An Evolving Biologics Landscape and Driving Innovation and Opportunity

As seen in Pharma's Almanac

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Tim Roberts is Chief Commercial Officer at PCI Pharma Services and is responsible for their global multi-segment Sales team and aligning PCI's go-to-market strategies across Clinical, Commercial and CDMO. With over 22 years pharmaceutical packaging and manufacturing experience and a proven track record of organizational/revenue growth, Tim is highly service-oriented with a firm understanding of the full business equation, client service and consultation. Previously Tim successfully led PCI's Global Clinical & Manufacturing Sales Team, where his entrepreneurial leadership style and passion made a significant and positive impact on team members, overall business results and most importantly PCI's client base. Prior to joining PCI, Tim delivered strong results within similar healthcare solution providers focused on sales, program management and operations leadership roles.

The biologics segment, already growing in importance before the COVID-19 pandemic, is expanding even faster in its wake with respect to both the level of investment and number of new startups. PCI Pharma Services is keeping pace with the changes and remaining focused on addressing the growing need for outsourcing support by these new small and medium-sized biopharmaceutical companies.

COVID-19 Pandemic Drives Greater Investment in Biologics R&D

Interest and investment in biologic drugs were accelerating before the COVID-19 pandemic, because biologics offer a richness of new avenues for treating disease. With their ability to bind to receptors and interact with specific cells, targeted therapies operating by entirely new mechanisms of action are possible. The value of biologics became even more prevalent during the race to develop vaccines and therapeutics against the SARS-CoV-2 virus.

The pandemic provided a new global lens through which investors viewed the healthcare sector. There is an even greater case today for investment in healthcare and specifically in research and development of new drug candidates, most notably biologics and large molecules.

While the majority of approved drugs on the market are formulated with small molecule APIs, the rate at which small molecule drug candidates are entering the clinic is decelerating. Drugs based on biomolecules, on the other hand, are growing in number at an accelerating rate. There's only a finite period of time until biologics will dominate the market.

This trend toward biologics and greater investment in small and emerging biotech companies is clearly reflected by our experience at PCI Pharma Services. In the last year alone, we have welcomed 50% more new customers — not customers switching from one CDMO to another, but new entrants into the market — than we have had in any previous year.

More Collaborative Investment Model

The increase in investment in emerging and mid-sized biopharmaceutical companies is in part driven by excitement about our increasing understanding of human biology and disease mechanisms combined with increased innovation leading to the continual introduction of new technologies. That excitement is often injected into investment houses via active participation of people who have served as CEOs or CTOs or in other leadership positions with small and mid-sized pharmaceutical companies, whether as advisors or operating partners.

The small and emerging biotechs receiving investment funds are benefitting greatly as a result. There is a much more collaborative investment model in play today. In addition to an influx of cash from investors, companies are gaining access to the knowledge and experience that leaders in the industry bring to the table. The result is a more collaborative approach to drug development than has ever existed before.

Opportunities and Challenges Created by Operation Warp Speed

Operation Warp Speed — if nothing else — has shown how a collaborative approach to drug development can lead to great accomplishments, not only commercially, but with respect to solving problems and technology development in general. The push to develop COVID-19 vaccines and therapeutics to manufacture billions of doses has, however, placed strains on the supply chain.

Many of the largest CDMOs are focused on producing as many doses as possible, and the effort is consuming capacity for not only drug manufacturing but the production of pharmaceutical-grade glass vials, syringes, stoppers, crimpers, and so on. As a result, there is little capacity left for non-COVID medicines.

In particular, there is a severe shortage of small-scale capacity for the sterile fill/finish of small-volume products (a few hundred vials), such as oncology therapies into prefilled syringes. As a result, there is a real need for specialist niche capacities, whether that is for the production of Phase I or Phase II clinical trial material for novel therapies or commercial products that treat rare or orphan diseases. This issue will only become more intense given the rate at which new biopharma startups are being formed.

