

## CROs See Brighter Future Despite Cancellations

Contract research organizations (CROs) continue to feel the adverse effects of cancellations and negative foreign exchange, but their most recent earnings reports show some promise.

"To paraphrase the words of Mark Twain, 'Reports of the death of the CRO industry have been greatly exaggerated,'" ICON CEO Peter Gray told investors last week.

The Dublin, Ireland-based CRO reported strong first quarter net revenues with an increase of 9.2% to \$201.3 million compared with the same quarter last year, a 25% hike in profit and hopes to add to that performance by acquiring a phase I unit in Omaha, Neb.

Income from operations was \$26.9 million, compared with \$21.5 million for the same quarter last year. Net income was \$20.9 million or 35 cents per share on a diluted basis, compared with \$16.9 million or 28 cents per share last year.

ICON purchased a phase I facility out of bankruptcy from Qualia Clinical Services for \$380,000. The 33,000-square-foot unit, which currently holds 180 beds, will be turned into a 100-bed unit to be operational in May. The acquisition is expected to dilute 2009 earnings by about four to six cents.

Despite a reported increase in project delays

page 3

## Bio-Imaging Changes Name, Plans Acquisitions

Now that Newtown, Pa.-based contract research organization (CRO) Bio-Imaging Technologies has completed its integration of Phoenix Data Systems, which it acquired in March 2008, the company has changed its name to BioClinica. The new name also marks the start of an active acquisition phase for the 450-employee company, which wants to buy more companies in the clinical research services space.

"We started this whole re-branding about four months ago. This is a situation that is not going to be a yearly event. We're going to do this once," said Mark Weinstein, president and CEO, BioClinica. The change was announced at

IIR's 18th Annual Partnerships with CROs conference in Orlando.

He explained that the name "Bio-Imaging Technologies" did not make it obvious to investors that the company had an eClinical component. "Plus, we're looking at a lot of other acquisitions, and how do we come up with an umbrella brand—a super brand—that we can really start to leverage the power of 450 people?"

BioClinica offers medical image management and electronic data capture. In addition, the company offers solutions that combine these core services.

page 3

**Kendle** CFO is leaving...2

**Encorium** posts another loss...2

### Company Profile... 4

An interview with Bob Borysko, vice president of programming and development

### DZS Software Solutions

### Drug & Device Pipeline News... 6

CenterWatch has identified 17 drugs and devices that have entered a new trial phase this week.

### Trial Results... 7

CenterWatch reports on results for four drugs. Visit [www.centerwatch.com](http://www.centerwatch.com) for real-time updates on drugs in clinical trials.

### Biotech Review... 8

Biotech briefs from *Bioworld Today*.

**The CenterWatch Monthly**

A monthly newsletter featuring in-depth stories on the clinical trials industry and grant opportunities. Annual subscription is \$425.

**JobWatch**

A web-based service listing clinical research jobs, career resources and a searchable resume database. Visit the JobWatch web site at <http://www.centerwatch.com/jobwatch/>

**CenterWatch Clinical Trials Listing Service™**

[www.centerwatch.com](http://www.centerwatch.com)  
An international listing of clinical trials actively seeking patients, and directories of research centers and industry providers. To use this service, contact [support@centerwatch.com](mailto:support@centerwatch.com).

**CenterWatch Publications**

CenterWatch publishes a wide range of CME-accredited training manuals, directories, brochures and drug intelligence information. For more information, visit our bookstore on [www.centerwatch.com](http://www.centerwatch.com)

CenterWatch Main and Editorial Offices  
100 N. Washington St, Suite 301, Boston, MA 02114  
Tel (617) 948-5100 Fax (617) 948-5101  
[editorial@centerwatch.com](mailto:editorial@centerwatch.com)

**CWWeekly** (ISSN 1528-5731)

**Steve Zisson** Editorial Director  
**Sara Gambrill** Senior Editor  
**Molly Rowe** Senior Associate Editor  
**Tracy Lawton** Drug Intelligence  
**Melissa Nazzaro** Advertising  
**Steven Hasomeris** Designer  
**Danielle Wooding** Designer

Send news submissions to Steve Zisson  
Tel (617) 948-5142 Fax (617) 948-5101  
[stephen.zisson@centerwatch.com](mailto:stephen.zisson@centerwatch.com)

