CDM Adds SCIENTIFIC CONSULTING DIVISION

Cline Davis & Mann (CDM) has launched a new division that offers fully integrated strategic and scientific consulting services for pharmaceutical, biotechnology, and medical-device companies.

Platform Advisors is led by Lori Klein, managing partner at CDM. Services provided by the division include portfolio strategy, licensing, valuations, forecasting, early commercialization, and clinical strategy. The new division provides services that include portfolio strategy, licensing, valuations, forecasting, early commercialization, and clinical strategy.

Chairman and CEO Ed Wise with Lori Klein, Managing Partner, who leads Platform Advisors.

CDM created the Platform Advisors division in response to a growing customer need for early commercialization strategies. Platform Advisors combines the expertise of seasoned healthcare professionals and commercial strategists, an integrated approach that provides a single source for strategic and scientific needs at every stage of a product's life cycle.

"We are really pleased to offer these services for our clients," says Ed Wise, chairman and CEO of CDM. "Now we can partner with companies from discovery to launch and beyond."

IMS Establishes HEALTHCARE RESEARCH CONSORTIUM

IMS Health has joined with 10 leading U.S. academic researchers in medicine, health economics, and public health to establish the Health Services Research Network (HSRN), a consortium that will apply IMS's evidence-based information to address key healthcare issues. HSRN is studying a number of areas critical to effective healthcare delivery, including the impact of treatment variability on patient care and overall costs; disparities in treatments and their effect on outcomes; identification of best practices; and assessments of quality of care. Members of HSRN include leading experts in medical ethics, patient safety, pharmacy, public health, epidemiology, statistics, and economics.

"The Health Services Research Network provides an unmatched opportunity for cross-disciplinary collaboration on health research," says Randall Stafford, M.D., Ph.D., associate professor of medicine at the Stanford Prevention Research Center, Stanford University, and charter member of HSRN.

Five HSRN projects are already under way, focused on healthcare topics such as pediatric treatment outcomes; benchmarks of hospital drug costs; drug safety in key therapeutic classes; variability in treatment patterns; and how quickly the public accepts new medical technology.

"The need to understand how patients are treated in practice, and the outcomes of those treatments, has never been greater," says Robert Hunkler, director of professional relations at IMS and HSRN coordinator.

Appian Labs Focuses on DRUG-DELIVERY, DESIGN SOLUTIONS

Appian Labs is a newly launched biopharmaceutical company specializing in comprehensive and strategic drug delivery and design solutions for pharmaceutical and other bioactives companies worldwide. The company provides solutions for a number of drug-delivery problems, including poor bioavailability or solubility, dose timing, and toxicity.

Named for the Appian Way, a leading delivery route of the ancient world, Appian is funded and managed by venture firm Emergent Technologies (ETI). Its laboratory is led by Chief Scientist Nicholas Peppas, Sc.D., a pioneer in the field of drug delivery and controlled-release chemistry.

We can design delivery solutions tailored to pharma companies' drugs and that improve bioavailability, dosing, or timing of a drug, says Dr. Brian Windsor, President of Appian Labs.

"Building on the drug-delivery leadership of our scientific team, we can design delivery solutions that are tailored to pharma companies' drugs and that improve bioavailability, dosing, or timing of a drug," says Brian Windsor, Ph.D., president of Appian. "Our breadth of expertise and technologies enable us to match virtually any kinetic profile desired."

The company's first marketing initiative is an invitation to "draw your own profile," and Appian will design a custom drug-delivery system to match.

Good Products Adds CLINICAL TECHNOLOGY CONSULTING UNIT

Good Products has launched a clinical technology consulting division designed to enable biopharmaceutical sponsors and CROs to optimize their use of clinical technology.

The new division offers remote and onsite technology experts throughout North America and Europe to offer advice designed to maximize efficiency in clients' outsourced, in-house, and hosted clinical technologies. These experts also offer guidance on deploying new technologies to complement existing workflows, and they can advise on changing business strategy and working practices to increase the value of new and existing technologies. Companies and CROs can gain advice on data integration, optimizing workflows, and choosing best-fit solutions.