Changing Healthcare with Personalized Medicines

Those innovations are increasingly driving the industry toward personalized medicines, which ultimately will be the end of traditional healthcare as we know it. One example is autologous cell therapies that involve changing patient cells outside the body, growing them up, and then readministering them to the patient. These and other biological treatments, such as gene therapies, have the real potential to cure diseases and eliminate the need for ongoing doctor visits and frequent and repeated treatments for even very challenging disorders.

Other technology advances include CRISPR gene editing and mRNA therapies. All of these technologies are at the baseline, initial level of development. The potential for further significant advances is tremendous. The ultimate goal for cell therapies, for instance, is to develop autologous, off-the-shelf treatments for widespread diseases, such as diabetes. The hope and the prayer for humanity is that, through diving deeper into the biology of rare diseases, scientists will be able to unlock

Need for Greater Public Awareness of Pharmaceutical Development

One potentially positive outcome of the COVID-19 pandemic has been the focus on the development of therapies and vaccines to fight this terrible disease. Even though the pharmaceutical industry has been in the spotlight, not enough has been done to educate the general public about the complexity and time-consuming nature of drug development.

With every relevant stakeholder committed to achieving the commercialization of new therapies and vaccines, development of the COVID-19 vaccines was realized in less than one year. But that success was only possible because of the work on mRNA and viral vector technologies that had been completed over the previous 10–20 years.

Indeed, vaccine technologies have been evolving ever since the first vaccines were introduced. We no longer collect samples from pustules on infected people or animals and inject them into healthy people. Most recent vaccines are based on recombinant proteins produced via established cell culture processes rather than live or killed viruses. Leveraging RNA and DNA technology was a natural next step and one that has been explored extensively.

That foundational work — and the unheard-of level of cooperation across the supply chain from raw material and equipment suppliers to manufacturers to governments and insurers — is what made the accelerated development timeline possible. People need to understand that it takes years to establish the deep level of understanding of new technologies necessary to ensure safety and efficacy and get new drugs and vaccines based on those technologies to patients.

Fortunately, researchers and scientists in the biopharmaceutical industry are driven to find new technologies that will help treat and ideally cure diseases, so there are always many new technologies under development and moving towards the point where they can be safely applied.

the knowledge needed to achieve major advances in biopharmaceutical technology.

New Delivery Devices Impactful

Advances are not just occurring in the development of novel biologic drug substances. Significant progress is also being made in the development of novel devices and delivery technologies that improve the administration of complex biologic drugs — particularly with respect to devices designed to enable self-administration, such as prefilled syringes and on-body delivery systems. The goal is to make it as easy and convenient for patients and caregivers to deliver the right dose of medicine in the right place at the right time, even for some biologics that have in the past required intravenous administration.

One noteworthy example is the development of fast-acting insulin, which is now delivered as micro doses by wearable insulin pumps. Fifteen years ago, patients were mixing their own insulin.

There are also significant research efforts focused on developing solutions for the oral delivery of biologics, which is by far the preferred method of administration. Of course, changing the delivery method can impact how the drug behaves in the body at different times — where it is distributed or how quickly it is degraded, for instance, which determines bioavailability. That in turn affects how the body reacts and thus the efficacy of the drug.

Maintaining Balanced Development

The industry does need to be careful, however, about balancing development efforts. Personalized medicines are clearly enabling much better treatment of many different diseases. However, the shift in emphasis away from developing drug candidates that treat common diseases to highly targeted medicines that often treat specialized cancers and rare diseases must not come at the cost of finding solutions for the millions of patients suffering from diabetes and heart disease. Technology developers should also be working to identify curative treatments for these types of diseases that afflict so many people around the world.

Transformation from Biopharma to Biopharma Technology Companies

The increasing role of technology in both novel therapies and delivery approaches is leading to a transformation of biopharmaceutical companies. They are no longer simply seeking to identify new potential drug candidates. Whether it is antibody–drug conjugates, mRNA therapies, AAV vectors, or CRISPR tools, companies are focused on identifying new mechanisms of action and new modalities to leverage them. They are also often establishing technology platforms for the discovery, development, and manufacture of those novel drugs. As a result, many have become biopharmaceutical technology companies.

