of blending these cultures into a new, unified identity that draws on the strengths of each legacy company.

This integration is not just about merging operational practices; it's about creating a culture where the unique characteristics of each original entity are respected but combined in a way that enhances our overall service offering. While each site maintains aspects of its original culture, we are fostering an environment where open communication and collaboration are paramount. Everyone is connected, and there is a concerted effort to ensure that we are more than just a collection of locations — we are a single, unified entity that benefits from the pooled knowledge and experiences of all our teams.

From a customer perspective, this integration provides access to a richer and more diverse set of expertise and capabilities. It's a dynamic process, and our culture continues to evolve, not just in response to internal factors but primarily in response to our customers' needs. This customer-focused adaptation helps us avoid the pitfalls of internal bureaucracy and ensures that our culture is continuously evolving to create more value for those we serve.

DA: How do you see the landscape of mRNA and related technologies evolving in the coming years, and what opportunities do you foresee for ReciBioPharm?

NY: The mRNA sector has matured significantly since the COVID era. During the pandemic, the global health need allowed for rapid vaccine production with less stringent purity profiles. The focus has shifted toward higher purity standards, especially in therapeutic applications that demand smaller batch volumes but higher quality. This shift is challenging many CDMOs who had capitalized on the urgency of vaccine production without needing to meet these stringent criteria.

At ReciBioPharm, we're leveraging our expertise in design of experiments and new technologies to meet these elevated standards. We're not just producing large volumes; we're ensuring that each batch meets exacting purity profiles, which is crucial as we move beyond basic mRNA to more complex constructs like siRNA, circular RNA, and self-amplifying RNA. These new nucleic acid formats are not only more complex but also hold the potential for multivalent applications, which could revolutionize how we approach vaccines and therapeutics.

Our readiness to handle a diverse set of RNA constructs places us at a competitive advantage. We're equipped with the technologies and expertise necessary to meet the market's evolving demands and to push the boundaries of what's possible in nucleic acid–based therapies.

DA: Can you discuss the work on developing continuous manufacturing for mRNA?

NY: The push for a continuous manufacturing platform for mRNA vaccines originated from a three-year, $82 million FDA grant awarded during the pandemic. We collaborated with MIT to conceptualize not just a continuous process but also a digital twin of the machinery, enhancing our ability to conduct digital R&D.

Continuous processing itself hasn't been the challenging part; this approach has been utilized in monoclonal antibodies production for decades. The more complex aspects involve the analytics — ensuring the quality and timely release of the product. Furthermore, some of the main bottlenecks encountered during the pandemic were related to LNPs and their sterile filling, not the availability of mRNA.

Our focus swiftly expanded beyond vaccines to therapeutic applications, where process analytical technology (PAT) and machine learning models showed significant promise. These technologies enable us to predict and refine manufacturing processes based on inputs from various constructs, potentially reducing lab work by up to 60%. This efficiency could drastically cut development time, allowing innovations to reach clinical stages faster and extend their funding runway.

We are currently advancing these models to not only streamline the process but to control it in real time and ensure immediate product release. The next phase involves integrating these models into a continuous, modular system, focusing more on the digital and PAT aspects than on the continuity itself.

As a CDMO, we are uniquely positioned to develop this tech, due to our process and analytical knowhow. Every data point is captured in building a knowledge hub that drives the whole project. If a bioprocess tool provider were to try to develop this, they would be constrained by limited data capture.

DA: In the context of the saturated AAV market, do you foresee any disruptive transformations in the near future?