To subscribe to *CWWeekly* or other CenterWatch publications, contact our customer service department.  
Tel (800) 765-9647 Fax (800) 850-1232  
P.O. Box 105109, Atlanta, GA 30348-9891

To order reprints, contact Rick Lavallee.  
Tel (617) 948-5126  
[rick.lavallee@centerwatch.com](mailto:rick.lavallee@centerwatch.com)

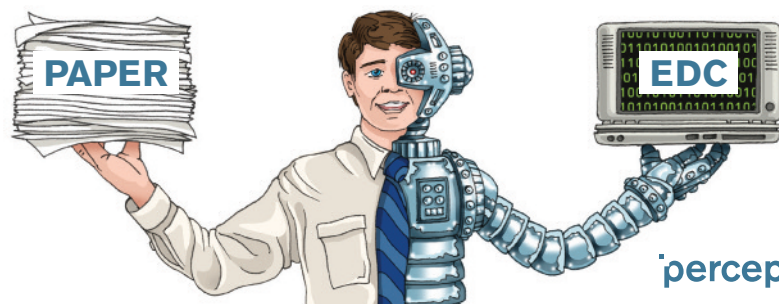
**Industry Briefs****CROs**

- **Kendle** senior vice president and chief financial officer (CFO) and secretary **Karl "Buzz" Brenkert III** is leaving the contract research organization (CRO) effective May 6, 2009. He will be replaced by **Keith Cheesman**, currently Kendle's vice president of accounting. Brenkert was CFO of the company for six years, overseeing the CRO's global financial operations, including finance, accounting, budgeting, tax, investor relations and financial planning. Cheesman served as a member of Kendle's finance senior management team from 2000 to 2004 and from January 2008 to present. Cheesman's departure comes as Kendle is struggling with project cancellations and a halving of its stock price.
- Wayne, Pa.-based CRO **Encorium** posted a net loss and a decrease in revenues for both the fourth quarter 2008 and the year ended December 31, 2008. Net loss for the quarter was \$13.7 million, or \$(0.67) per diluted share, compared with a loss of \$732,000, or \$(0.04) per diluted share, in the fourth quarter 2007. This includes a non-cash \$12.5-million impairment charge related to the company's goodwill and certain of its intangible assets. Net revenue for the fourth quarter was \$7.1 million, a decrease of 14.5% from \$8.3 million for the fourth quarter 2007. The CRO's net loss for the full year 2008 was \$21.1 million, or \$(1.02) per diluted share, compared with a net loss of \$2.8 million, or

\$(0.14) per diluted share for 2007. Net revenue for the year decreased to \$30.2 million, compared with \$31.7 million for 2007. Encorium's latest financials were prepared on a going-concern basis.

- Wilmington, N.C.-based CRO **PPD** earned accreditation by the College of American Pathologists (CAP) for its global central lab operations in Beijing, China. This is the third PPD central lab to receive CAP accreditation, with other accredited labs operating in Highland Heights, Ky., and Brussels, Belgium. PPD expanded its global central lab services into China last year, and, based on growing client demand in Southeast Asia, the company plans to open a central lab in Singapore later this year.
- Indian CRO **SIRO ClinPharm** (SIRO) signed a strategic alliance with **Advanced Clinical Trial Solutions** (ACT Solutions) to expand its oncology clinical development and patient recruitment services to North America. Headquartered in Flemington, N.J., ACT Solutions provides oncology drug development services primarily in North America and hopes to benefit from SIRO's clinical study management, patient recruitment, data management, biostatistics and medical writing capabilities in India and Europe. SIRO is based in Mumbai, India.

Get the best  
of both worlds  
with DataLabs®



perceptive  
INFORMATICS®

## Earnings

and cancellations across the CRO industry, ICON's net business wins for the quarter finished strong at \$265 million with a book-to-bill of 1.2, and Gray told investors that new business activity had accelerated toward the end of the quarter.

Josef von Rickenbach, chairman and CEO of Waltham, Mass.-based Parexel, echoed Gray's sentiments. Parexel's cancellation rate for the quarter was 4.8%, within the company's projected cancellation rate of 3.5% to 5%, and von Rickenbach told investors that new business wins are increasing.

The company recorded service revenue of \$264.5 million for its third quarter up 8% from \$245.3 million a year ago.

Parexel recorded flat net income of \$14.2 million, or 25 cents a share for the quarter, but increased its 2009 profit forecast to 97 cents to 99 cents per share, up from 94 cents to 98 cents.