The complexity of which product to use and how to implement it for optimal results is something that represents a confusing and potentially expensive picture, says Patrick Hughes, Senior VP at Good Products.

ON THE SHELVES

- The 2008 edition of **MANAGED MEDICARE AND MEDICAID FACTBOOK from Atlantic Information Services (AIS)** includes data and analysis to help pharmaceutical companies accurately forecast trends and plan strategies in the Medicare Advantage program, Medicare Part D, and managed Medicaid.

  The new edition is available in print and CD formats and features information on enrollment trends, Medicare Advantage plan marketing, regional offerings and market share, state initiatives in Medicaid, prescription drug benefits, and mergers and acquisitions. These data are becoming more important as companies seek to minimize the impact of Medicare Advantage program cuts and to sustain growth and expand enrollment in Medicare Advantage prescription drug plans and stand-alone Prescription Drug Plans (PDPs).

  Also available from AIS is the DIRECTORY OF HEALTH PLANS: 2008, which contains enrollment data and contact information for health plans and primary care preferred provider networks operating in the United States as of the end of 2007.

  Available in print and CD formats, the directory helps clients conduct accurate market-share analysis, get enrollment benchmarks for comparison, identify potential business partners and clients, and compare network-access fees. The listings include national and state-level enrollment data by company; national enrollment by product type; company contact information; types of primary-care products offered; key executives; and complete status for all accredited commercial, Medicare, and Medicaid plans.

  For more information, visit aishealth.com.

- **Parexel's BIO/PHARMACEUTICAL R&D STATISTICAL SOURCEBOOK 2008/2009 is now available in hardcopy and electronic formats from Barnett Educational Services**. The publication includes a wide range of proprietary research and development intelligence and analyses, such as new proprietary analyses on U.S. clinical-trial starts and overall active clinical trials, both segmented by therapeutic category; and a comprehensive analysis of clinical research offshoring that highlights the countries in which pharma companies are now locating their new clinical trials.

  For more information, visit barnettinternational.com.

- A newly released book from **Bioplan Associates, A QUICK GUIDE TO CLINICAL TRIALS, presents the rules and regulations governing clinical trials in a reader-friendly yet authoritative format**, allowing readers from all backgrounds to easily grasp the topic.

  In addition to providing an overview of the clinical-trials process, the book reviews the history of clinical trials and presents the evolving ethical and regulatory considerations related to these trials, as well as the commercial angle. The book also provides first-hand insights into the role of the patient in clinical trials.

  For more information, visit bioplanassociates.com.

- **The Food and Drug Law Institute (FDLI)** has issued **PHARMACEUTICAL RISK MANAGEMENT: PRACTICAL APPLICATIONS**, a comprehensive handbook to help pharmaceutical companies, consultants, and other drug-industry stakeholders prepare for and comply with the Food and Drug Administration's new rules on risk evaluation and mitigation strategy (REMS).

  The 300-page book provides practical guidance to enable drug companies to effectively negotiate the maze of REMS pre- and postmarketing surveillance, including what actions to take to determine if the benefits of a drug outweigh its risks and what to do if the FDA decides new safety information requires companies to make changes in the marketing of existing drugs. It also includes chapters outlining the environmental and historical context for risk management; proven strategies for designing and measuring REMS effectiveness; practical examples and case studies of successful risk management strategies; and crisis-management considerations.

  For more information, visit fdli.org.

- **THE GLOBAL GUIDE TO PHARMA MARKETING CODES, developed by the members of GlobalHealthPR**, is designed to help pharmaceutical marketers and public relations specialists maximize opportunities in the international communications landscape.

  Available in print and online, the guide provides information on country-specific codes and regulations surrounding the promotion of medicines in France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States.

  GlobalHealthPR plans to incorporate additional countries and updated practices into the guide, with the first of these updates to include healthcare communications information pertaining to Mexico and Argentina.

