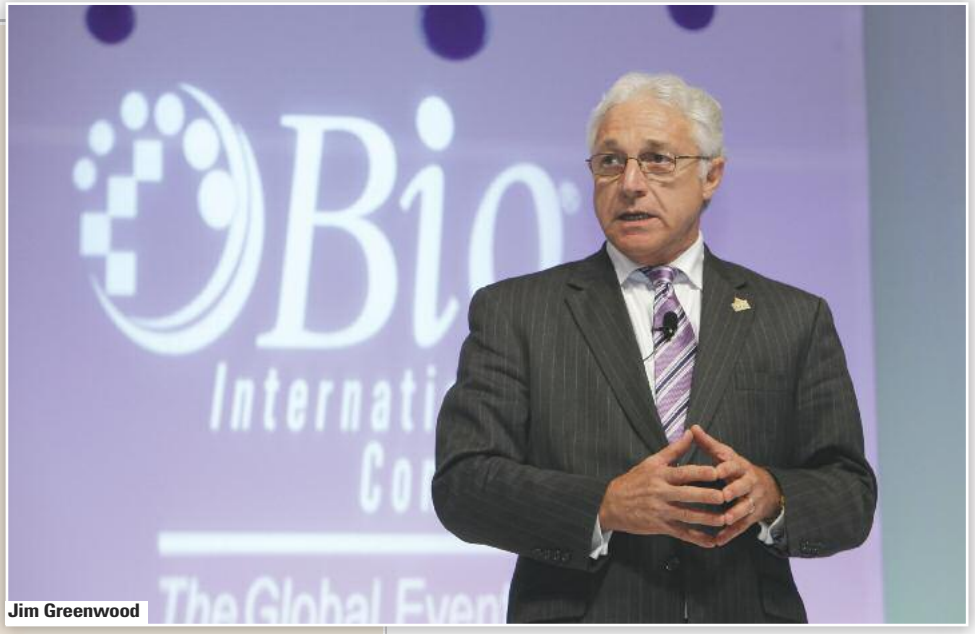
What's New

NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

By Carolyn Gretton

BIO Continues Strategic Initiatives to Speed Scientific Breakthroughs

TRENDS: Despite the current constrained economic environment, industry leaders and advocates continue to formulate strategies and solutions aimed at transforming policy and incentivizing investment in the biotech sector.



Jim Greenwood

The Biotechnology Industry Organization (BIO) has released a summary of legislative proposals designed to reform the investment and regulatory environment for biotech innovation by unleashing the innovation required to cure disease and make the U.S. healthcare system more affordable, efficient, and of higher quality.

In addition to its focus on healthcare, BIO's policy proposals aim to foster the development of breakthrough technologies to provide alternative energy sources, combat hunger, and protect against bioterrorism.

BIO President and CEO Jim Greenwood observes that society's need for innovative, biotech-based solutions to curing disease has never been more urgent. In fact, results of a recent national survey of 800 American voters found that during the current economic slowdown, while the nation's leaders are making hard choices about our national economic policies, a majority (53%) of voters believe the federal government should support the biotechnology industry through either tax policies or direct funding.

"Yet despite the extraordinary hope offered by biotechnology, government policies and the capital formation environment necessary to support these policies are insufficiently conducive to enable our industry to most effectively meet these challenges," Mr. Greenwood says. "Our policy proposals are designed to improve the odds for biotech innovation and the patients and communities we serve."

BIO's comprehensive set of policy proposals address two vital needs for ensuring robust biotechnology innovation and industry growth: the need to re-engineer the biotech economic model and the need to reinvent the idea-to-market pathway for biotech cures and other products. BIO plans to pursue these proposals by advocating for legislation, specifically by turning the relevant findings into language that will be used to advocate for introduction and passage of legislation.

"BIO has consistently succeeded in contributing to the development of important and effective policy at the federal, state, and international levels," Mr. Greenwood observes. "Our efforts notwithstanding, the legal and regulatory structures in place remain woefully insufficient to incentivize the magnitude of investment necessary in the biotechnology sector to translate the scientific potential that resides in the thousands of small, medium, and large American biotech companies into products that save lives and fuel and feed the world in environmentally sustainable ways. "

For more information, visit bio.org.

