New Biopharm Company to Focus on ONCOLOGY SUPPORTIVE CARE

EKR Therapeutics Inc. is a new specialty pharmaceutical company developing prescription products and therapeutic solutions that support and improve the quality of life for cancer patients.

EKR is headed by Howard Weisman, chairman and CEO, who previously was president of ESP Pharma. Mr. Weisman has cofounded EKR with Cathy Kerzner, who serves as president. In addition, Ms. Kerzner is president-elect of the Healthcare Businesswomens' Association. Also part of the executive team is Richard DeSimone, who serves as chief financial officer.

"We recognize that there is a tremendous opportunity to focus on significant unmet needs of cancer patients, many of whom are now able to live as cancer survivors and, as a result, require various support products that enable them to undergo treatments over increasingly longer time horizons," Mr. Weisman says. "The specialty pharmaceutical model of a focused therapeutic franchise will ensure that these patients get access to the best products our industry has to offer."

In June, EKR completed its first institutional financing led by NewSpring Capital and ESP Equity Partners.

The company expects to launch its first product in the third quarter.

GSW Launches PINK TANK

Specialty marketing group offers expertise in understanding and speaking to women.

GSW Worldwide has launched Pink Tank, a new specialty group focused on marketing to women. Partnering with the agency's client teams, Pink Tank offers insight and direction on how to effectively connect with women who influence the healthcare market.

The creation of Pink Tank was driven by the growing impact of women on the healthcare industry. As consumers, women influence up to 80% of the healthcare decisions for their households, resulting in buying power estimated at more than $1.2 trillion.

Pink Tank is staffed by a diverse group of brand counselors with expertise in psychology, patient advocacy, and gender and cultural studies. Staff members have extensive experience in marketing leading consumer and healthcare brands. The team includes planners, who provide insight into how women consumers think and behave, as well as client services and creative staff, who translate that insight into strategic approaches for effectively reaching women.

Remarkably, many marketers don't realize that women connect with brands differently from men. We established Pink Tank to help companies understand those differences and to counsel them on how they can find the 'female voice' in their marketing efforts, says Marcee Nelson, Executive Creative Director, GSW Worldwide, and Founder, Pink Tank.

Pink Tank provides clients with a proprietary set of research tools that can help healthcare brand managers better understand how women consumers respond to marketing messages and select products.

"When the healthcare market doesn't effectively connect with women, conditions go undiagnosed, prescriptions go unfilled, and brand loyalty dwindles," says Gretchen Goffe, customer insight planner and principal partner of Pink Tank. "By understanding how women's attitudes, emotions, and beliefs impact brand performance, Pink Tank has helped clients make relatively simple changes in the ways they represent and speak to women in their marketing materials, which can lead to measurable results."

New Brand for CERTIFIED EDUCATION BUSINESS

i3, an Ingenix business that provides services and solutions for the healthcare industry, has renamed its accredited medical education unit i3 CME to better reflect the extensive services that the business unit provides and to accommodate newly developed education delivery platforms.

Originally named for its trend-setting distance learning network (DLN), which provides certified education via satellite broadcasting, Webcasting, and Video DIALogues, i3 CME also reflects the unit's broad range of educational activities, including grand rounds, independent medical education forums (IMEFs), dinner meetings, symposia, online activities, interactive educational round tables (small group workshops), enduring materials, and outcomes measurements.

i3 CME is a full-service, accredited provider of certified education with strong capabilities in central nervous system (CNS), oncology, cardiology, and infectious disease. Its recent acquisition of psychCME, a leader in the CNS CME arena, further strengthens the unit's CNS capabilities. This division is now known as i3 psychCME and joins i3 cardiologyCME, i3 oncologyCME, and i3 infectious diseaseCME to provide full certified education design and support in these key therapeutic areas.

FDA Forms Task Force on HUMAN TISSUE SAFETY

The Food and Drug Administration has formed a multidisciplinary FDA task force on human cell and tissue safety.