"I think we did a very good job of manag-

ing costs, collecting cash and winning new business, all despite a challenging environment. Looking forward, we expect continued—albeit somewhat lower—revenue growth and profitability improvements," von Rickenbach said.

For fiscal year 2009, consolidated service revenue is expected to be in the range of \$1.075 to \$1.080 billion, down from previous guidance of \$1.095 to \$1.115 billion. Parexel senior vice president and CFO James Winschel told investors that this guidance reduction reflects overall conservatism rather than concern about a particular client or service area.

"The world is still a little off kilter at the current time, and while we have very clear visibility to the fourth quarter, we certainly also are aware of the reports of some of our competitors and wanted to just be cautious as we went into the latter half of the year," Winschel said.

The future is not as rosy for all CROs, however.

Covance reported last week an 18% decline in first quarter, and the company cut its

2009 profit guidance to \$2.50 to \$2.70 per share from \$3.00 to \$3.20 per share. Covance recorded first quarter net income of \$40.3 million, or 63 cents a share, down from \$49.1 million, or 76 cents a share, a year ago. First quarter net revenue was up 7% to \$468.4 million, but early stage revenue, where Covance is traditionally strong, slipped 5% to \$192.5 million.

Cincinnati-based Kendle recently warned investors that first quarter revenues would be significantly lower than original forecasts—news that caused the company's shares to plummet more than 50%. Almost two weeks later, Kendle's share price continues to hover at around \$9 a share. The company attributed the revenue shortfall to pricing pressures and "unprecedented biopharmaceutical industry conditions," resulting in project delays and cancellations. Kendle's project cancellation rate for the first quarter was 45%, compared with original projections of 18%.

## Bio-Imaging

"Our mantra, or our goal, is to say, 'Everything needs to go into a single database such that you do not have to clean up at the end.' You can save a tremendous amount of time and money when you combine those data sets earlier," Weinstein said.

BioClinica was founded in 1990 and the company went public in 1992. The company

has grown organically and through acquisitions, its first being Netherlands-based Heart Core in 2004, then France-based Theralys in February 2007, followed by Phoenix Data Systems.

The company plans to make more acquisitions, despite the global economic downturn.

"It's a very interesting time in the marketplace. A lot of people would say it's not a great time. I can't tell you that I'm happy that my

stock price has come down with everybody else's, but I will tell you that having \$15 million in the bank, being a public company, not having any debt, being profitable and growing puts us in a very interesting position because there are a number of good companies out there in a different stage of their life cycle where the storyboard that they laid out two years ago is no longer feasible," Weinstein said.



### Full-service CRO specialized in Cardiovascular and Metabolic Trials

- Comprehensive trial management, data & analysis services
- Expert advisory services
- Ambulatory Blood Pressure Monitoring core lab services
- Multinational capabilities

[www.integrium.com](http://www.integrium.com)

## Profile: Technology Company

### DZS Software Solutions, Bound Brook, N.J.

#### An interview with Bob Borysko, vice president of programming and development

#### How and why was DZS Software Solutions founded?

My two partners, Doron Steger and David Horowitz, and I founded DZS in 1996. In 1992, I was working with a consulting group to develop a data management system for a pharma company, and I retained the rights to that software. At the same time, Doron Steger's company developed a reporting solution for another pharma for authoring statistical tables and data listings, and his company retained the rights to that as well. We joined forces when I responded to an RFI for a data management system by Doron's company. We both saw the value and potential to market both SAS-based systems under one brand as did David who was providing strategic marketing and sales support for Doron's company at the time. As a result, we decided to form DZS Software Solutions. Most of the popular data management systems at the time were Oracle-based. Our SAS-based system was easy-to-use and provided a flexible alternative to the more cumbersome Oracle-based systems. On the report side, our system provided powerful tools for programmers to easily produce complex statistical tables and listings in a validated environment.