Centocor Ortho Biotech Assumes Janssen Identity

Centocor Ortho Biotech has changed its name to **JANSSEN BIOTECH** as part of a global effort to unite and increase collaboration between the Janssen pharmaceutical companies around the world.


Robert Bazemore

Beyond its new name and logo, Janssen Biotech has experienced no changes in legal structure and continues to pursue redefining the standard of care in the therapeutic areas of immunology, oncology, urology, and nephrology.

"The Janssen name has been used by our affiliate companies for more than 50 years and has long been associated with high scientific ideals and groundbreaking advances," says Robert Bazemore, president of Janssen Biotech. "Uniting together under a common identity will allow us to operate more effectively and efficiently with the same passion and commitment that has led us to the forefront of patient care in our therapeutic areas."

For more information, visit janssenbiotech.com.

In other news…

Professional services firm **Skysis** was formed in June to provide clients with life-sciences expertise in the areas of new product planning, brand management, business development, transaction advisory, and executive management services.

The expanded services are in response to a growing demand for highly relevant and experienced commercial experts, leveraged on a variable cost basis, to manage complex issues and dynamic workloads across a product's life cycle. Skysis has established a team of seasoned professionals to augment existing internal resources and take on key initiatives that will help clients achieve a higher level of success.


Dan Twibell

"For small and emerging clients, we can implement proven and tested processes and manage necessary commercial activities while delaying the need to bring on high-cost infrastructure prior to achieving key milestones," notes Co-Founder and Managing Director Dan Twibell.

"We strongly believe that the traditional approach to launching and promoting products — reliance on fixed-cost infrastructure — is being replaced by hybrid models that leverage the efficiency, flexibility, and deep expertise associated with variable-cost resources," adds Co-Founder and Managing Director Jeff Martini.


Jeff Martini

For more information, visit skysisllc.com.

BBK Worldwide has partnered with online health platform **PATIENTSLIKEME** to jointly offer services to pharmaceutical companies and other industry stakeholders interested in enhancing patient recruitment and retention for ongoing and upcoming clinical research studies.

To help expand its targeted patient population for recruitment purposes, the two companies will launch national and regional multimedia campaigns to help drive patients to sign up for PatientsLikeMe.

While patients benefit from sharing their health data and experiences on the site, BBK and PatientsLikeMe can offer industry partners tiered access to interested patient members who meet their trial criteria.

Trial sponsors also are able to leverage the PatientsLikeMe platform and the BBK technological solutions and communications expertise to establish powerful retention programs.

"This is a crucial next step in bringing exposure of clinical trials to our members, beyond just giving them access to ClinicalTrials.gov listings on our website," adds David S. Williams III, chief marketing officer of PatientsLikeMe. "By partnering with BBK, an established leader in the space, we can now reach many more patients to let them know about potential clinical trial opportunities that address their specific, unmet medical needs."

For more information, visit bbkworldwide.com or patientslikeme.com.

INC Research has completed its acquisition of **KENDLE INTERNATIONAL**, giving the CRO enhanced global scale and expanded therapeutic expertise and strengthening its position to deliver

clinical trials of all sizes across the drug development spectrum.

Operating as INC Research, the CRO is led by CEO James Ogle. Other key corporate roles include Jamie Macdonald as chief operating officer; John Potthoff, Ph.D., president; Neil MacAllister, executive VP, corporate and business development, INC Research, and president, AVOS Consulting; and Mark Roseman, D.Sc., executive VP, business development and marketing.


James Ogle

"Biopharmaceutical companies of all sizes are relying on outsourcing partners earlier in the clinical trials process," Mr. Ogle says.

For more information, visit incresearch.com.

Omnicare Clinical Research has rebranded as **THEOREM CLINICAL RESEARCH**, marking the final step in the global, full-service CRO's separation from its former parent company, Omnicare Inc.

Under its new name, Theorem Clinical Research continues to provide full-service clinical trial management services to pharmaceutical, biotechnology, and medical device companies. Theorem also provides technical services, such as biometrics and clinical data management.

Dr. James Pusey, president and CEO of Theorem, says the rebranding allows the company to be more efficient across its 32 locations worldwide.

"We believe that this rebirth creates a powerful new voice in the clinical services space," he adds.

