



Dr. Broeze credits the company's innovative processes that allow for full-service production from cell-line through delivery as one of the reasons for being honored by the Eastern Technology Council.

THE GROUNDWORK

What steps were undertaken that led to the company being honored by the Eastern Technology Council?

BROEZE: Over the past few years, we have put in place a game plan that involved acquiring new customers, expanding our Princeton, N.J., facility, creating strategic alliances, and focusing on quality services. To the first point, we developed a full portfolio of services, which involved enhancing our project management programs and adding to our salesforce.

Secondly, we completed a \$13 million expansion, which has involved adding services, enhancing our cGMP compliance processes, and bringing a pilot facility on line. The pilot facility allows the scientists who are doing the process development to work side by side with the manufacturing experts to make sure the process is transferred efficiently and effectively. Clients can participate in the pilot plant and are able to see the process transfer. We've also added to and enhanced workflow processes.

The third part of the plan is centered around partnerships. We are always looking for potential strategic partners to help us expand the portfolio of services or technical capabilities that the company can provide.

A recent alliance is with Boehringer Ingelheim (BI), which was signed in 2007. Under this agreement, clients have access to BI's protein expression system; moreover, it provides a pathway to larger-scale manufacturing capabilities when needed.

The final step in our plan centers on quality. This is the name of the game in our business because quality is clients' highest priority. We continue to be focused on developing robust and broad GMP experiences.

Laureate's President and CEO

DR. ROBERT BROEZE

positions the biopharmaceutical development and protein production company for the future.

Over the past few years, Dr. Robert Broeze and his team at Laureate Pharma have improved business growth and driven service innovation, which led to the company being named Emerging Life Science Company of the Year by the Eastern Technology Council.

Focused on two active segments of the biopharmaceutical industry — monoclonal antibodies and recombinant protein products — Laureate and Dr. Broeze have a four-step game plan to move the company forward.

MARK OF A LEADER

What do you believe defines great leadership in the life sciences and particularly in the area of contract manufacturing?

BROEZE: In this business, it's important to be on the cutting edge. Technologies are often changing; clients want the best and most up-to-date technologies built into the processes that are used for the manufacture of their products. To be a leader, it's necessary to stay ahead of the curve with respect to these technologies as they're being developed for the marketplace.

Next, it's essential to provide quality. To be successful, CMOs must have robust documentation systems and strong GMP systems in place; if they don't, they won't survive.

Finally, it's important to have a proven track record since clients are looking for companies with experience— those that have helped other clients get their product into the clinic. It's equally important to have a strong track record with the regulatory agencies since clients are looking for CMOs that have been inspected by the FDA or other regulatory agencies.

THE CUTTING EDGE

What recent technologies have emerged that help CMOs operate, develop, and respond to companies' needs?

BROEZE: There are several advances that have been made over the past few years that have had a huge impact on the contract manufacturing business. One relates to increased protein expression levels — an increase of roughly 10- to 15-fold over the past 10 years. This has allowed companies to make more product using the same size bioreactors, meaning the product lasts longer once it's in the clinic.

The second advancement is related to single-use and disposable technologies in the biopharmaceutical manufacturing space. In protein produc-

CAREER Highlights

Robert J. Broeze, Ph.D., has more than 20 years of experience in the biopharmaceutical industry. His technical expertise spans research, development, characterization, validation, testing, and cGMP manufacture of biopharmaceutical products from pilot to Phase III clinical and commercial scale with a strong emphasis on monoclonal antibody products for therapeutic and diagnostic use. Before joining Laureate in 1999, Dr. Broeze held positions as VP, Biologics Research, at Purdue BioPharma and VP, Operations, at Bard BioPharma. He also has held a variety of positions at Cytogen Corp. and at Collaborative Research. Dr. Broeze worked as a Postdoctoral Fellow in the Department of Molecular Biophysics & Biochemistry at Yale University, where he studied the molecular biology of the interferon system. He is a graduate of Rensselaer Polytechnic Institute, where he earned both his B.S. and Ph.D.

tion, disposable bags— rather than large stainless steel tanks for storage of all types of solutions, including buffers, product, and waste solutions that come through the chromatography processes — can help decrease capital requirements and assure clients that the solutions used for the production and purification of their products are in vessels used only once.

MEETING THE CHALLENGES

What do you regard as the biggest challenges facing CMOs and how can companies respond?

BROEZE: One of the biggest challenges right now is the economy. It's tough for smaller client companies that are having difficulty attaining funding. It's meant we've had to extend our sales cycle, which leads to longer timelines.

