

Unlocking the Future

Insights into Biologics and Pharmaceutical Manufacturing

Bill Humphries, CEO of Alcami, a global player in the pharmaceutical and biotechnology sectors, sits down for an exclusive interview with Christene Smith from CHEManager International. In this conversation, Humphries unveils his ambitious plans and vision for the future, offering a unique perspective on the dynamic trends currently shaping the market. Steering Alcami's growth trajectory, Humphries shares insights into the company's commitment to excellence and innovation. From the development of cutting-edge pharmaceutical solutions to the navigation of global market complexities, Alcami, under Humphries' leadership, is poised to redefine the industry's landscape. This enlightening conversation explores Alcami's strategic direction, accomplishments, and the challenges that lie ahead.

CHEManager International: *Since taking over as CEO in June last year, you have led Alcami through the acquisition of Pacific Pharmaceutical Services (PPS) and initiated partnerships with other companies. Could you elaborate on how these activities enhance Alcami's offerings?*

Bill Humphries: Our acquisitions and partnerships are strategic and intentional, based on both opportunity and careful planning. Our company has six campuses right now, and prior to the PPS acquisition, the furthest West we went was St. Louis, and so there's an entire ecosystem on the West Coast that may or may not know the Alcami name because they don't get to inter-

act with us regionally as much as others do, say in the Carolinas or in the Northeast. The acquisition of PPS allowed us to plant an Alcami flag on the West Coast. This not only broadens our geographical reach but also allows us to serve a new base of clients who may not have known Alcami.

PPS tended to work with organizations with more pre-clinical assets, and so introduced us to early-stage clients who we hadn't worked with before, as we'd mainly focused on clinical and commercial. That's created an opportunity for us to share the other services we offer with these new clients, from storage and pharma services to lab services and drug product manufacturing.

In January 2023, Alcami was acquired by Global Healthcare Opportunities (GHO) Capital Partners and The Vistria Group. Has this change in ownership influenced the strategic and operational direction of Alcami?

B. Humphries: The acquisition hasn't changed us, but rather enhanced us. With Madison Dearborn's exit and Ampersand's stay, we've gained the support of one of the world's preeminent healthcare private equity firms. Joining forces with GHO and Vistria has brought us incredible sponsors, board members, and collaborators.

GHO, with its deep bench in life sciences, and Vistria, a newer entrant into healthcare services, have both proven their depth and value. One of the best outcomes of this partnership is Pat Walsh, our former CEO, staying on as chairman of the board. His leadership has been instrumental in navigating our company forward.

With the combined strengths of Ampersand, GHO, and Vistria, we've become stronger. GHO's transatlantic thesis is particularly beneficial as we look to grow beyond our US-only business. With the acquisition of PPS, we've expanded across the United States and are now thinking more globally. We have plenty of organic growth ahead, but this partnership equips us well for inorganic growth too.

Which market sectors do you address and how is Alcami positioned in these markets in terms of portfolio range and core competences?

B. Humphries: We provide three primary services: drug product, laboratory services, and pharma storage services.

In drug product, we offer formulation development, tech transfer, manufacturing, and packaging for sterile fill finish and oral solid dose. We have facilities in Charleston, South Carolina, Research Triangle Park, North Carolina and Wilmington, North Carolina where we manufacture everything from vials to prefilled syringes and capsules to tablets. We cater to both big pharma and smaller biotech companies with a focus on clinical to commercial programs.

Our laboratory services cover almost all capabilities with the excep-



Bill Humphries, CEO, Alcami

tion of NMR, although we are in talks with a client about potentially offering it in the future. We have labs in Wilmington, Research Triangle Park, Charleston, and St. Louis, offering services from release and stability testing to method development and validation for both small molecules and biologics.

Our pharma storage services handle everything from room temperature to ultra-cold storage, including aliquoting/fractioning to delivery and pickup. We also offer validation and calibration services.

These primary services create a synergistic flywheel, allowing us to manage a client's product from manufacture to storage. Our project managers work by client, not by service offering, ensuring continuity for clients.

Do you think that the consolidation of the CDMO market will continue or even accelerate? What do you identify as the underlying drivers of this consolidation phase?