For more information, visit theoremclinical.com. PV

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AROUND THE GLOBE

ALMAC GROUP's clinical services business unit has strengthened its presence in the Asia Pacific region by adding five new depots for clinical trial supply distribution in Japan, Thailand, Hong Kong, and Taiwan. The additions bring the number of depots within Almac's extensive global network to 36, with an additional five planned for 2012, enabling Almac to provide customers with even more flexibility in their supply-chain solution for their specific country clinical trial requirements.

For more information, visit almacgroup.com.

BIOMARIN PHARMACEUTICAL is acquiring an Ireland-based bulk biologics manufacturing plant from Pfizer. The plant, which was completed and validated in 2009, is built on 10 acres occupying 133,000 square feet of floor space. The purchase is expected to close in the third quarter of 2011 following the wind-down of current operations and the transfer of the Irish EPA license.

For more information, visit bmrn.com.

CATALENT PHARMA SOLUTIONS is expanding its clinical supply services facilities in Schorndorf, Germany. The expansion includes both additional controlled substance storage and increased warehousing space and is expected to be finalized by the end of the year.

For more information, visit catalent.com.

CHILTERN INTERNATIONAL has established a new legal entity in Israel. Armand Czaplinski, Chiltern's executive director, global country management, is leading Chiltern's Israel effort.

For more information, visit chiltern.com.

Glasgow-based contract research organization **CLINTEC INTERNATIONAL** has continued its international expansion by opening fully registered offices in China, Singapore, and Thailand. Over the next quarter, strategic moves into South Korea, Taiwan, Malaysia, and Indonesia will also take place, consolidating ClinTec's presence in the Asia Pacific region.

For more information, visit clintec.com.

GILEAD SCIENCES is expanding its global access program in an effort to provide accelerated access to Gilead medicines for the treatment of HIV/AIDS. The changes include a licensing agreement with the Swiss nonprofit Medicines Patent Pool Foundation and new licensing terms with four India-based drug manufacturers — Hetero Drugs, Matrix Laboratories, Ranbaxy Laboratories, and Strides Arcolab — for three drugs currently in late-stage clinical development.

For more information, visit gilead.com.

LIFE TECHNOLOGIES has launched a regional distribution hub in India to address customer demand in the south Asia region. The India distribution center is located in Bangalore and boosts the availability, timely delivery, and quality of products to Life Technologies' customers in the region.

For more information, visit lifetechnologies.com.

Biopharmaceutical firm **MEDICINOVA** has formed a joint venture company with **ZHEJIANG MEDICINE CO.** to develop and commercialize MediciNova's MN-221 in China. MN-221 is a novel, highly selective beta 2-adrenergic receptor agonist in development as an intravenous treatment for acute exacerbations of asthma and chronic obstructive pulmonary disease (COPD).

For more information, visit medicinova.com.

PRA INTERNATIONAL has added operations in two European countries. The CRO has opened an office in Lund, Sweden, enhancing local staff members' ability to provide quality clinical services across Scandinavia. The Swedish office is located in Oresund, a life-sciences hub.

PRA also has created a legal entity in Bulgaria to support growth and expand operations in the Balkan area. Located in Sofia, the new entity enhances PRA's local presence.

For more information, visit praintl.com.

QUINTILES is strengthening its position in Italy through the acquisition of **TEMAS**, a regulatory and market access commercial services provider. In other global moves, the life-sciences research and consulting services provider has purchased $1 million in shares in Melbourne-based **PRANA BIOTECHNOLOGY**. The funding supports the development of Prana's PBT2 through Phase II for Huntington's disease and Alzheimer's disease.

For more information, visit quintiles.com.

THOMSON REUTERS has formed a partnership with Morocco's **INSTITUT MAROCAIN DE L'INFORMATION SCIENTIFIQUE ET TECHNIQUE** (IMIST). The three-year contract will bring Thomson Reuters' Web of Knowledge discovery search platform to scientists and researchers at 14 IMIST institutions.

For more information, visit thomsonreuters.com.

New Firm Focuses on Bringing More

Preclinical Candidates to Trial

Oncobiologics is a recently launched specialty firm founded by scientists and engineers from top-tier global pharmaceutical and biotech companies to commercialize a new one-stop, proof-of-concept engine that will enable biologic drug developers to economically and efficiently develop more of their preclinical drug candidates.

Founder and CEO Pankaj Mohan, Ph.D., says Oncobiologics was created to "help unleash the tremendous wealth of preclinical assets generated by the U.S. biopharmaceutical industry," an estimated 40% of which suffer significant delays due to capacity and financial constraints.

