Biolines

Winter 2000

Biotechnology Council of New Jersey, Inc.

Second Annual High-Tech Hall of Fame draws 150

The Biotechnology Council of New Jersey, Inc. and the American Electronics Association (AEA) hosted the Second Annual New Jersey High-Tech Hall of Fame Induction Dinner on Wednesday, October 18, at the Garden State Arts Center in Holmdel, New Jersey.

This year's inductees included Congressman Rodney Frelinghuysen, Senator Robert Singer, and industry leaders Dr. Lisa Drakeman and Dr. Donald Drakeman of Medarex, Inc. and Mr. Reuben F. Richards, Jr. of EMCORE.

Congressman Rodney Frelinghuysen was inducted for his leadership and support of the high-tech and biotechnology industries in New Jersey. He was a strong supporter of an increase in H1-b Visas to bring highly trained workers from overseas.

Senator Singer was honored for his leadership in promoting the biotechnology industry in New Jersey. He was the founder of New Jersey's bipartisan, bicameral Joint Legislative Biotechnology Task Force. Senator Singer was the sponsor of the famed High-Tech Tax Bill package, including the groundbreaking Technology Tax Transfer program as well as the legislation, which enabled and encouraged the New Jersey Pension Fund to invest in biotechnology companies.

Drs. Donald and Lisa Drakeman were honored for their immense contributions to

Continued on page 3

High-Tech Inductees: Senator Robert Singer, Dr. Lisa Drakeman, and Dr. Donald Drakeman.

Seventh Annual Meeting and Annual Industry Report slated

The Biotechnology Council of New Jersey, Inc. will host its Seventh Annual Meeting on Wednesday, December 6, 2000 at the Doral Forrestal in Princeton, New Jersey. The program will begin at 5:00 p.m. with cocktails and hors d'oeuvres followed by the meeting and presentation from 6:00-8:00 p.m.

Robert Esposito, National Director, Biotechnology and Life Sciences of KPMG LLP and Gordon Ramseier, Executive Director of The Sage Group return for the Seventh Annual Industry Report. They'll discuss the deals, the successes, the downfalls and more. They'll unveil the year's KPMG/Sage New Jersey Biotech Company Stock Index.

A limited number of tabletop displays are available for companies to showcase products and services at $600 each. For more information on this opportunity, contact BCNJ Headquarters at 609-890-3185.

BCNJ
Biotechnology Council of New Jersey, Inc.

Board of Trustees

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PLACE JOHN'S PICTURE HERE

Message from the Chair

John Jackson, BCNJ Chairman

I would like to begin my last message as Chairman of BCNJ by thanking our Board of Trustees members for their support over the past two years. As I conclude my term, I know that BCNJ will continue to work towards its mission of promoting the importance of this industry in New Jersey.

The Seventh Annual Meeting featuring the 2000 Annual Industry Report will take place on Wednesday, December 6, 2000 at the Doral Forrestal in Princeton, New Jersey. Bob Esposito of KPMG LLP and Gordon Ramseier of The Sage Group return once again to give their view of the industry.

Planning is underway for next year's symposium, entitled *Biotech 2001: Opportunities in the Nation's Pharmaceutical Center*, to be held on April 23-24, 2001 at the Atlantic City Convention Center and the Atlantic City Sheraton.

The Second Annual High-Tech Hall of Fame was a great success with 150 in attendance. Congratulations to this year's inductees including Congressman Rodney Frelinghuysen, Senator Robert Singer, and industry leaders Dr. Lisa Drakeman and Dr. Donald Drakeman of Medarex, Inc. and Mr. Reuben F. Richards, Jr. of EMCORE.

Thanks to the support of Senator Robert Singer, the Joint Legislative Biotechnology Task Force will be reconvened. The task force will work with BCNJ to identify and address industry needs.

Rutgers University has been commissioned to conduct an Industry Study for BCNJ. The study will examine various issues in the biotechnology industry including composition, size, employment, real estate, education and other needs.

As I move into the role of Immediate Past Chair, I encourage you to support BCNJ.

