CHRISTOPHER MOLINEAUX discusses the challenges impacting the bioscience industry.

The requirements that bioscience companies have to meet to attract funding have become much more rigorous. They have to prove the probability of technical and regulatory success and they have to prove that they will be able to get reimbursement for the product.

Christopher Molineaux, President of Pennsylvania Bio, is helping to advance the mission of developing a community that unites the region's biotechnology, pharmaceutical, medical device, and diagnostic strengths. He discusses some of the biggest challenges facing bioscience companies today.

CURRENT CHALLENGES IN BIOSCIENCE

What are some of the hot button issues in biotechnology today?

MOLINEAUX. For small companies, it is all about funding and the difficulties associated with raising capital. There is a great deal of risk aversion in the capital community today, which is making things exceedingly difficult. Smaller companies are spending a lot of time trying to piece together syndicates of funding so they can survive. The requirements that bioscience companies have to meet to attract a venture fund have become much more rigorous. They have to prove the probability of technical and regulatory success. They have to be able to prove efficacy and safety. And they have to prove that they will be able to get reimbursement for the product.

Midsized bioscience companies that are starting to generate a profit face not only funding issues but policy issues, regulatory scrutiny, increased disclosure requirements, increased marketing surveillance, and all types of taxes that are really tough to handle for a company that just earned its first dollar.

For larger companies, there is healthcare reform and its implications. These companies are also grappling on the state level with preferred drug lists, public policy issues, and looking at the next best opportunities to build their portfolios, whether this comes from their organic pipelines — compounds in development — or licensing or acquisition deals.

CONNECTING SCIENTISTS AND OPPORTUNITIES

With bioscience providing an opportunity for scientists displaced by large pharma, what will the job market look like in Pennsylvania in the future?

MOLINEAUX. We are looking at a future model where there are more small organizations and fewer larger organizations doing the work that specific departments used to do in pharmaceutical companies. For example, a lot of clinical development work, analytical work, some sales and marketing functions, and some of the nonstrategic functions, such as human resources, can be outsourced and allow a company not to carry a large overhead.

We can connect the unemployed scientist who has a specialty or an area of therapeutic focus with an asset, compound, or technology that might be sitting on the shelf undeveloped in a pharma company and then bring in a third element of investment, whether it is government funding through grants or private equity or venture capital money. This is all part of our mission to be a catalyst to ensure that Pennsylvania is a global leader in the biosciences by connecting our diverse strengths. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Editor's Note: Registration is open for Biotech 2010, the annual PA/NJ/DE conference, October 27-28, 2010, Pennsylvania Convention Center, Philadelphia. For more information visit pennsylvaniabio.org.

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PENNSYLVANIA'S BIOSCIENCE INDUSTRY

- 81,000 bioscience jobs across 1,900 business establishments; with the multiplier effect, there is an employment impact of 354,300.
- $82,262 in average annual wages for a bioscience worker in the state, nearly twice the average private sector wage ($44,107) for all workers in the state.
- From 2001-2008, growth in the biosciences has occurred at almost five times the rate of the total private sector in Pennsylvania.
- Strong and specialized employment in two of the four major bioscience subsectors: drugs and pharmaceuticals, as well as research, testing, and medical laboratories.
- Pennsylvania ranks 4th in terms of bioscience-related patents issued.
- Pennsylvania ranks 4th among all states in bioscience academic R&D expenditures.
- Among all states, Pennsylvania ranks 4th in total research awards from the National Institutes of Health in FY 2009.
- Almost 850 clinical trials were initiated in Pennsylvania in 2009, ranking the state 5th nationally.

Source: State Bioscience Initiative 2010 Report conducted by Battelle and BIO

CAREER Highlights

As president of Pennsylvania Bio, Christopher Molineaux serves as spokesman for the bioscience industry in Pennsylvania, which includes biotechnology, device, diagnostic, pharmaceutical, research organizations, and the support networks in Pennsylvania.

Mr. Molineaux joined Pennsylvania Bio in September 2009 as senior VP for membership services. Before that, he served as worldwide VP of pharmaceutical communication and public affairs for Johnson & Johnson.

Mr. Molineaux is co-chair of We Work for Health Pennsylvania and is on the board of directors of the Chester County Economic Development Council. He also serves on the Hershey Center for Applied Research Scientific Advisory Committee, the University City Science Center Community Development Committee, and the Health & Science Advisory Committee at WHYY in Philadelphia.

PENNSYLVANIA: STRENGTHS ACROSS THE COMMONWEALTH

Many states boast of a single cluster of bioscience activity. Pennsylvania, however, has strengths across the Commonwealth.

- The Greater Philadelphia region ranks 2nd nationwide in bioscience strengths and is a global powerhouse in biopharmaceuticals.
- Central Pennsylvania has growing industry clusters in the State College, Harrisburg, Lehigh Valley, and the Scranton-Wilkes Barre areas.
- In addition to its established device and diagnostic center, Pittsburgh is internationally recognized for its strengths in tissue/organ engineering and regenerative medicine, and drug discovery tools and diagnostics.

Source: Pennsylvania Bio. For more information, visit pennsylvaniabio.org.