B. Humphries: I have two perspectives. Firstly, companies like Novo Nordisk and Lilly strategically acquire to ensure capacity, like Novo buying Catalent and Lilly buying the Nexus site. This trend might not continue unless there's a new wide-reaching molecule, similar to Botox or GLP-1s.

Secondly, private equity or strategic CDMOs will continue to be opportunistic, looking for assets that fill





their needs or provide growth potential. While it may not be rapid, I believe firms will continue to strategically build their portfolios with the best in breed.

The outsourcing trend in the industry has been prominent. Do you expect this to continue, and will the reshoring of critical substances or intermediates play a significant role in capacity build-up in Europe or the US?

B. Humphries: So, on outsourcing, look, I think that's going to continue, Pharma companies are managing their head count and deployment of capital. They will discern which services to own and which to outsource, driving outsourcing decisions that benefit their molecules, companies, and patients.

Reshoring has potential to be a tailwind for the industry, with shifts like the Biosecure Act. Companies like Phlow, under Eric Edwards' leadership, are thinking about how to ensure we have a stockpile of important medicines to serve our own citizens here in the United States.

I foresee a migration from WuXi to US-based CDMOs, with companies like Civica aiming to gain more control for the American population. This reshoring trend is about controlling our own destiny and being able to treat our own citizens.

Alcami has a long history in biologics manufacturing. Could you discuss Alcami's current biologics production capacity and any future expansion plans?

B. Humphries: We have two locations for biologics drug product manufac-



Alcami's advanced pharma storage and services facility in Garner, NC, USA

turing: Charleston, South Carolina and Research Triangle Park, North Carolina. In Charleston, we have two lines, one legacy lyophilization (Lyo) line and a newly commissioned dual Lyo automated isolator filling line. These lines can also handle liquid vials, offering flexibility for clients.

In Research Triangle Park, we have four isolator filling lines. One is a pre-filled syringe line, which we've recently qualified for larger batch sizes. Pre-filled syringes are becoming increasingly important. The second line is a traditional liquid vial line. The other two are Lyo vial lines that are under commissioning and set to be operational in 2024.

We continue to listen to our clients' needs as we build for the future. We believe large molecules are here to stay, though small molecules are not going away. Some of these will require different deliveries, like different vial

sizes or cartridges, or different types of assembly for pre-filled syringes. We're always listening to our clients and considering their needs in our future investments.

How crucial are the pharmaceutical storage capacities and services that Alcami provides to its overall operations?

B. Humphries: Our pharma storage facilities, mirroring the biotech triangle of Boston, San Francisco, and Research Triangle Park, are crucial to our business. However, the services we provide there, such as aliquoting, provides a value-add to our customers and expands our lab services reach.

Cold storage is becoming increasingly vital, especially with the growth of large molecules. By offering additional services and storage, we can

keep the molecule within our ecosystem. This minimizes the chance for quality issues and allows us to fully serve the client's needs.

Having storage capacity together with our other services is paramount to our success.

In terms of customer needs, where do you see market trends that Alcami aims to support and benefit from?

B. Humphries: We're focusing on large molecules growth, considering how we serve this trend with our current and future lines, and our center of excellence in Research Triangle Park, for large molecule biologics characterization and testing. We continue to invest in sterile fill finish, lyophilization, and other deliveries to capitalize on this trend.

Cold storage is another area where we see a growing need. We're ensuring that our storage facilities offer this and have room to expand these services. We offer a courier service as we feel that having the ability to transport samples or products to and from sponsors or clients to our testing facilities, particularly in Wilmington and Research Triangle Park, is crucial.

The services we provide as part of our pharma storage and services business, notably aliquoting, clinical trial supplies, and labeling, are key. We anticipate that clinical trials and the need for sampling will continue. The demand for cold storage, and even ambient storage, is only increasing. This all ties back to our focus and belief in the continued growth of large molecules-based products.

www.alcami.com



Accelerating Your Peptide to Market

- US Headquarters
- Global Peptide Manufacturing & Development
- NCE Peptide APIs & GLP-1 Agonists
- FDA-Inspected Facilities
- Sustainable & Green Chemistry (EcoVadis certified)
- Research, Clinical, & Large Commercial Scales
- Experts in SPPS, LPPS, & Hybrid Synthesis



US Campus & HQ



Shanghai Campus

CPHI Milan - Join us at booth 1B105

Learn more > www.ambiofarm.com