  GlobalHealthPR is an international partnership of independent healthcare public relations firms and their affiliates from major markets in Europe, the United States, and Asia. It is represented in the United States by Spectrum Science Communications.

  For more information, visit globalhealthpr.com.

- **Lippincott Williams & Wilkins (LWW)**, part of Wolters Kluwer Health, **has launched a new journal for the practicing orthopedic surgeon, CURRENT ORTHOPAEDIC PRACTICE (COP)**, as the successor to the LWW-published review journal, Current Opinion in Orthopaedics.

  The bimonthly print and online journal combines the previous publication's in-depth review articles focusing on the latest developments in orthopedic practice with original clinical research and special departments. COP addresses the full scope of orthopedics, covering the latest techniques and newest thinking in general orthopedic disorders, as well as issues and controversies in pediatric orthopedics, orthopedic trauma, and sports medicine.

  In addition to the print and online journal, subscribers receive Current Orthopaedic Practice eNews, an electronic newsletter to be distributed in the months the print journal is not published. The e-newsletter distills current news and research into a quick-read, user-friendly format. Subscribers to COP also have access to LWW's online archives, including the complete online archive of Current Opinion in Orthopaedics from 1990 to 2008, and archives of Clinical Orthopaedics & Related Research from 1976 to 2007.

  For more information, visit lww.com.

M&A ACTIVITY

- **CYTRX has agreed to purchase INNOVIVE PHARMACEUTICALS**, an Atlanta-based biopharmaceutical company with four clinical-stage oncology drug candidates, for an estimated $21.3 million plus the assumption of debt. CytRx, Los Angeles, is a biopharmaceutical company engaged in the development and commercialization of therapeutics based on molecular chaperone amplification technology.

  The acquisition of Innovive provides CytRx with an expanded portfolio of clinical development programs in oncology, amyotrophic lateral sclerosis, stroke recovery, and diabetic foot ulcers. In addition, the combined company owns a 49% interest in RXi Pharmaceuticals, a Worcester, Mass.-based discovery-stage biopharmaceutical company pursuing the development and commercialization of proprietary therapeutics based on RNA interference (RNAi) technology.

  For more information, visit cytrx.com.

- Market research and advisory services provider **DECISION RESOURCES**, Waltham, Mass., **has acquired MANHATTAN RESEARCH**, a New York-based provider of access to physician and consumer opinions on the global healthcare market. The acquisition expands Decision Resources' portfolio of market research and data businesses for the healthcare industry and gives it a larger footprint in the consumer market research arena.

  For more information, visit decisionresources.com.

- **GLAXOSMITHKLINE**, Research Triangle Park, N.C., **has acquired Sirtris Pharmaceuticals** for about $720 million, significantly enhancing its metabolic, neurology, immunology, and inflammation research efforts by establishing a presence in the field of sirtuins, a recently discovered class of enzymes believed to be involved in the aging process. Sirtris is now part of GSK's drug-discovery organization while continuing to operate from laboratories in Cambridge, Mass., as an autonomous unit. It continues to be led by Christoph Westphal, CEO and vice chair, and the rest of the Sirtris management team.

  For more information, visit gsk.com.

- Contract management solutions provider **I-MANY**, Edison, N.J., **has acquired EDGE DYNAMICS**, a Redwood City, Calif.-based provider of channel demand management solutions for the life-sciences industry, for an undisclosed cash payment and assumption of Edge Dynamics' debt.

  The acquisition is expected to add about $5 million in revenue to I-many's business in the first year following the transaction, with the potential to grow to a $20 million business in about four years.

  For more information, visit imany.com.

- Global biopharmaceutical services provider **PAREXEL INTERNATIONAL**, Waltham, Mass., **has acquired CLINPHONE**, a global clinical technology organization based in Nottingham, United Kingdom, for an estimated $182 million. The acquisition of ClinPhone enables Parexel to provide clients with a more comprehensive e-clinical suite of technology solutions that allow clients to realize more significant process efficiencies, greater visibility across studies, improvements in data quality, and accelerated decision-making. It also fits with Parexel's strategy to provide a wide array of geographic locations for clients' clinical-development programs.