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BY DENISE MYSHKO

Biosimilars, Reimbursement, and GREENHOUSES

On March 30, 2010, President Barack Obama signed into law a reconciliation bill that finalizes Congress' healthcare reform legislation, the Patient Protection and Affordable Care Act. In addition to the much-discussed provisions regarding health insurance, the act creates a regulatory pathway for the approval of follow-on biologics (FOBs).

Key features of the Biologics Price Competition and Innovation Act include:

- Twelve years of market exclusivity (with a possible further six months of pediatric exclusivity) for pioneer products during which time FOB applications cannot be approved.
- Two standards of FOB approval — biosimilarity and interchangeability — to be implemented by the Secretary of Health and Human Services.
- Exclusivity for the first FOB product found to be interchangeable with the pioneer product.
- Confidential, choreographed exchanges of highly detailed, substantive disclosures between the FOB applicant and the pioneer regarding the FOB product, pioneer patents, and the parties' respective contentions relating to the product and the patents.

OPPORTUNITIES IN PENNSYLVANIA

Pennsylvania is unique in that it is home to the entire continuum of the biosciences: world-class basic research, emerging companies, mature industry, and global pharmaceuticals. These all interact to create a strong, vibrant community that is not found in other places.

Research institutions in Pennsylvania garnered about $1.66 billion in NIH funding in FY 2009. Two universities — University of Pennsylvania and the University of Pittsburgh — consistently rank in the top 10 in the nation.

From these research institutions have come new therapies, new devices, and innovative academic/industry partnerships. The University of Pennsylvania is among the most prestigious and accomplished research universities in the country, with more than $750 million in NIH funding in 2008. Penn's 12 graduate and professional schools generated 330 new disclosures in 2008. In addition, the University of Pittsburgh, in FY 2008, had 244 invention disclosures, 58 licensing and option agreements, was awarded 36 patents, and started 3 companies. Also in FY 2008, Pitt's total revenue from intellectual property transfers was about $9.09 million.

Source: Pennsylvania Bio

The new act differs from the Hatch-Waxman Act in several significant procedural and substantive ways. Although some of the act's impact will not be clear until the FDA sets specific guidelines and requirements, several provisions will impact patent litigation, as well as FDA practice.

According to Christopher Molineaux, president of Pennsylvania Bio, the legislation allows for compounds that are similar enough to the original molecule to be considered a biosimilar.

"There are certain compounds, particularly in the EPO and the human growth hormone space, that are large and complex molecules but are relatively simple in the biologics space," he says. "And when I say relatively simple, I mean relative to monoclonal antibodies, which are highly complex and are incredibly expensive to make."

Biosimilars were met with open arms by the generic drug industry, he says, because people think the cost of these drugs is going to drop by 70% to 80% just as they have with small molecules.

"The reality is, biologics is an incredibly capital-intensive business," Mr. Molineaux says. "Unlike small molecules where production can be increased more easily, as it is done through chemical synthesis, biologics require significantly more time for fermentation, incubation, and subsequently, for production. To increase the volume of biologic products, companies have to build more manufacturing capacity."

Mr. Molineaux predicts that there will be fewer entrants into the biosimilar space than originally expected.

"But when they do enter, it will be a welcome addition to the marketplace because they will bring down the price, and some products will be more accessible to patients," he says.

Larger bioscience companies, which have the capacity and the knowledge, can create biosimilars based on their innovative products.

"I have a hard time envisioning entrepreneurial companies entering this space because of the tremendous costs," Mr. Molineaux adds. "They need to have the infrastructure in place to be able to take this on; it's not a start-up enterprise."

REIMBURSEMENT ISSUES

The reimbursement environment is becoming more difficult for all companies, not just biologics. The hurdle is innovation. Payers are evaluating whether companies are providing not just incremental improvements but substantial improvements or transformational improvements to patient care. This is the case with biotech and with small-molecule drugs.

"The challenge that companies will face is if their products offer no substantial or transformational improvements; at that point they are not going to be reimbursed, or they are going to be reimbursed at a lower rate," Mr. Molineaux says. "And this will turn away investors and hurt companies' development programs."

THE GREENHOUSE EFFECT

There are opportunities, especially in Pennsylvania, for companies with an entrepreneurial spirit.

"We are helping to make the strategic connections between stakeholders that will make those new entities possible; this is a top priority for Pennsylvania Bio," Mr. Molineaux says.

Pennsylvania's tobacco settlement has enabled growth in the state's bioscience industries. Three of the programs funded under the Tobacco Settlement Act of 2001 have been significant to the growth of the state's life-sciences industry: the Commonwealth Universal Research Enhancement (CURE) Program, the three regional Life Sciences Greenhouses, and the Health Venture Investment Account. ✦

HOW PHYSICIANS SEE BIOSIMILARS

U.S. physicians will require less clinical trial data than physicians in Europe before they are comfortable prescribing biosimilars, according to Decision Resources. In fact, 33% of surveyed U.S. physicians would be comfortable prescribing a biosimilar that launched with only one Phase III study for support, compared with an average of 20% of physicians in France and Germany.

Experts from Decision Resources find that European physicians have less confidence than U.S. physicians in a traditional generics manufacturer to develop large, complex molecules.

Source: Decision Resources. For more information, visit decisionresources.com.

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