I would also like to extend my thanks to Prosperity New Jersey for generously underwriting the costs for production of the BCNJ membership brochure.

I have been honored to serve as your Chairman over the past two years, especially during the time that we saw the Tax Credit Transfer become a reality. It is our greatest success to date and we have many people to thank including Don and Lisa Drakeman, Senator Bob Singer and Governor Christine Whitman. As I move into the role of Immediate Past Chair, I encourage you to support BCNJ.

Stop Right Now and Put Us on Your Press Release list

BCNJ biotechnology and pharmaceutical company members are invited to send in their press releases for inclusion in the Member Company News column. Please add BCNJ to your list and either fax them to 609-581-8244 or email them to bcnj@hq4u.com. Please call Headquarters with any questions at 609-890-3185.

BCNJ announces Industry Study

The Biotechnology Council of New Jersey, Inc. Board of Trustees has voted to engage Rutgers University MBA students to conduct an industry study. The goal of this initiative is to identify, quantify, and assess growth and future needs of the industry in New Jersey.

The study will compare New Jersey's industry with that of other states to assess how New Jersey can improve its initiative on behalf of biotech. It will examine the economic impact of state programs and assess the number of established as well as projected jobs in the industry to determine the employment needs of the sector and how they can be filled. The study will identify additional needed efforts, especially in the areas of education and real estate.

Continued from page 1

the biotechnology industry. Dr. Donald Drakeman is a founding Board member of the Biotechnology Council of New Jersey, and served as Chairman in 1997 and 1998. He also served as a member of Senator Singer's Joint Legislative Biotechnology Task Force and is a current member of the BIO Board. Dr. Lisa Drakeman was honored for serving BCNJ in the appointed position of Vice President of Public Affairs from 1997 through earlier this year. One of her most notable accomplishments was her lobbying and research efforts in support of the Technology Business Tax Certificate. Lisa is the current CEO of Genmab A/S, a publicly held European biotechnology company. Lisa Drakeman was honored by Bio in 1997 for her leadership in promoting the industry.

Mr. Richards was inducted for the pivotal role he played in making EMCORE one of the top 10 IPO's of 1997, the year he took the company public.

Richard Goldberg of the Commerce and Industry Association of New Jersey, BCNJ Executive Director Debbie Hart and Senator Robert Singer

Robert Hugin of Celgene Corporation presented the award to Senator Robert Singer on behalf of BCNJ.

Mayor James McGreevey met with the BCNJ Board of Trustees in October. Pictured from left to right are: Robert Esposito, Robert Hickey, Elizabeth Tallett, Gordon Ramseier, Marvin Miller, John Jackson, Kenneth Moch, Mayor McGreevey, Howard Tuckman, James Marino, Alice Leung, Carol Webb, Paul Thomas and Debbie Hart.

Calendar of events

December 6
Seventh Annual Meeting
Annual Industry Report
Doral Forrestal
Princeton, NJ

April 23-24, 2001
Biotech 2001 Symposium
Atlantic City Sheraton and the
Atlantic City Convention Center
Atlantic City, NJ

June 2001
BCNJ Golf Outing

NJ Biotech Task Force reconvened

The New Jersey Biotechnology Task Force, chaired by Senator Robert Singer, will be reconvened. A bipartisan, bicameral body of the New Jersey State Legislature, this is the entity from which the important body of legislation that exists on behalf of biotechnology was borne. The Task Force was originally convened at the request of Senator Singer in 1994 and allowed the biotechnology industry the opportunity to identify and voice its needs. Ken Moch, CEO of Alteon, Inc. will represent the Biotechnology Council of New Jersey, Inc. on this task force. The joint Senate/ Assembly task force will again be active in promoting the biotechnology industry and working along with the Biotechnology Council of New Jersey to do so.

Legislation which grew out of the task force's 1994 recommendations includes limits on access to trade secrets, immunity to biomaterials suppliers from certain product liability suits, a resolution discouraging further state regulation of the biotechnology industry, and a series of tax bills including the landmark legislation which allows high technology companies to sell net operating loses to profitable companies for cash.