  For more information, visit parexel.com.

- Swiss pharmaceutical giant **ROCHE has offered to buy the rest of biotechnology company Genentech** for $43.7 billion in cash. Roche acquired a majority stake in Genentech in 1990 and presently owns 55.9% of the company.

  The combined entity will be the seventh-largest U.S. pharmaceuticals company in terms of market share, generating more than $15 billion in annual revenue, and will employ around 17,500 pharma employees in the United States alone, including a combined salesforce of about 3,000 people. Including diagnostics, the Roche Group will employ around 25,000 people in the United States.

  Genentech will operate from its existing campus in South San Francisco, Calif., as an independent research and early development center within Roche. Roche's Palo Alto, Calif.-based virology research and development activities will relocate to South San Francisco, while its Palo Alto inflammation group will become part of Roche's Nutley, N.J.-based research and development organization. The Nutley site will host two global disease biology areas, oncology and inflammation, as well as key functions in metabolism.

  For more information, visit roche.com.

  EDITOR'S NOTE: At press time, Genentech's board of directors declined Roche's offer, saying it undervalued the company.

- **STIEFEL LABORATORIES**, a privately held dermatology specialty pharmaceuticals company based in Coral Gables, Fla., **has agreed to acquire Princeton, N.J.-based dermatology firm Barrier Therapeutics** for about $148 million. The acquisition further expands Stiefel's oral and topical product development portfolio and increases its sales of novel treatments for skin conditions. Barrier Therapeutics currently markets three pharmaceutical products: Xolegel, for seborrheic dermatitis; Vusion Ointment, for diaper dermatitis complicated by documented candidiasis; and Solagé Topical Solution, for solar lentigines.

  For more information, visit stiefel.com.

CRI Establishes RESEARCH CENTER FOR PAIN DISORDERS

The opening of our Center for the Research of Pain Disorders is a very exciting milestone for CRI as we continue our growth in the central nervous system space, says Ken King, President and CEO of CRI.

CRI Worldwide has opened its Center for the Research of Pain Disorders at its new clinical research facility at the Kirkbride Center in Philadelphia.

The center conducts Phase I through Phase IV inpatient and outpatient clinical-trial services, with specific expertise in bioequivalence, bioavailability, pharmacokinetics and pharmacodynamics (PK/PD) studies, cardiac safety (QTc), and proof-of-concept work. Its staff has conducted more than 100 clinical trials, including extensive experience in neuropathic pain, post-hepatic neuralgia back pain, and fibromyalgia.

The new center is led by Daniel Gruener, M.D., a recognized expert in the areas of analgesic and neuropathic pain research.

"The opening of our Center for the Research of Pain Disorders is a very exciting milestone for CRI as we continue our growth in the central nervous system space," says Ken King, president and CEO of CRI.

AROUND THE GLOBE

- **CAMPBELL ALLIANCE GROUP**, a Raleigh, N.C.-based management consulting firm specializing in the pharmaceutical and biotech industries, **has opened a new branch office in London**, its first location outside the United States. The London office provides a convenient location from which to serve Campbell's existing pharmaceutical and biotech clients in the United Kingdom and continental Europe.

  For more information, visit campbellalliance.com.

- U.K.-based global research organization **CHILTERN** **has opened new offices in Portugal and Russia** and strengthened its strategic development efforts in Latin America. Chiltern's new Lisbon-based office is headed by Ricardo Diaz, country manager of Portugal. Mr. Diaz has more than 10 years of experience in clinical research and holds master's degrees in pharmacology and clinical trials, as well as an MBA.

  In other global moves, Chiltern has appointed Oscar Podestá general manager, Latin America, with responsibility for the strategic development of Chiltern's Latin American business. Mr. Podestá has nearly a decade of experience in clinical research, including executive positions in the contract research organization (CRO) sector.