The FDA Human Tissue Task Force (HTTF), which is led by senior FDA officials from within the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA), was established as part of the agency's efforts to strengthen its comprehensive, risk-based system for regulating human cells and tissue.

The main priority of HTTF is to assess the effectiveness of the implementation of the new tissue regulations, which went into effect in 2005. Of particular interest will be a review of reported findings that some tissue recovery establishments are not following requirements.

IMS and IntrinsiQ Collaborate for ONCOLOGY MARKET INTELLIGENCE

Our clients, including those in the biotech market, have a compelling need to better understand the various dimensions of clinicians' decisions for a line of therapy at various stages of cancer, says Gilles Pajot, Executive VP, IMS Health.

IMS Health Inc. and IntrinsiQ Research Inc. have established a multiyear alliance to support the industry's growing need for comprehensive, global insights into cancer treatments.

Through the alliance, IMS has gained an exclusive license to incorporate IntrinsiQ's U.S.-based anonymized, patient-level oncology information into its multicountry oncology offering, IMS Oncology Analyzer.

IntrinsiQ's oncology database contains information captured at the point of care, including data on 80 tumor types and more than 13,000 unique, anonymized patient records, updated monthly.

The combination of these data with IMS's core-information assets — including anonymized, patient-level data, as well as global sales and prescription insights — creates one of the largest commercially available oncology repositories. The compilation is a complete view of cancer care in seven major markets, including the United States, the United Kingdom, Japan, Germany, France, Italy, and Spain.

Additionally, this information — integrated with IMS's advanced analytics and global consulting capabilities — provides the evidential database and expertise to help pharmaceutical and biotech clients make better-informed decisions across the entire oncology product lifecycle — from licensing and forecasting, to pricing and reimbursement, to health economics and health outcomes, to promotion and sales.

"Oncology is the second-largest and fastest-growing therapy class in the world, one where patient treatment is highly complex and variable," says Gilles Pajot, executive VP, IMS Health. "Our clients, including those in the biotech market, have a compelling need to better understand the various dimensions of clinicians' decisions for a line of therapy at various stages of cancer. This alliance between IMS and IntrinsiQ leads to new offerings and expanded consulting insights that will guide key commercial decisions in oncology, locally and globally."

M&A ACTIVITY

- **GILEAD SCIENCES INC.** has acquired **Corus Pharma Inc.**, a developer of specialty products for respiratory and infectious diseases, for $365 million.

  Gilead, Foster City, Calif., a biopharmaceutical company focused on areas of unmet medical need, has retained Corus' Seattle-based operations, establishing a center of expertise in respiratory therapeutics for the company. Additionally, A. Bruce Montgomery, M.D., founder and CEO of Corus, has joined Gilead's executive committee as senior VP and head of respiratory therapeutics.

  In conjunction with its acquisition, Gilead has entered an agreement with Novartis Vaccine and Diagnostics Inc. whereby Novartis has agreed to dismiss its ongoing litigation with Corus for an undisclosed payment.

  For more information, visit gilead.com.

- **GREY HEALTHCARE GROUP**, New York, a global healthcare communications network and part of the WPP group of companies, has acquired **Catalyst On-line Inc.**, a specialized advertising, marketing, and consulting firm with targeted expertise in the Internet-search marketplace.

  Catalyst's founders, Heather Frahm and Beth LeTendre, continue to lead the agency from its Boston-based headquarters. They manage its expanding client base, which includes Biogen Idec, Novartis, and Pfizer.

  For more information, visit ghgroup.com.

- **ICON PLC.**, a Dublin, Ireland-based provider of outsourced development services to the pharmaceutical, biotechnology, and medical-device industries, has entered into a definitive agreement to acquire **Ovation Research Group**, a patient registries, outcomes research, and health economics firm based in Highland Park, Ill. The transaction was expected to close in the third quarter of 2006.

  For more information, visit iconclinical.com.

