



Meet Zylidac: A New CDMO with Forty-Plus Years of Experience

An Interview with: **Alfred Dadson, Jr.**, Chief Manufacturing Officer, **Steve Lavezoli**, Chief Commercial Officer, and **Mandy Sharma**, Vice President, Technical Operations

Zylidac is a new CDMO subsidiary of India-based biopharma company Zydus Lifesciences. Although launched in early 2026, the Zylidac team has over four decades of experience shepherding biologic therapeutics, including antibodies, bispecifics, and fusion proteins, from preclinical development to commercial production. At its state-of-the-art facility in Emeryville, CA, Zylidac supports clients from cell-line development through fill/finish, labeling, packaging, and distribution.

In this Q and A, three leaders of the Zylidac team, Al Dadson, Jr., Chief Manufacturing Officer, Steve Lavezoli, Chief Commercial Officer, and Mandy Sharma, Vice President, Technical Operations, discuss the genesis of the company and what sets it apart from other CDMOs, including its extensive experience working with many different clinical and commercial products, the longevity of the team, their experience on the sponsor side of sponsor-CDMO relationships, and its ability to support projects across the entire product lifecycle.

Q: How would you describe the genesis of Zylidac Bio and its position within the Zydus Lifesciences organization?

Dadson: The first step toward creating Zylidac Bio occurred in mid-2025, when Zydus Lifesciences Limited acquired two state-of-the-art biomanufacturing facilities in California from Agenus Inc. and announced it would offer global bio CDMO services through these facilities. Zylidac will be the sole provider of drug substance and drug product manufacturing services for Agenus Inc.'s Phase 3 immuno-oncology candidates Bortezomib (BOT) and Bortezomib (BAL). Zydus has secured exclusive rights to commercialize BOT and BAL in India and Sri Lanka. Zylidac, a dedicated U.S.-based subsidiary of Zydus, was formally launched in January 2026.

Zydus is an India-based, innovation-led life-sciences firm with an international presence. The company produces monoclonal antibodies, bispecifics, antibody-drug conjugates, and fusion proteins across five facilities in India and has 13 approved biosimilar products in the global market.

The opportunity to acquire the California facilities arose as Agenus sharpened its focus on advancing and commercializing BOT and BAL. At the same time, Zydus was looking to expand its manufacturing footprint in the United States. The transaction brought together two complementary

strategic objectives, providing Zydus with a state-of-the-art biologics manufacturing and development facility while establishing a strong foundation for future. Agenus had built the facility in Emeryville specifically for the commercial production of BOT and BAL. The deal with Agenus also gave Zydus access to BOT and BAL and secured business with two committed commercial products right out of the gate.

Q: Can you share some thoughts about the leadership team at Zylidac?

Dadson: Although Zylidac is technically a brand-new biologics contract development and manufacturing organization, the team at the helm is highly experienced in biopharma production, with many coming from the biggest biotechs. We have collectively supported 40 to 50 molecules that have entered the clinic, 18 of which have been commercialized. They include simple monoclonal antibodies and biosimilars, as well as more complex bispecifics and multi-fusion proteins. We have seen a wide range of molecules and challenges, and we can develop processes for even unusual molecules that present peculiar and daunting manufacturing difficulties.

Some of us have been together for decades, starting with XOMA Royalty Corporation, continuing through the Agenus acquisition, and now with Zylidac and Zydus. We've worked with a wide variety of molecules and many large biopharma companies, including Merck, Pfizer, Bristol Myers Squibb, Gilead, and others. These companies took on molecules discovered and developed by this team, and this team also handled and manufactured the material to advance them into the clinic.

All of us have been involved in projects from the preclinical or Phase 1 clinical stage through commercialization. Even though Zylidac doesn't yet have any commercial products, this group has the knowledge and experience to develop a drug from inception through commercial launch. We know what it means to carry a molecule through that pathway, and that's the critical part.

Q: How does having a team with experience working with CDMOs help Zylidac provide a superior customer experience?

Lavezoli: Nearly every Zylidac scientist spent years on the sponsor side, working with contract development and manufacturing organizations. This experience has directly informed our strategy from the ground up. Zylidac emphasizes delivering superior customer service and directly

addresses common industry frustrations, such as poor communication and flawed documentation.

We reflect on past problems with CDMOs and ensure we don't repeat them. We won't over-promise, delay reporting deviations, conduct flawed root-cause analyses, or provide messy, inconsistent documentation. We provide data quickly to enable client decision-making, assign a single point of contact per project to avoid confusion, prioritize communication and proactive problem-solving, maintain a "source of truth" for data to prevent errors, employ a lean review process with relevant SMEs, and operate a clean, organized facility that reflects our competence and control. We are also building a secure, password-protected portal that will enable clients to access their project data in real time.

Q: What is the status of the Emeryville, CA manufacturing facility?

Dadson: Our state-of-the-art plant, completed in 2024, was designed from the ground up with FDA input for commercial manufacturing. It houses four 2,000-liter bioreactors, in-house cell line development, purification, fill-finish, labeling, and packaging, and dedicated QC with brand-new instruments, all in one building. This design allows customers to go from vector construction to product distribution in one location.