2001 Symposium Sponsors announced

Seven companies have signed on as lead sponsors for the 2nd Annual Joint Symposium between the Biotechnology Council of New Jersey and the Pennsylvania Biotechnology Association (PABIOTECH). They are: Aventis Pharmaceuticals; SmithKline Beecham; Wyeth Ayerst Laboratories; Ernst & Young LLP; Ortho Biotech, Inc.; PSE&G Company and PECO Energy Company. The symposium will be held on April 23-24, 2001 at the Atlantic City Convention Center and the Atlantic City Sheraton. This year's symposium, entitled *Biotech 2001: Opportunities in the Nation's Pharmaceutical Center,* will offer sessions such as Capital Formation, Biopartnering and Fundamental Strategies. Watch for additional information.

Since the last issue . . .

- Ken Moch, President of Alteon, Inc. spoke on "Pharmaceutical Biowizards Unraveling Nature's Secrets" at the Assembly Speaker Jack Collins' Northern Regional Business Summit entitled "Exploring the Region's Industry Sectoral Growth: Legislative and Economic Development Strategies to Build a Strong State Business Climate."

- Gordon Ramseier, Executive Director of The Sage Group and founding Vice President of the Biotechnology Council of New Jersey, Inc., represented BCNJ at a Hunterdon Economic Partnership program to discuss the relationship between the pharmaceutical and biotech industries.

- The Biotechnology Council of New Jersey, Inc. and New Jersey's Biotech Industry will be featured in an article for Biotech Magazine's December 2000/ January 2001 issue.

- BCNJ Executive Director Debbie Hart represented BCNJ at a focus group convened by the New Jersey Economic Development Authority to discuss the development of a South Jersey Technology Centre.

- BCNJ Executive Director Debbie Hart was interviewed for an NJN documentary on the biotechnology and pharmaceutical industry in New Jersey. The documentary will air on NJN in November.

November 2000 is Biomedical Research Month. Thank you for your continued support of biomedical research in the State of New Jersey.

BCNJ welcomes the following new members:

American Stock Exchange
Anthra Pharmaceuticals, Inc.
Cambrex Corporation
Coelacanth Corporation
DEVCOM
DVL, Inc.
EpiGenesis Pharmaceuticals, Inc.
Hurley Consulting Associates Ltd.
Interferon Sciences, Inc.
Johnson Controls, Inc.
King Interests
Orchid BioSciences, Inc.
PharmaceuticalResearch
Manufacturers of America
Purdue BioPharma L.P.
Physiome Sciences, Inc.
Radpharm
Sabinsa Corporation
Speedel Pharmaceuticals
Senesco Technologies, Inc.
Synthon Chiragenics Corporation
The NASDAQ Stock Market
The Trillium Group, LLC
Willis, Inc.