- **JOBSON MEDICAL INFORMATION LLC (JMI)**, a New York-based healthcare information provider, has acquired **Rogers Medical Intelligence Solutions (MIS) Inc.** from Rogers Communications.

  Rogers MIS, New York, provides information and insights on the latest medical and clinical research worldwide, based on its unparalleled database of clinical information.

  For more information, visit jobson.com.

- **UNITED BIOSOURCE CORP. (UBC)** has acquired **Muse & Associates**, Washington, D.C., a healthcare consulting firm specializing in Medicare and Medicaid cost estimates and projections, policy analysis, reimbursement and coding, market analysis, and special studies for the pharmaceutical, biotechnology, medical-device, health insurance, and health service industries.

  UBC, Bethesda, Md., provides evidence-based solutions to help pharmaceutical and biotech companies deliver the scientific evidence necessary to demonstrate the clinical benefits, safety, and economic value of their products.

  For more information, visit unitedbiosource.com.

- **WEBMD HEALTH CORP.** has entered into a definitive agreement to acquire the interactive medical-education, promotion, and physician-recruitment businesses of **Medsite Inc.**, a New York-based e-pharmaceutical marketing company.

  WebMD, New York, is a leading provider of online health information services to consumers and physicians.

  The deal, which was expected to close in September, was valued at $41 million in cash.

  For more information, visit webmd.com.

NEW CRO Specializes in Medical Devices

A new contract research organization, Symbios Clinical Inc., has been launched. Symbios specializes in the medical-device industry, offering start-to-finish clinical-trial management services, including study design, site activation, data management, monitoring, data analysis, and publication support. The company has secured more than $500,000 in start-up financing.

"We believe the ideal outsourcing experience should be as seamless as possible, and we want to be a natural extension of the customers we serve," says Cofounder Ethan Rooney. "This requires a true specialization and a willingness to focus on serving a select market segment rather than trying to be everything to everyone."

The new company also is focused on customer-centric execution.

Cofounder Ryan Wilson says Symbios serves customers who value the organization's industry-specific expertise.

"Our goal is to operate on the principles of superior customer service and quality clinical-trial execution," Mr. Wilson says.

"At the end of the day, people want results, and that's what we're here to provide," he continues. "Accordingly, the company places a high value on training and continuing education to sustain high levels of performance and job satisfaction."

Collaboration Will Develop DATA STANDARDS FOR CLINICAL TRIALS

The U.S. Food and Drug Administration's (FDA) Critical Path Initiative has formed a collaborative group to support the development of data-collection standards for regulated biomedical/clinical research.

The collaborative effort is part of the FDA's Human Subject Protection/Biomedical Research (HSP/BIMO) effort, which falls under C-Path. The effort is led by the Clinical Data Interchange Standards Consortium (CDISC) and will encourage broad stakeholder involvement. Participating organizations include: the Association of Clinical Research Organizations (ACRO), the FDA, the National Institutes of Health (NIH) — including the National Center for Research Resources (NCRR) and the National Library of Medicine (NLM) — the American Medical Informatics Association (AMIA), C-Path Institute, and the Pharmaceutical Research and Manufacturers of America (PhRMA), among others.

The HSP/BIMO initiative, which was launched in June, facilitates the modernization of the regulation of clinical trials and bioresearch monitoring, specifically the protection of human subjects and the integrity of data in clinical trials, and it encompasses devices, foods, human drugs, biological drug products, and veterinary medicine. The new effort is part of an HHS-wide initiative to employ recent advances in basic science, including genomics and molecular analysis, to bring about more effective development and review of therapies and to enable increasingly targeted and individualized care management for patients.

"We must have high-quality data to support new product applications," says Dr. Janet Woodcock, deputy commissioner for operations at the FDA. "Data collection standards will be enormously helpful to regulatory review and decision-making, and I applaud the efforts of ACRO, CDISC, and others to significantly move this project forward."

This initiative will provide value to all levels of the clinical-trial enterprise. We look forward to working on data-collection standards as one way to make the clinical-trial process more efficient, says Douglas Peddicord, Ph.D., Executive Director, ACRO.