  For more information, visit chiltern.com.

- U.K.-based clinical technology organization **CLINPHONE** **has opened a new office in Paris**. The Paris office provides a local point of contact for ClinPhone's current France-based pharmaceutical clients, as well as new customers in the region. The new office is led by Damien Tremolet, director of operations at ClinPhone, and supported by Jacques Rudelle, associate director of business development.

  For more information, visit clinphone.com.

- Japanese pharmaceutical firm **DAIICHI SANKYO** **has established a subsidiary in Istanbul, Turkey**, whose initial focus is on marketing the osteoporosis medication Evista (raloxifen). The Turkish affiliate is strategically managed from Munich, where the European headquarters of Daiichi Sankyo is located. The Munich office also directs the company's affiliates in Germany and a number of other European pharmaceutical markets such as France, the United Kingdom, Spain, and Italy.

  For more information, visit daiichisankyo.com.

- Full-service healthcare communications agency **HEALTHSTAR PUBLIC RELATIONS (HSPR)**, New York, **has entered into a partnership agreement with the GlobalCom PR Network** to extend HSPR's international presence to all member states of the European Union, Asia Pacific, Latin America, South Africa, and the Russian Federation. In return, HSPR has become GlobalCom's exclusive healthcare partner in the U.S. market.

  For more information, visit healthstarpr.com.

- Global contract research organization **PPD**, Wilmington, N.C., **has opened an office in Istanbul**. PPD is using the Turkey location to provide clinical monitoring services in key therapeutic areas beyond Russia and Ukraine, countries where the company is expanding through its pending acquisition of InnoPharm Ltd.

  For more information, visit ppdi.com.

INC Research Strengthens **FOCUS ON WOMEN'S HEALTH**

The women's health division at INC Research combines clinical expertise in the diseases that most affect women, with an understanding of the challenges our customers face in developing drugs for this population that must factor in gender and age nuances, says Dr. Cynthia Madden, who heads the new division at INC Research.

INC Research has launched a division specifically focused on providing multi-therapeutic drug-development services that target the diseases and disorders that most affect women. Leading this new women's health division is Cynthia Madden, M.D., M.P.H., who has worked for FDA's Division of Investigational New Drugs, and received additional training at the National Institutes of Health.

"Dr. Madden has 19 years of direct clinical-care experience focusing on women's health issues, and has developed a distinctive acumen for the complex underlying medical, recruitment, and retention issues that so dramatically impact the success of clinical trials in women," says John Potthoff, chief operating officer of INC Research.

"The women's health division at INC Research combines clinical expertise in the diseases that most affect women, with an understanding of the challenges our customers face in developing drugs for this population that must factor in gender and age nuances," Dr. Madden adds.

Follow up

APPIAN LABS LLC, Austin, Texas, is a biopharmaceutical company specializing in advanced therapeutic drug-delivery and design solutions for biotech, pharmaceutical, and life-sciences companies worldwide. For more information, visit appianlabs.com.

CLINE DAVIS & MANN, New York, is a healthcare advertising agency and part of the Omnicom network. For more information, visit clinedavis.com.

CRI WORLDWIDE INC., Clementon, N.J., is a provider of clinical development testing and research services for central nervous system, psychiatric, pain, and other drug compounds. For more information, visit criww.com.

GOOD PRODUCTS LTD., with offices in Nottingham U.K., and Irvine, Calif., is a provider of enterprise content management (ECM) solutions for the pharmaceutical, biotechnology, and medical-device sectors. For more information, visit goodproductsltd.com.

IMS HEALTH INC., Norwalk, Conn., provides market intelligence to the pharmaceutical and healthcare industries. For more information, visit imshealth.com.

INC RESEARCH INC., Raleigh, N.C., is a contract research organization that provides customized Phase I through Phase IV programs in therapeutic areas of specialty, and in innovative pediatric and women's health trials. For more information, visit incresearch.com.