"Oncobiologics aims to deliver the world-class technical capabilities found at top-tier companies, with a cost structure that more closely resembles low-cost country outsourcing, thus easing this critical bottleneck," Dr. Mohan says. "Our team sees a great business opportunity here, but we are equally committed to opening up the flow of promising drug candidates to the patient populations that so desperately need them."

The Oncobiologics business model features a core set of expert services supplemented by strategic partnerships with external industry specialists. Internal services include cell and molecular biology; and process, analytical, and formulation development. Manufacturing services include stability studies, nonclinical manufacturing, and quality control testing, with clinical manufacturing commencing in 2012. Partner offerings include preclinical animal studies, immunogenicity studies, clinical study design and execution, and regulatory affairs.

For more information, visit oncobiologics.com.

Everyday Health's **MEDPAGE TODAY** has joined forces with the American Heart Association to provide coverage of breaking cardiovascular news via the recently launched Cardiovascular Daily e-newsletter, sent to healthcare professionals who have opted in to receive news via AHA's website, americanheart.org.

In other moves, Everyday Health has teamed with Litton Entertainment to produce a television series derived from the popular health brand. The show, titled Everyday Health, joins Litton's Weekend Adventure, which began airing Saturday mornings in August in most markets following ABC's Good Morning America.

The Everyday Health TV show showcases extraordinary Americans who are facing or have overcome health issues and are paying it forward, and integrates Everyday Health's portfolio of experts, online tools, and mobile applications as part of the all-original content.

"This show celebrates health-related philanthropy, demonstrating how one person can make a world of a difference in someone else's life," says Everyday Health President and Co-founder Mike Keriakos, who is a co-producer of the show with CEO and Co-founder Ben Wolin.

For more information, visit everydayhealth.com.

Decision Resources and **InnerVation Health**'s collaborative Global Regulatory Advisory Service: Type 2 Diabetes features InnerVation's Regulatory Advisory Panel (IRAP), whose experts offer immediate and long-term opinions and insights on events and critical shifts regarding regulatory issues impacting all stakeholders.

The IRAP includes former FDA and European Medicines Agency (EMA) directors, medical officers, and current consultants with expertise in the type 2 diabetes regulatory environment, all of whom provide their perspective on the approach that regulatory agencies may be considering in the process of type 2 diabetes drug development. Components of the service include analyses of regulatory surveillance, regulatory insights and perspectives, and regulatory best practices.

For more information, visit decisionresources.com.

ON THE SHELVES

The release of **CenterWatch**'s **GLOBAL REGULATORY SYSTEMS: A STRATEGIC PRIMER FOR BIOPHARMACEUTICAL PRODUCT DEVELOPMENT AND REGISTRATION** provides regulatory and clinical professionals, professors, and students with a comprehensive guide to the complexities of drug approval and regulation around the world.

Written by Henrietta Ukwu, M.D., senior VP and head of global regulatory affairs for PPD, the book helps professionals navigate the dynamic landscape of all the major global biopharmaceutical regulatory agencies and consolidate the most pertinent and relevant facts and guidelines into one resource.

In other news, CenterWatch has released revised and expanded editions of two of its top-selling training resources: **THE CRA'S GUIDE TO MONITORING CLINICAL TRIALS, 3RD EDITION** and **THE CRC'S GUIDE TO COORDINATING CLINICAL TRIALS, 2ND EDITION**.

The revised CRA guide includes a new review exercises and updated content with new chapters on CRA roles and responsibilities, monitoring for device and biologic trials, globalization of studies, and issues around EDC. The latest version of the CRC guide includes new chapters on investigational product accountability, device and biologics trials, and data safety monitoring boards.

For more information, visit centerwatch.com.

The Regulatory Affairs Professionals Society (RAPS) has published **FUNDAMENTALS OF US REGULATORY AFFAIRS, SEVENTH EDITION**. The latest edition covers U.S. regulatory requirements across healthcare product lines, including pharmaceuticals, medical devices, biologics, and other product classifications. It has been updated to address current regulatory requirements from the FDA and other state and federal agencies. Also new are chapters on drug, biologic, and device regulatory pathways; FDA communications and meetings; patents and exclusivity; and veterinary products.

For more information, visit raps.org.