#### What differentiates DZS products from other software solutions?

ClinPlus Data Management and ClinPlus Report are

both written completely in SAS and help differentiate DZS by putting our systems in the hands of actual users rather than IT departments. The technology provides a great deal of flexibility, scalability and time savings. Typically, when you deliver a submission to the FDA, the data is always in SAS and the analysis is always done in SAS. Because our data management system is written in SAS and the database is in SAS, there is no conversion required as there is when taking data from an Oracle database. Analysis can be done immediately on the data as it is being entered, in real-time, saving countless hours of converting data from Oracle or other databases. That's really what differentiates DZS products from the competition. Our system design has always stressed flexibility and usability. All our programmers have either come from a CRO or Big Pharma environment and really understand what clients require and expect in a system. Since the software has been in use for many years in real-world trials, it is very stable, very intuitive and well supported. DZS is able to offer what is probably the best support model available in the form of developer-level support. When a client calls with a question or a problem, they're talking to one of the actual application developers, not just a help-desk person. I think that's why our customers stay with us. We've lost very few customers over the years. Most of the customers that we've lost have left because they went out of business, not because of dissatisfaction with DZS as a vendor.

**Year founded:** 1996

**Employees:** 15

**Contact:** Keith Ward, director of global marketing

**Tel:** (732) 764-6969 ext. 129

**Email:** kward@clinplus.com

**Web site:** www.clinplus.com

#### What challenges do you face?

On the development side, a major challenge has been trying to keep up with the ever-changing regulations and standards like CDISC, HL7, eCTD, RPS, CFR21 Part 11, and so on. Another is adapting to emerging technologies. Traditionally, DZS was exclusively SAS-based, but we are now offering other software architectures that provide distinct advantages to delivering software and collaboration using the Internet.

On the marketing side, increasing brand and product awareness is our main challenge. In the past 10 or 15 years, there's been a huge shift in the way software is procured and implemented within an organization. In the past, clients would review vendors and software by attending industry tradeshows and conducting on-site demos. These days, almost everybody uses the Internet to determine potential technology solutions. Accordingly, DZS is redefining our marketing spend to utilize the Internet for branding and delivering marketing campaigns that explain the value of our software and services. In fact, we're in the process right now of revamping the ClinPlus web site and improving our search engine optimization, so people can find us easily when they search the web for technology solu-

page 5

*The Industry Leader In Clinical Trial Portal Solutions*



www.epharmasolutions.com

**Profile:** (continued from page 4)

tions. Another thing that's helped us significantly is our shift to utilizing WebEx technology for product demonstrations rather than traveling to client locations for in-person demos. It's a good thing for everyone. Instead of wasting a day or so traveling to do a three-hour demo, we're able to present in the morning and be back in the office working the same afternoon.

**What changes to the industry have you observed?**

One of the most significant changes in this industry has been the continued movement toward electronic data capture (EDC). Roughly 10 years ago, we started hearing about EDC and predictions that, within five years, paper would disappear. Today of course, that hasn't really happened. There are still many studies being done in paper and although the hype has died slightly, people are still looking steadily toward EDC as a solution. Our SAS-based software has kept up with that with the addition of capabilities that allow the software to function as an EDC system. Since the system was born out of a paper-based system, it lends itself perfectly to being used as a hybrid system. Many of our clients actually require this. Of late, we've seen many studies where some sites use our EDC system, yet other sites that are unable or unwilling to implement EDC are sending traditional case report forms (CRFs) that are double-key entered straight into the same system.

Another significant change is the emergence and continued acceptance of electronic submissions. About 10 years ago, DZS was doing CANDAS—Computer-Aided NDAs—where we would develop software and pretty much deliver a computer to the FDA with software to help them review the data. That's completely changed now with more and more submissions being done electronically and across multiple global regions utilizing eCTD and CDISC SDTM standards. That's a significant and technologically challenging change, but one that DZS is prepared to respond to.

**What are your plans for growth?**

At DZS, we've expanded many of our software offerings. We've just released a new module for our ClinPlus Report software called the SDTM/ADaM conversion and reporting toolkit. This module supports the CDISC SDTM standard and takes that standard a step further by converting SDTM data to an analysis data model called ADaM for submitting analysis data and traceability metadata about how the data was derived or calculated to reviewers at the FDA. This new module includes an extensive template library of tables and listings that eliminates thousands of hours of custom programming when preparing safety and efficacy data. Additionally, DZS offers complete tables, listing and graph programming support.

While our report system traditionally supported biostatisticians and the statistical programmers' requirements to produce tables and listings, DZS is now offering what we call a 'lite' version of ClinPlus Report to appeal to the data management group. This version includes the ability to produce patient profile listings and custom listings with random selection of data, extremely valuable when source data goes through final QC.

Our new version of our ClinPlus Coding software is probably the first coding software to support the WHO Drug Enhanced Dictionary that's just now starting to gain popularity.

