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7 CEOs Say It's About The "Bios": Biotechs, Biopharmaceuticals and Biosimilars

By Louis Garguilo (/author/louis-garguilo), Executive Editor, Outsourced Pharma
Follow Me On Twitter @Louis_Garguilo (https://twitter.com/Louis_Garguilo)

It's the booming "Bios" – biotechs, 
(http://vertassets.blob.core.windows.net/image/ca96ad45/ca96ad45-b68f-4016-9ac9-fa76443ce85a/garguilo_photo_2015.jpg) biopharmaceuticals and biosimilars – spurring capital expenditures and technology advancements, supply-and-demand questions and business decisions that grab the attention of our CEOs in this second part on trends they are seeing in 2015. (see part one here (http://www.outsourcedpharma.com/doc/ceos-say-outsourcing-advancing-on-swirling-currents-part-0001))

The FDA approves the first biosimilar for sale in the U.S. market, catching the U.S. up to other global markets. Biotech IPOs and investor sentiments – in the U.S. and increasingly globally – run high: Biotech outperforms other industry groups on stock exchanges in 2014 and into this year. Pharma places sizeable pipeline bets on biologics, and (like it or not) warm up to biosimilars. Technologies like ADCs (antibody drug conjugates) continue to garner investment and help spur the oncology field. In a recent Biotechnology Industry Organization (http://www.bio.org) (BIO) survey, *every company* surveyed said it plans on maintaining or increasing its contract service budget over the coming year.

Impressive … but caution, you're entering a no spin zone. (Sort of.)

Biologics Bouncing Supply And Demand

Stephan Kutzer, CEO at AAI Pharma Services (http://aaipharma.com)/Cambridge Major, keeps an historic eye on current supply and demand. Kutzer, who spent years at Lonza (http://www.lonza.com), sees demand for biologics services growing – particularly for large-scale mammalian-based programs – to the point of creating a "short-term accessible capacity shortage."

He points to multiple programs throughout the global biopharma industry reaching Phase III and adding to a "short-term peak in demand for clinical supply and launch material." Notice the modifier "short-term" in both quotes.

"While multiple players have announced capacity additions, demand expectations have to be carefully evaluated," says Kutzer. "I think supply and demand will balance out as early as 2017." He adds this historic caution: "The industry is experiencing the same 'yoyo' effect as in 2006, when due to short-term capacity shortage and overstated product demand, construction of several new production sites were started." Left unstated – too painful to say? – is that many of these sites were left empty of new orders.

If Peter Coleman, CEO at Cobra Biologics (http://www.cobrabio.com), shares those concerns for future demand, they are tempered by current orders. Leaders need to focus on the future, but they get there by meeting current customer needs.

"We've seen more orders from large pharma interested in biologics outsourcing," says Coleman. "There's also strong growth in gene-therapy products, both GMP and non-GMP DNA, virus and other products." Cobra has decided to make investments to meet the demand that Kutzer (and some others) are a bit more cautionary about.

"We've taken on extra capacity for DNA with the purchase of a microbial disposable SUB unit, and have a new 1000L SUB mammalian bioreactor. We've invested in a dedicated fast throughput HQ DNA lab, to name a few," says Coleman. He's also recruiting the scientists to deliver the additional revenues that should flow from these investments, including a new CSO "to determine what the next trend will be."

WuXi PharmaTech (http://www.wuxiapptec.com) Chairman and CEO, Dr. Ge Li, never one to spurn new investment or hesitate to head into new markets, is bullish in spades. His company invested in new capabilities and technologies throughout 2014, including in manufacturing, biologics and genomics, as he says, "to sustain our business growth."

Among other projects, WuXi has begun construction of commercial-scale biologics manufacturing facilities in Wuxi city with construction planned for completion in late 2016. There're also the two cell-therapy manufacturing facilities in Philadelphia that are scheduled for completion in 2015 and 2016, respectively.

And while above Coleman of Cobra sees pharma customers on the move, Jim Foster, Chairman, President and CEO of Charles River (http://www.criver.com), sees things a bit differently.

"Biotechs are increasingly becoming the discovery engine for pharmaceutical companies," he says. According to Foster, virtual biotech clients are also benefiting from robust funding, both from the capital markets and from global biopharma. These start-ups find themselves with the funds to invest more heavily in their drug pipelines. Foster also mentions that partnerships with life-science venture-capital firms help develop strategic relationships with emerging biotech companies.

"As a result of all this," he says, "for the last two years we had more sales to biotech customers than to our pharmaceutical clients."

Final (Bios)Analysis

We've focused part two of our CEO discussion on the "Bios," as we're calling the triumvirate of biotechs, biopharmaceuticals and biosimilars. However, to be clear none of our CEOs see nor forecast a slowdown in work on the small molecule side. In the biopharma engine, all pistons seem to be running in unison at full speed.

Neither can therapeutic category be overlooked as a contributing business driver. Despite the talk of the end of the blockbuster era and the onset of personalized medicine, Vivek Sharma, CEO, Pharma Solutions, Piramal Enterprises (http://www.piramal.com/piramal-enterprises), for example, doesn't overlook the importance in the growth of oncology-focused research, and the new science and technologies to support the efforts. He says that recognizing this customer emphasis, Piramal has invested and grown its ADC business and associated capabilities, such as sterile injectables. "We've observed a growing need for quality capacity in this space, and we want to continue as one of the global leaders in ADC manufacture," he says.

Another example of a company investing in technology platforms to lure customers is Catalent (http://www.catalent.com/index.php). In 2014, it bolstered its own ADC technology with the acquisition of Redwood Bioscience, for example.

In part one of this investigation, we looked at the potential for biopharma to acquire CDMOs (and suppliers) and thus bring the supply chain in-house to handle recent issues of control, quality and product shortages. We also mentioned the continued search for more strategic provider-sponsor relationships. Could these two feed off of each other?

If pharmaceutical manufactures are in fact dissatisfied with attempts to garner more strategic partnerships – most specifically right now from its supply chain – perhaps in some cases that will push them to more in-house manufacturing. How pervasive this actually becomes can't be predicted by our CEOs yet, or perhaps even manufactures themselves. And it won't be for a lack of trying to forge relationships on the part of service providers (and in most cases supply-chain suppliers) if this does occur.

Tim Scott, President, Pharmatek Laboratories (http://www.pharmatek.com), says, "As an industry, I would argue we are still learning how to use the outsourcing model. Some companies are good at it and some are not. I think we'll see modifications to the model going forward, and blended outsourcing based on the skill set and technology a company has in-house. We'll see new kinds of partnerships."

For the time being at least, the consistent growth that has brought the biopharma outsourcing industry back from a difficult recessionary period just a few years ago, looks to continue.

"It's good to once again be talking with clients about how we can help them get many more shots on goal," says Scott.