MEMBER COMPANY NEWS

Celgene was recognized as one of the state's 50 fastest-growing technology-based companies at the sixth annual 2000 New Jersey Technology Fast 50 Program Awards Breakfast. . . AxCell Biosciences Corporation, a subsidiary of **CYTOGEN Corporation**, and Molecular Staging, Inc., initiated a scientific plan to investigate potential synergies between their technologies to map protein pathways more rapidly and efficiently. MSI's Rolling Circle Amplification Technology (RCAT (TM)) is a proprietary, highly sensitive and efficient amplification method for detecting the presence of target molecules micro-arrayed on a biochip. By combining AxCell's domain-ligand interaction technology with MSI's protein arrays, the two companies believe that they may be able to increase the rate of protein interaction measurements by 10 fold more than AxCell's current rate of approximately 10,000 interactions per day. . . CYTOGEN announced an agreement with Draxis Health to market and distribute the Canadian firm's BrachySeed radioactive implants. These are implanted in the body, delivering their dose of radioactivity to kill cancer cells with fewer complications, lower costs and quicker recovery than surgery. The market for such products has grown by 95% over the last three years, and CYTOGEN expects it to reach $200 million soon. . . and announced that it has entered into an equity financing facility from Acqua Wellington North American Equities Fund, Ltd. for up to $70 million. Over the next 20 months, CYTOGEN may, at its discretion, sell additional shares of its common stock to Acqua Wellington pursuant to this financing facility at a small discount to market to be determined before each sale. . . *Business Week* named **Medarex, Inc.** as a technologically sound, young biotech company and **Celgene** a smart biotech buy. **Bristol Myers-Squibb** was also named as one of the leading companies in the field. . . **Medarex, Inc.** announced an alliance with Oxford GlycoSciences to develop novel therapeutics produced through the joint application of Medarex's fully human monoclonal antibody technology and OGS's proprietary proteomics technology for high-throughput protein analysis and target validation. Medarex and OGS expect the first joint product from an OGS-discovered antigen to enter Medarex's T-12 Development℠ program in the near future and that the collaboration may generate multiple product candidates a year thereafter. . . Medarex's independent spin-off, Genmab A/S announced clinical trial results of a Phase I/II dose escalating, placebo controlled study using Genmab's HuMax-CD4 as a therapy for rheumatoid arthritis. The results of the trial were presented at the American College of Rheumatology Meeting in Philadelphia recently. . . announced an alliance with ZymoGenetics to develop fully human antibody therapeutics. The companies plan to combine Medarex's fully human monoclonal antibody development technology and ZymoGenetics' expertise in the field of genomics and protein therapeutics to create antibodies to multiple disease targets identified by ZymoGenetics. . . . and announced that they have entered into a definitive agreement whereby IDM has acquired rights to certain of Medarex's therapeutic products and technology in exchange for ownership rights in IDM. . .and appointed Christian S. Schade as Senior Vice President and Chief Financial Officer. Michael A. Appelbaum, who has served as Chief Financial Officer since 1991, will continue to serve as Director and Executive Vice President of Medarex and President and Chief Operating Officer of GenPharm International, Inc., a wholly owned subsidiary of Medarex. . . **Orchid BioSciences, Inc.** granted a nonexclusive license to **Amersham Pharmacia Biotech** to use Orchid's patented SNP-IT™ single base primer extension technology for single nucleotide polymorphism (SNP) applications. . . **Unigene Laboratories, Inc.** announced that it has achieved a milestone associated with the ongoing clinical studies for its oral calcitonin program and has received a payment from Pfizer. . . and received additional payments for testing services, as well as for calcitonin supplies provided to Pfizer for future clinical studies. . . also announced the establishment of additional collaborations to investigate the feasibility of orally delivering peptides for the treatment of specific endocrine disorders. . . and now has one product approved in Europe, two in clinical trials and several peptides being investigated in collaboration with other companies.

Maximizing Clinical Development in Biotechnology

Anup K. Dam
President and CEO, Stat-Trade Inc.

The Beginnings of Biotech

When a gene was first successfully relocated from one organism to another by Stanley Cohen and Herbert Boyer about 25 years ago, it marked the launch of a new industry—biotechnology. From that singular beginning, the evolving technologies of molecular biology and related fields have converged, spearheading the development of novel solutions that can treat a variety of previously unmet needs.

The advent of biotechnology changed the landscape of a variety of fields, from medical applications to agriculture. But the emerging field also paved the way for small-to-medium sized business to enter categories like drug development, which were formerly dominated by large pharmaceutical companies. These smaller companies may not have been able to match the deep pocket budgets of the pharma giants, but they did have a higher appetite for risk and tended to incur lower operating costs. They also replaced pharma's broad-based massive research approach with a tightly focused, engineered strategy that enabled them to develop and launch a wide variety of niche products.

Despite the cost advantages enjoyed by biotechs, the smaller firms encounter many of the obstacles that pharma giants face. Perhaps this is most evident in a product requiring approval by the FDA. The procedure means rigorous testing, documentation, and clinical trials that can take up to 15 years while racking up indirect

Continued on page 6

Continued from page 5

costs, like foregone sales, and direct costs that can range from $500 to $600 million for pharmaceutical development and from $50 to $300 million for biotech-related development.

Without a solution, this bottleneck will only get worse. According to Harvard University's Center for International Development, an estimated 1,200 biotech-based drugs are in clinical trials and the pace of advancement continues to accelerate. In 1997, for instance, 10% of the pharmaceutical product launches were attributed to biotechnology, while by 1999 the industry was responsible for about 25% of the activity.