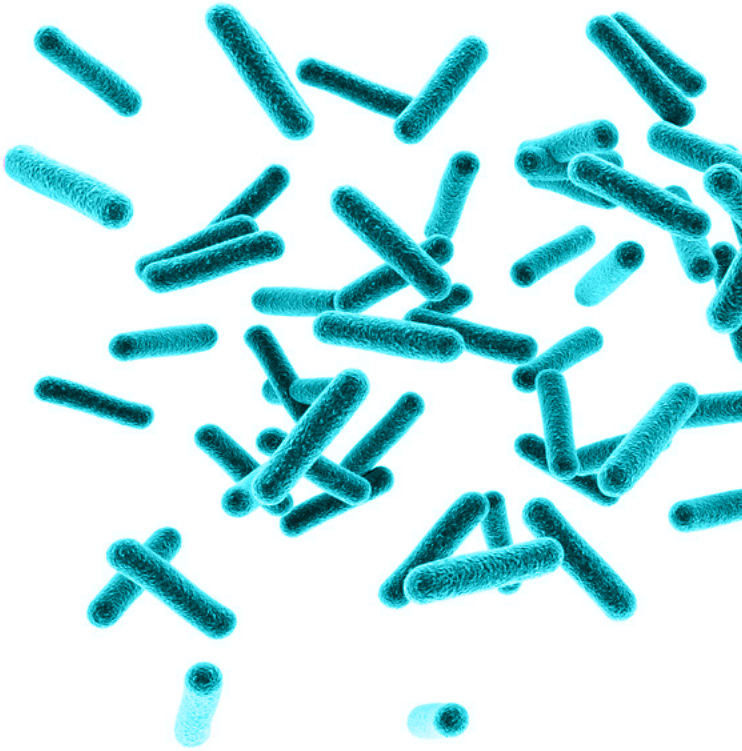
NY: In the AAV market, the challenges are substantial, especially around reducing the cost of goods and improving production efficiency. One of our strategic responses has been our partnership with NewBiologix in Switzerland. Recipharm made a strategic investment in NewBiologix, and we view them as an integral partner in our offerings.

NewBiologix is currently exploring the development of transient, packaging, and producer cell lines that could significantly reduce the production complexities for AAV. These new cell lines would allow us to consolidate multiple steps of the AAV production process, reducing costs and simplifying the supply chain.

Our focus isn't merely on leveraging new bioreactors or making incremental improvements that marginally increase titer yields — those approaches won't be enough to overcome the existing market challenges. Instead, we're aiming for breakthroughs that significantly reduce the costs and time in production, ultimately making them more commercially viable.

I believe that real transformative shifts might come from advancements in alternative delivery technologies. For instance, if we achieve better tissue targeting with lipid or polymeric nanoparticles, it could significantly change the delivery system landscape. Currently, LNPs primarily target the liver, and the newer polymeric methods are still in early stages, but once these new delivery systems demonstrate efficient and precise targeting, they could become the new leading technology in terms of both interest and investment.

DA: What are the barriers to growth faced by the microbiome sector, and how might they be overcome?



NY: I believe that microbiome therapies have transformative potential just awaiting broader realization. The main challenge lies in the complexity of the microbiome itself. Quantifying the effects of specific bacteria — or groups of bacteria within the gut (consortia)— is incredibly complex. Issues such as how to measure whether bacteria have successfully engrafted in the intestines and to what extent they must engraft to be therapeutically effective are considerable hurdles.

These complexities have tempered investor enthusiasm, as traditional pharmaceutical metrics struggle to capture the nuanced impacts of microbiome therapies. However, I'm optimistic that novel methodologies or new perspectives on the microbiome's role in health could spark significant breakthroughs.

We're seeing a resurgence of interest, particularly as more data become available. This mirrors the trajectory gene therapy experienced — initial skepticism followed by gradual acceptance. With continued research and perhaps one landmark clinical trial, I believe we could see a dramatic resurgence in investment and development in this sector. The key will be systematic and realistic approaches to product development, ensuring we don't overpromise but rather deliver tangible, scientifically backed benefits.

DA: Do you foresee any further significant acquisitions, or will organic grown and partnerships be more important for ReciBioPharm in the coming years?