Emerging technology is another challenge because as the tools change, certain aspects of the business can change. For example, a few years back the increased level of protein expression in production cells created a huge challenge because the bioreactors began producing 10 times more product than they had been, and purification procedures were needed to handle larger amounts of protein.

The other challenge is client diversity. Every client has a slightly different perspective on how things should be done and on what's needed to get their product into the clinic. This complexity requires flexible processes and services. ♦

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

SEE DIGITAL PUBLICATION FOR BONUS CONTENT
WWW.PHARMAVOICE.COM

Is your media plan this personal?

With Catalina Health Resource, each and every message is hand-delivered to the patient you want to reach. And each and every time, it's the patient's own pharmacy that delivers it.

So while we like to boast about our ability to educate and influence more than 125 million patients this year alone, we know that our real value comes from connecting just the right patient with one especially important message.

Yours.


CATALINA HEALTH RESOURCE

The World's Largest Personalized Health Media Network™

catalinahealthresource.com

EMERGING LIFE SCIENCES COMPANY OF THE YEAR



We are honored to receive this prestigious Enterprise award from Eastern Technology Council, says Robert Broeze, Ph.D., President and CEO of Laureate Pharma. Dr. Broeze, who is with Dr. Michiel Utee, VP of Process Sciences, in front of an Applikon 20L Bioreactor, says the award validates the company's commitment to the advancement in human health.

The Eastern Technology Council, the Philadelphia region's largest technology and life-sciences trade association with more than 600 member companies, named Laureate Pharma Inc., a full-service biopharmaceutical development and protein production company, the "Emerging Life Science Company of the Year."

The Emerging Life Science Company Award honors a company that has at least four years of strong operating results and revenue of less than \$50 million. Key considerations for the award include product or service innovation, strategic decisions that led to growth in revenue and/or earnings, and demonstrated ability to raise capital and achieve profitability.

The Enterprise Awards celebrate the vitality of the technology and life-sciences communities. More than 1,200 business leaders and executives were in attendance at the 16th Annual Enterprise Awards in November, where top companies, leaders, and entrepreneurs were honored.

"These companies and leaders have overcome the challenges of growing successful businesses, by taking the necessary risks and making sacrifices and tough decisions," says Dianne Strunk, CEO of the Eastern Technology Council.

2008 Enterprise Awards Winners

LEGEND AWARD FOR LIFETIME ACHIEVEMENT

Lawrence D. Alexander, Ph.D., Director of Advanced Technology at Lockheed Martin Information Systems & Global Services

ENTERPRISER AWARD FOR WORLD-CLASS TALENT

Leo Daiuto, former Corporate VP at Unisys

TECHNOLOGY STARTUP COMPANY

MODA Technology Partners

EMERGING TECHNOLOGY COMPANY

StarCite

TECHNOLOGY CEO OF THE YEAR

Ned Moore, Portico Systems Inc.

TECHNOLOGY COMPANY OF THE YEAR

Precyse Solutions

APPLIED TECHNOLOGY EXCELLENCE

CeelLite

LIFE SCIENCES STARTUP COMPANY

Neuro Diagnostic Devices

EMERGING LIFE SCIENCES COMPANY

Laureate Pharma

LIFE SCIENCES CEO OF THE YEAR

Christopher M. Cashman,

Protez Pharmaceuticals

LIFE SCIENCES COMPANY OF THE YEAR

Globus Medical

"The 2008 Enterprise Awards finalists and winners represent the strength of the Greater Philadelphia business community."

In acceptance of the award, Robert Broeze, Ph.D., President and CEO of Laureate Pharma, responded: "This is a tribute to our leadership and our talented and committed staff. It is a great recognition of our world-class operations and our strategy for business success." ♦

GOT INFO?



THE RESOURCE FOR LIFE SCIENCES

GIVE INFO!

WWW.ACCESSFYI.COM

For information about the site or about content partnerships, sponsorship and advertising opportunities, contact Dan Limbach at dan.limbach@accessfyi.com or 847-594-0157.

Launch Intensity. It's what drives us. It's what makes us different. It's what every opportunity, every project, every brand deserves. Let us bring launch intensity to you.

torrelazur.com

A NEW INDICATION IS PENDING.
A VOLATILE MARKET SURROUNDS YOU.
READY TO JUMP IN?

WE LIVE HERE.

LIVE_BREATHE_LAUNCH

TORRE LAZUR McCANN