In June, we're releasing a brand new web-based CTMS (clinical trial management system) system, and we'll also have a more enhanced EDC system in early 2010. Our current data management system is SAS-based, but this new EDC system will be a more traditional EDC system, completely web-based and built on a .NET architecture.

Editor's Note: Organizations featured in our profiles have been selected by CenterWatch editorial staff. If you would like to be considered for a profile, please send an email to [editorial@centerwatch.com](mailto:editorial@centerwatch.com)

**CBI's 4th Forum on** \_\_\_\_\_

# Patient Reported Outcomes (PRO)

**May 27-28, 2009 • Hilton Alexandria Mark Center • Alexandria, VA**

**Mention Promo Code: QZB884 and Save \$300!**

- Instrument Development and Validation
- Quantitative and Qualitative Analysis
- Regulatory Guidance
- Novel Applications of PRO Data
- Leading Technology

## Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Sponsor Info
ConjuGon	C-1205	catheter-associated urinary tract infections	IND approved by the FDA, phase I trials planned	(608)441-2794 www.conjugon.com
Genetic Immunity	DermaVir Patch	HIV	phase II trials initiated enrolling 16 subjects in Italy	(703) 287-8720 www.geneticimmunity.com
Gilead Sciences	elvitegravir, GS 9350 and Truvada	HIV	phase II trials initiated enrolling 75 subjects in the U.S.	(650) 574-3000 www.gilead.com
Mesoblast	NeoFuse	fusion of the cervical spine	phase II trials initiated enrolling 24 subjects in Australia	+61 3 9639 6036 www.mesoblast.com
Palau Pharma	dersalazine sodium	ulcerative colitis	phase II trials initiated enrolling 80 subjects in Europe	+34 93 864 96 92 www.palaupharma.com
Phytopharm	Cogane	Parkinson's disease	phase II trials initiated enrolling 36 subjects in the UK	+44 (0)1480 437697 www.phytopharm.co.uk
Targacept	TC-5214	resistant hypertension	phase II trials initiated enrolling 12 subjects in North Carolina	(336) 480-2100 www.targacept.com
TOPICA Pharmaceuticals	luliconazole	tinea pedis	phase II trials initiated enrolling 120 subjects in the U.S.	(650) 473-3800 www.topicapharma.com
Biolex Therapeutics	Locteron	hepatitis C	phase IIb trials initiated enrolling 100 subjects in the U.S. and Europe	(919) 542.9901 www.biolex.com
Emergent BioSolutions	MVA85A	tuberculosis	phase IIb trials initiated enrolling 2,784 subjects in Africa	(301) 795-1800 www.emergentbiosolutions.com
Ocera Pharmaceuticals	AST-120	hepatic encephalopathy	phase IIb trials initiated enrolling 150 subjects	(858) 436-3900 www.oceratherapeutics.com
Pharmasset,/ Roche	R7128	hepatitis C	phase IIb trials initiated enrolling 400 subjects internationally	(609) 613-4100 www.pharmasset.com
OncoGenex	OGX-011	prostate cancer	phase III trials planned enrolling 300 subjects internationally	(425) 686-1500 www.oncogenex.com
Antisense Pharma	trabedersen	anaplastic astrocytoma	phase III trials initiated enrolling 130 subjects in the U.S., Europe and Asia	+49-941-9201-30 www.antisense-pharma.com
Impax Pharmaceuticals	IPX066	Parkinson's disease	phase III trials initiated enrolling 350 subjects in N. America and Europe	(510) 476-2000 www.impaxlabs.com
Ferring Pharmaceuticals	degarelix	prostate cancer	phase IIIb trials initiated	(858) 657-1400 www.ferring.com
Antigenics	Oncophage	brain cancer	Orphan status granted by the FDA	(781) 674-4400 www.antigenics.com

### Technology | Consulting | Outsourcing FOR CLINICAL TRIALS

- :: ClinPlus® Data Management
- :: ClinPlus® Coding
- :: ClinPlus® Report



1-866-ClinPlus | [www.Clinplus.com](http://www.Clinplus.com)