As Costs Rise, Development Stalls

Just as pharmaceutical drug development costs continue to escalate, biotech-related product development costs are also rising. Even as competition reaches new levels, companies are experiencing difficulties in building up product pipelines. In response they're being forced to develop projects quickly, and are terminating poorly performing products earlier in the development stage.

But if biotech products could be quickly ushered through the development and regulatory processes, both direct and opportunity costs would be reduced. A faster development cycle would also improve a product's revenue potential by extending its patent-protected life cycle and by facilitating earlier entry in the market. Additionally, with the prospect of greater returns, venture capital investors would potentially be encouraged to extend their investment period beyond the usual two-to-three year period.

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But conducting a clinical trial is a complex, expensive process. Ironically, for an industry that is known for creating exciting new drugs, the clinical trial segment of drug development is entrenched in a long-term methodology that has not changed much over the past three decades. The off-line, manual management of patient data, communications to and from the clinical sites, budgeting and contracting, and study payment tracking and disbursement are just a few of the essential tasks that significantly slow the process.

A Web-Enabled Solution

New technologies and applications, however, are now available to aid companies in their clinical development, enabling them to achieve proof of concept/ Phase II results in a significantly shorter time frame and at considerably less cost. The Internet is the key, and it is aided by the fact that much of the clinical trial process lends itself to Web-based technology. For biotech companies, the Web can offer a dramatic collapse in the clinical testing timeline–from on-line patient recruitment through making electronic regulatory agency filings.

The industry has arrived at the brink of real change, but clinical trials sponsors need to do a great deal of new thinking, while application analysts must toss their off-line mentality and embrace on-line technology. The industry's adoption of the Internet to facilitate the clinical trial process will be painful and exciting, but it is a necessary step. The Internet can change the way clinical trials are implemented, processed and conducted. It can make incremental changes or revolutionary ones, depending on which model is adopted.

Embracing a comprehensive, end-to-end solution, rather than a fragmented set of solutions, will offer a faster lab-to-market journey, and will also yield cost savings that an incremental approach cannot match. Companies that embrace a total Internet solution will slash their development time, saving an average of 18 to 24 months and transform themselves into "speed demons." The 18 to 24 month jump they get over competitors will let them enter markets early, generate higher sales volumes and grow their markets faster.

The ClinSmart™ Approach

Responding to the need for biotech companies to accelerate the pace of their clinical trials while maintaining their quality, Stat-Trade has developed the Web-based ClinSmart System, which offers end-to-end implementation and management of the clinical development process. Designed by a team of clinical development and information technology professionals, ClinSmart offers a streamlined solution, providing an integrated clinical data warehouse that readily provides information needed to make decisions and prepare reports for regulatory agencies.

Because ClinSmart is a modular-based system, it can provide a comprehensive corporate solution for clinical development from the initial stage through regulatory submission and post-approval marketing activities. This solution includes: protocol development and study implementation, patient screening, real time, secure, web-based electronic data capture, data management with automated queries, accelerated analysis and reporting, preparation of clinical study reports, integrated summaries for NDA, PLA or PMA (all in electronic format and in compliance with regulatory requirements 21 CFR Part 11), and earlier product submission.

ClinSmart can also help companies to complete Phase I to III clinical programs faster than their peers, offering a competitive advantage in today's intense investment environment. Besides slashing overall development time for biomedical companies, ClinSmart lets their marketing departments focus on market penetration, positioning and other concerns at an earlier stage, optimizing investor return on equity and helping to ensure investors' confidence. After all, biotech product development is not only about rapid registration, but also rapid commercialization.

The end-to-end solution provided by the ClinSmart System gives smaller biotech/ device companies the same armamentarium as the big pharma companies have, allowing them to expedite Go/No Go decisions, shorten regulatory submission timeframes, enhance their infrastructure utilization and achieve market penetration at an earlier date. In addition to satisfying the company, it will boost investor confidence.

Thanks to Stat-Trade, Inc for sponsorship of this issue of "Biolines".