NY: Our strategy post-COVID has evolved to focus more on forging strong partnerships rather than pursuing aggressive acquisitions. We've learned that building meaningful collaborations can be more beneficial and sustainable. We just announced a significant partnership with Hongene Biotech, a leader in the oligonucleotide and nucleic acid raw material space based in China. This collaboration allows us to integrate the entire process of offering single guide RNA (sgRNA) for gene editing within our facilities, which is a substantial step forward, especially considering the growth potential in that space.

Additionally, partnerships are crucial in areas like drug delivery, where we aren't prioritizing holding intellectual property. Working with companies like Acuitas and Genevant, who are experts in delivery mechanisms, enhances our capabilities and ensures that we can effectively meet the complex needs of our clients. These collaborations not only provide mutual access to innovators readying for the clinic but also ensure that we are in step with the latest advancements in drug delivery technologies.

We're also expanding our high-throughput screening capabilities to engage more effectively in the preclinical phase of drug development. This area is crucial because it allows us to support clients earlier in the candidate discovery and selection process, helping them determine the most promising construct(s) before full-scale development begins, especially those still operating on seed funding or early investment rounds.

DA: Can you describe how ReciBioPharm's approach to customer service and flexibility compares to your experiences at other CDMOs?

NY: My experience at ReciBioPharm has been refreshingly dynamic compared with other CDMOs. Typically, I've seen a rigid approach where the conversation revolves around doing things a certain way because that's just how it's done, without much room for flexibility. On the flip side, I've also encountered scenarios where customer suggestions that might not be optimal are accepted without much pushback, just to accommodate their wishes.

We operate differently at ReciBioPharm. For matters that are less critical, we're very flexible. If a customer needs us to adjust our process or provide something unusual, we're open to making those changes. More importantly, when it comes to significant decisions where a customer might propose an approach that we believe is not in their best interest, we are candid about our concerns. We don't just agree for the sake of agreement; we explain why we think there might be a better approach and offer better alternatives based on our expertise and experience.

This balanced approach — being accommodating when possible but firm and advisory when necessary — has made our customer interactions not only more meaningful but also more valued. Customers really appreciate this honesty and the tailored guidance we provide, which fosters a much deeper and productive partnership.

DA: How would you characterize ReciBioPharm's goals right now, both the proximal and more distal ones?

NY: In the immediate future, our realistic goal is to establish ourselves as the go-to experts for nucleic acid work, building a strong reputation in this specialized area. We're confident in our ability to achieve this given our current trajectory and the expertise we possess.

On a more visionary level, our aspiration is for ReciBioPharm to become synonymous with advanced therapies. We aim to be the first name that comes to mind when people think about pioneering treatments in this space. This isn't just about having a strong business development presence; it's about being recognized for our substantial scientific contributions. We envision our team, which includes a lean but highly knowledgeable business development group supported by a network of brilliant subject matter experts, making significant impacts at industry conferences not with generic presentations but with compelling data that showcases our technological advancements.

Additionally, we're encouraging our customers to collaborate on public disclosures to help build momentum in the industry. By sharing success stories and case studies, we can demonstrate the speed and efficiency of our solutions, further solidifying our standing in the market.

Our vision is to lead in the advanced therapy sector, leveraging our transparency, superior technical capabilities, and strategic market initiatives to distinguish us from competitors and drive our growth in the field.

About us

ReciBioPharm, a division of Recipharm, is a contract development and manufacturing organization (CDMO) specifically established to focus on serving companies seeking to develop and commercialize advanced therapy medicinal products (ATMPs). ReciBioPharm's specialized CDMO capabilities include pre-clinical to clinical and commercial development and manufacture for new biological modalities encompassing technologies based on live viruses and viral vectors, live-microbial biopharmaceutical products, nucleic acid-based mRNA and plasmid DNA production. Led by a management team and technical experts with a proven track record in both process development and contract manufacturing, ReciBioPharm offers the knowledge and resources necessary to help customers develop and manufacture promising new therapies to meet the needs of patients across the world.