Natural Evolution in the CDMO Space

Changes are also occurring in the biopharmaceutical CDMO space as well. CDMOs are getting involved earlier in the development cycle than they have in the past. That requires highly specialized skills and expertise, and some CDMOs are looking to establish a competitive advantage by offering these capabilities. More recently, some of the smaller CDMOs that have garnered a foothold in this area have been acquired by larger CDMOs to expand their offerings across entire drug development spectrum from discovery to commercialization. Access to better technological insights into cellular functions can benefit all aspects of drug development projects.

There has, in fact, been significant merger and acquisition activity among CDMOs as strong firms seek to grow and offer a wider array of capabilities across both small and large molecule drug substance and drug product manufacturing in many different geographies.

Smaller CDMOs continue to be formed, however. Just as CEOs and CTOs of Big Pharma companies leave to start their own firms, spin-offs are always being created in the CDMO sector. There is a role to play for all sizes of CDMOs in different locations with different specialized capabilities and equipment volumes and different business models with different levels of service. Drug developers vary from the small to the large and require different levels of

support. Similarly, specific projects vary in volume and complexity. The key for CDMOs is to offer their customers the appropriate level of support and loyalty to meet their customers' needs.

Providing More than Capacity at PCI Pharma Services

PCI Pharma Services is committed to helping small and medium-sized biopharmaceutical companies get their drug candidates — both chemical and biologic — into the clinic and to patients. We all know someone affected by a devastating disease, and the desire to get them the new treatments they need is genuinely what drives us.

It is our strategy at PCI to provide these organizations with a partner that truly listens. We work hard to make sure they realize we are invested in their success. The higher cost of goods and additional challenges of cold chain management create greater risk for biologics. We provide a tailored service designed to facilitate accelerated development, commercialization, and launch of biologics while minimizing that risk.

In addition, for small and medium-sized companies developing mRNA therapies, monoclonal antibodies, proteins, oligonucleotides, and other biologics, we recognize that there is much more to being an effective CDMO partner than providing manufacturing capacity. They need an outsourcing partner with the right culture and organizational fit, which is a focus at PCI. These innovators also need a CDMO with integrated capabilities that can support clients with drug development, manufacturing and packaging needs, reducing supply chain complexity, and accelerating speed to market for their much-needed treatments.

PCI has taken steps in recent years to provide that full spectrum of capabilities. Most recently (October 2021), we signed a definitive agreement to acquire Lyophilization Services of New England, Inc. (LSNE), a premier CDMO with high-quality cGMP aseptic fill/finish capabilities and expertise in and ability to scale lyophilization, an important manufacturing process commonly used with injectable and biologic therapies.

LSNE marks our fourth acquisition in three years, all of which have been designed to enhance our global specialty manufacturing capabilities and expand our clinical and commercial packaging expertise. Other significant investments in our biologics capabilities include the expansion of cold-chain clinical supply storage and distribution capabilities at several locations around the world and expansion of biologics clinical and commercial packaging and release testing capabilities at our Biologics Center of Excellence in Philadelphia.

Clients of PCI also benefit from our approach to leveraging digitization and technology, which we refer to as The PCI Way. Significant investments have been made as PCI has traveled on its digital transformation journey with the goal of improving our processes, increasing both efficiency and transparency and effectively transforming the firm from a successful packaging and labeling company to a successful pharmaceutical supply chain company.

Our pci | bridge digital solution provides real-time supply-chain information, including inventory, production, distribution and shipping data, to customers. This platform technology enables customers of PCI Pharma Services to make informed decisions based on real-time insights, collaborate more effectively, speed validations, create customized reports for greater efficiency, and do so knowing their sensitive project information and data is protected in a cyber-secured platform.

Overall, our solution-focused culture and broad range of capabilities enable us to provide seamless service throughout the development journey for even the most complex supply chains. As a result, PCI Pharma Services is an important bridge between our clients and the patients for whom they are developing novel, life-improving, and lifesaving medicines.