## Trial Results

### Dermatology

- **Isotechnika** issued positive results from a phase III trial of **voclosporin** for the treatment of psoriasis. This randomized trial enrolled 642 subjects with moderate-to-severe psoriasis, across sites in Canada, Germany and Poland. The subjects received voclosporin (0.4mg/kg twice daily), cyclosporine (1.5mg/kg twice daily) or placebo, for a 24-week treatment duration. At the end of 12 weeks of treatment, subjects in the placebo arm were converted to the voclosporin treatment arm. The primary endpoint was superiority in the proportion of subjects achieving a score of "clear" or "almost clear" in the Static Physician's Global Assessment (SPGA) score. In the voclosporin arm, 35% of subjects achieved this endpoint at 12 weeks compared with 6% of subjects receiving placebo ( $p$  (less than) 0.001). In addition, in the voclosporin arm, 43% of subjects at 12 weeks and 46% of subjects at 60 weeks achieved a 75% reduction in the Psoriasis Area and Severity Index (PASI-75) and 67% of subjects at 12 weeks and 68% of subjects at 60 weeks achieved a 50% reduction in PASI (PASI-50). A key secondary endpoint, non-inferiority of voclosporin compared to cyclosporine in the proportion of subjects achieving a "clear" or "almost clear" in SPGA, was not reached. In the cyclosporine arm, 53% of subjects met this endpoint compared to 35% in the voclosporin arm. Isotechnika plans to move forward with the development of voclosporin.

### Gastroenterology

- **Salix** reported positive results from a phase III trial of **rifaximin** for the treatment of hepatic encephalopathy (HE). This multinational, randomized, double-blind, placebo-controlled trial enrolled 299 subjects who received either rifaximin 550mg twice daily or placebo. It was designed to assess the long-term (six months) efficacy, safety and tolerability of rifaximin in maintaining remission compared to placebo. The primary endpoint was time to first breakthrough HE episode. Rifaximin significantly reduced the risk of an HE breakthrough episode by 58% compared to placebo ( $p < 0.0001$ ). At six months, breakthrough HE episodes were experienced by 22% in the rifaximin group and 46% in the placebo group ( $p < 0.0001$ ). This reduction of the risk of HE breakthrough was maintained across all subgroups in the study, indicating a high degree of consistency in the intent-to-treat population. In addition, rifaximin, had a safety profile that was comparable to placebo after six months of treatment. Salix plans to continue with the development of rifaximin.

### Oncology

- **Dendreon** released positive results from a phase III trial of **Provenge** for the treatment of prostate cancer. This multicenter, randomized, double-blind, placebo-controlled study enrolled 512 male subjects with asymptomatic or minimally symptomatic, metastatic, androgen-independent prostate cancer. The primary endpoint, overall survival, was

reached with statistical significance. Data revealed that Provenge extended median survival by 4.1 months compared to placebo (25.8 months versus 21.7 months) and improved three-year survival by 38% compared to placebo (31.7% versus 23%) ( $p = 0.032$ ). In addition, Provenge reduced the risk of death by 22.5% compared to placebo. The treatment effect was consistent across multiple patient subsets and remained consistent using the log rank test and an unadjusted Cox model ( $p$ -value=0.023. Prostate cancer-specific survival also favored the Provenge arm ( $p$ -value=0.036). Dendreon plans to file an amendment to their existing BLA in the fourth quarter of 2009.

- **GlaxoSmithKline** issued positive results from a phase III trial of **dutasteride** for the prevention of prostate cancer. This international randomized trial enrolled 8,200 male subjects, ages 50 to 75, with elevated PSA levels (2.5 to 10 ng/ml) indicating that they were at increased risk of prostate cancer. The subjects were randomly assigned to receive a placebo or a daily 0.5mg dose of dutasteride. Biopsies were scheduled two years after enrollment and four years after enrollment. After two years, prostate cancer was found in 17.2% of the subjects who took a placebo, compared with 13.4% who took dutasteride. After four years, prostate cancer was diagnosed in another 11.8% of the placebo group and 9.1% of the dutasteride group, a 23% reduction in the risk of biopsy-detectable prostate cancer.

page 8

## Need to **conduct** your Clinical Trials at a new level?

**Clinical Conductor CTMS**, the most comprehensive enterprise workflow software for clinical trial sites.

- Recruit faster
- Increase advertising ROI
- Improve visit planning and scheduling
- Balance workload
- Manage finances pro-actively
- Automate stipend payment
- Always know where you stand,
- And more...