Improving the efficiency of product development is a key objective of the Critical Path Initiative. In 2005 ACRO, in consultation with the FDA, initiated a pilot project aimed at standardizing the collection of clinical-trial data. ACRO produced template forms for the collection of adverse event (AE) and concomitant medication (CM) clinical-trial data and outlined principles for standardizing the myriad case report forms (CRFs) in use today.

WHAT'S NEW ON THE SHELVES

- **FDA: A CENTURY OF CONSUMER PROTECTION**, edited by Wayne L. Pines, crisis, regulatory, and media consultant, APCO Worldwide, and **published by the Food and Drug Law Institute**, commemorates the 100th anniversary of the 1906 Pure Food and Drugs Act, which brought foods and drugs under federal regulatory jurisdiction.

  The book covers all aspects of the FDA over the last century, including captivating, personal accounts from 43 contributing authors, who were selected by a committee of former FDA commissioners, deputy commissioners, and general counsels. The volume also includes a preface by the acting FDA commissioner and photographs depicting the FDA story.

  For more information, visit fdli.org.

- **FDA DIRECTORY — SPRING/SUMMER 2006**, **published by the Food and Drug Law Institute**, is the biannually updated reference book that includes up-to-date contact information for FDA personnel, as well as a comprehensive general information section. The directory is organized by FDA Center and includes organizational charts and mission statements for each. The book also contains information for the Office of Regulatory Affairs, including ORA field operations broken out by region, as well as the Office of the Commissioner, with photos and biographies for key individuals.

  The general section provides an overview of the FDA's international role, as well as other federal agencies with FDA-related responsibilities.

  For more information, visit fdli.org.

- **PORTFOLIO OF CME POLICIES AND PROCEDURES**, **published by PTR Educational Consultants LLC**, is a practical resource for busy continuing medical education (CME) professionals.

  The portfolio is useful for CME providers applying for initial accreditation, as well as those preparing for re-accreditation. It comprises more than 100 documents, including procedures, forms, templates, checklists, and examples.

  For more information, visit ptredconsultants.com.

Follow up

THE ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS (ACRO), Washington, D.C., represents the world's leading clinical research organizations that provide specialized services that are integral to the development of drugs, biologics, and medical devices, as well as advancing clinical outsourcing to improve the quality, efficiency, and safety of biomedical research. For more information, visit acrohealth.org.

EKR THERAPEUTICS INC., Cedar Knolls, N.J., is an emerging specialty pharmaceutical company focused on the oncology supportive care segment. For more information, visit ekrtx.com.

GSW WORLDWIDE, Westerville, Ohio, an inVentiv Health company, is one of the largest healthcare advertising agencies in the world with offices in 13 major global markets, providing liberating ideas that generate new energy around products, build stronger connections with customers, and create leadership brands. For more information, visit gsw-w.com.

I3 CME, Basking Ridge, N.J., an i3 Ingenix business, is a full-service, accredited provider of certified education with strong capabilities in central nervous system (CNS), oncology, cardiology, and infectious disease. For more information, visit i3cme.com.

IMS HEALTH INC., Fairfield, Conn., is a global source for pharmaceutical market intelligence, providing critical information, analysis, and services that drive decisions and shape strategies for the pharmaceutical and healthcare industries. For more information, visit imshealth.com.

INTRINSIQ RESEARCH INC., Waltham, Mass., has unique data, clinical expertise, and oncology market experience to aid companies to make sound, fact-based business decisions in the oncology care marketplace. For more information, visit intrinsiq.com.

SYMBIOS CLINICAL INC., Shoreview, Minn., is a privately held contract research organization specializing in clinical-trial management for the medical-device industry. For more information, visit symbiosclinical.com.

U.S. FOOD AND DRUG ADMINISTRATION (FDA), Rockville, Md., is responsible for advancing public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable. For more information, visit fda.gov.