Since acquiring Agenus, Zydus has focused on fully validating the facility and moving all production operations to the site. The goal is to complete commissioning and qualification for GMP readiness by Q4 2026, with engineering runs planned for September. This includes not only preparing the equipment and facility but also installing and implementing a phase-appropriate quality infrastructure and other support systems to ensure compliance.

Q: How is staffing the Emeryville facility going?

Sharma: Beyond the leadership team, about 50-plus people at the Emeryville facility have worked together for two decades or more, engaged in process and technical development and manufacturing. We have already added to these numbers, selecting from the highly talented and skilled pool of workers in the San Francisco area.

Today we are approaching a total of a hundred employees, a milestone we reached in just six months.

The strong response from prospective employees reflects the culture we are building. New team members consistently point to the organization's scientific expertise, collaborative environment,

and shared commitment to developing therapies that make a difference for patients. We are also a highly diverse team that values inclusion, respect, and continuous improvement. Everyone has a voice, regardless of tenure or role, and that spirit of collaboration, combined with the team's deep experience and passion for science, has been a key factor in attracting and retaining talent.

Q: Is anything being done with the second facility in Berkeley, CA?

Dadson: Currently, the focus is on the Emeryville facility, but Zylidac fully owns the Berkeley facility and may use it for specific needs in the future. It is a development facility that can support Phase 1 and 2 production and has been used to produce clinical drug substance for many years. While a very good facility, it is not suitable for commercial manufacturing.

Q: How does starting out with a contract for two commercial products benefit new clients coming to Zylidac?

Lavezoli: First, Agenus's and Zydus' decision to entrust Zylidac with two commercial products reflects confidence in our technical capabilities, manufacturing expertise, and quality systems. Supporting commercial programs requires robust process control, regulatory compliance, and supply chain management. In addition, having an established commercial manufacturing base from day one means clients benefit from operational maturity, strong quality oversight, and a team experienced in supporting products from development through commercialization. This allows us to focus on projects that are the right technical fit and provide clients with the expertise and attention needed to accelerate their programs.



Q: What types of services will Zylidac be offering? Will it be a specialized CDMO or one that can support clients across the full development cycle?

Lavezoli: Definitely the latter. We can support clients from cell-line development through labeling, packaging, and distribution from a GMP warehouse. We can develop the cell line, and perform early process development. Clones are handed off for upstream and downstream process development and drug substance manufacturing, final product formulation development and production, analytical method development, fill/finish in vials, syringes, or cartridges, and handling of temperature-sensitive products.

So instead of working with multiple service providers and managing numerous tech transfers, our customers can keep their programs with Zylidac and have a single project manager guide them until the product ships. They also don't have to worry about proper low-temperature packaging and shipment of drug substance—it can be formulated, filled, labeled and packaged all in one facility.

Q: What are the benefits of offering such comprehensive services at one facility?

Sharma: The biggest benefits for clients include eliminating tech-transfer risks, and shortening time to market. With decades of experience working together, our cell-line development and upstream teams ensure seamless handoffs and collaboration with downstream process development, analytical development, and drug product development within a single facility. Keeping critical development and manufacturing activities under one roof and under a single quality system also reduces reliance on multiple vendors and minimizes supply chain and cross-border coordination risks. A single project manager preserves legacy knowledge throughout the process. As a result, clients don't face the setbacks and hiccups that inevitably occur when transferring a program from one facility or CDMO to another.

Q: What details can you share about the tech transfer experience of the Zylidac team?

Dadson: For many years at Agenesis, the team managed numerous Phase 1 and 2 projects at the Berkeley facility. When those projects reached Phase 3, they transferred them to other CDMOs, and the team facilitated those tech transfers. We didn't just hand the processes

over and stand on the sidelines. We negotiated with the receiving CDMOs to ensure our active participation as the processes moved toward validation and became commercial-ready. As a result, we have extensive experience transferring processes, which helps us accelerate drug development within the Emeryville facility. There is also no siloing here. Our teams include representatives from many specialized functions, and we avoid communication gaps or miscommunication.

In addition to that foundation, we have strengthened our organization by bringing in experienced CDMO professionals with expertise across development, technology transfer, manufacturing, quality, and regulatory operations.

Q: What types of clients is Zylidac working to attract?

Lavezoli: We welcome clients that run the gamut from small, emerging biotechs to large biopharma companies. Customers can bring us a DNA sequence and need help with everything from cell line development. Others may have a fully developed process and need routine commercial manufacturing, process monitoring, and long-term continuous improvement. We have the capacity and capabilities to support both types of clients and everything in between.

Q: Overall, what do you see as the core differentiators for Zylidac compared to other biopharma CDMOs?

Lavezoli: The combination of several key attributes adds up to real differentiation compared to other CDMOs. Those factors include:

- Our long-term shared experience working with multiple, varied clinical and commercial products;
- The cohesiveness and longevity of the Zylidac team and backing of Zydus;
- Our unique experience as former clients working with CDMOs and the problems that we need to avoid; and
- Our ability to support projects from DNA to distribution in a single, state-of-the-art facility, saving clients significant time (12-24 months) and money by eliminating risky, lengthy tech transfers between vendors.

We look forward to applying our expertise and state-of-the-art facility to support organizations seeking a collaborative partner to advance their biologics programs. [Contact us](#) to discuss how we can help.

FEATURED



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