Proven to improve efficiency  
&  
productivity

**Clinical Conductor**  
www.clinicalconductor.com



## Biotech Review

### From *BioWorld Today*

- **GlaxoSmithKline** has bolstered its dermatology business with a \$2.9-billion purchase of **Stiefel Laboratories**, putting together a stable of products that represent an 8% share of the global prescription dermatology market. In addition to the \$2.9 billion in cash, GSK will pay up to \$300 million in potential milestones, and will take on more than \$400 million in Stiefel debt, sending the total deal to \$3.6 billion. GSK's existing prescription dermatological products will be combined with Stiefel's, and the new specialist global business will operate under the Stiefel brand within the GSK Group.
- A combination of monoclonal antibodies co-developed by Medarex and Massachusetts Biologic Laboratories has been licensed to drug giant **Merck** in a deal worth up to \$225M. Medarex and Massachusetts Biologic, part of the **University of Massachusetts Medical School**, will split equally a \$60-million upfront payment and an additional \$165 million in cash based on milestones associated with the development and approval of a drug candidate covered under the agreement. Under the deal, Merck gains worldwide rights to develop and commercialize CDA-1 and CDB-1, designed to target and neutralize the effects of toxin A and toxin B, respectively, the toxins produced by the bacterium *Clostridium difficile*.
- **Galapagos** and **Merck** have signed a multiyear drug development deal seeking therapies in inflammatory diseases, an alliance that could be worth more than \$250 million to Galapagos. Mechelen, Belgium-based Galapagos will be responsible for the discovery and preclinical development of new small-molecule candidate drugs based on its targets, and Merck will have the exclusive option to license each candidate for clinical development and commercialization worldwide. Under the terms of the agreement, Galapagos will receive an upfront fee of 2.5 million euro (US\$3.2 million) from Merck. Galapagos also could receive discovery, development and regulatory milestone payments potentially worth more than 192 million euro (US\$248 million) total for multiple products, as well as specific sales milestones and royalties upon commercialization of any products covered under the agreement.
- **Pharmacyclics** has entered a potential \$39.5-million deal with a private French pharmaceutical firm **Les Laboratoires Servier** that, in the words of Pharmacyclics CEO Robert Duggan, could shine the light on its pipeline products that inhibit the enzyme histone deacetylase, or HDAC. The alliance will focus on Pharmacyclics' Pan HDAC inhibitor, PCI-24781, which is in phase I/II trials in the

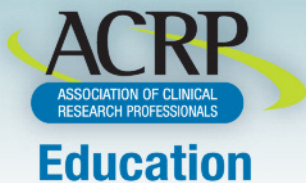
The stories included in Biotech Review have been provided to CenterWatch with the full permission of *BioWorld Today* and its publisher, AHC Media LLC. Copyright ©2009 AHC Media LLC.

BioWorld is located at 3525 Piedmont Road, Building 6, Suite 400, Atlanta, GA 30305 U.S.A. Please call (800) 688-2421 or (404) 262-5476 for more information. Or visit [www.bioworld.com](http://www.bioworld.com).

U.S. It is being developed to treat solid tumors and hematological malignancies, cancers that affect the blood, bone marrow and lymph nodes. Pharmacyclics would maintain all U.S. rights to the Pan HDAC inhibitor under the deal. Servier acquired the exclusive right to develop and commercialize the Pan HDAC inhibitor product worldwide except for the U.S., and will pay a royalty to Pharmacyclics on non-U.S. sales. Servier will pay Pharmacyclics upfront payments totaling \$11 million on signing the contract and an additional guaranteed \$4 million for a research collaboration over a 24-month period, paid in equal increments every six months with the initial payment due Oct. 1. The French drug firm, which does business in 140 countries, also will pay for all development costs outside the U.S. In addition, Pharmacyclics will receive \$24.5 million based on the achievement of certain milestones up to and including commercialization.



### Advance Your Career and Earn Contact Hours



- Fundamentals of Clinical Research
- Good Clinical Practice
- Project Management: Moving from Coordination to Control

Register Today at [www.acrpn.net/education](http://www.acrpn.net/education)



Navigating the regulations...

Qualifying the sites...

Finding the study patients...

Managing clinical trials...**WORLDWIDE.**



# AVERION

More than ever, bringing a new medical product to market is a worldwide enterprise. There are many reasons to take a clinical trial overseas – and Averion can help you. We have strengthened our international clinical trials capabilities, through the expansion of our European operations and research partnerships in India, Asia and South America.

There's a world of opportunity conducting trials in international markets. You need a clinical research partner with true worldwide capabilities – Averion is that partner.

[www.averionintl.com](http://www.averionintl.com)



Tomorrow starts Today