

Aspire IRB Acquires St. Davids HRRB

Aspire IRB, a San Diego-based independent review board, has acquired St. Davids Human Research Review Board (HRRB) located in Radnor, Pa. Financial terms of the deal were not disclosed.

According to Aspire officials, Aspire IRB is now the only independent review board with offices on both coasts. St. Davids HRRB will become a division of Aspire IRB. Aspire IRB will remain headquartered in San Diego and will maintain the administrative staff and board of the East Coast office, St. Davids HRRB.

The acquisition will not result in

staffing changes at either office. St. Davids has two employees and a review board of six primary members and six alternates; Aspire IRB has six full-time employees, four independent contractors and a review board of five primary members and five alternates, according to Cathryn Guidry, chief executive officer of Aspire.

"We are excited about this opportunity to serve the life science industry on both coasts, meaning our clients only need to hire one independent review board to meet the needs of various time zones,"

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Summit at Harvard Focuses on Post Approval

The recent, 2nd Annual Post-Approval Summit held at Harvard Medical School included two days of in-depth sessions focusing on the evaluation of marketed treatments in real-world patient outcomes.

Post-marketing studies and value-based patient care analysis are becoming the fastest growing sector in the health-care industry. The conference was co-hosted by Cambridge, Mass.-based technology company Outcome and included attendees from academia, industry and government, all interested in enhancing the role of outcome-based medical treatment.

"What we heard from both industry as well as from the FDA is that there is a

renewed interest in thinking about the importance of post-approval data and how that data can be simultaneously realized, making it useful for the pre-approval process," Richard Gliklich, M.D., told *CWWeekly*. Gliklich is the president and chief executive officer of Outcome and the director of this year's summit.

Among the speakers, Jean Slutsky, the director at the Center for Outcomes and Evidence, part of the Agency for Healthcare Research and Quality (AHRQ) walked attendees through the challenges of determining real-life treatment value. The AHRQ is an agency within the Department of Health and Human Services whose role is to improve the

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CenterWatch Main and Editorial Offices
22 Thomson Place, 47F1, Boston, MA 02210
Tel (617) 856-5900 Fax (617) 856-5901
cw.editorial@thomson.com

CWWeekly (ISSN 1528-5731)

Steve Zisson Managing Editor
Sara Gambrill Senior Editor
Stephen DeSantis Senior Associate Editor
Jody Kalt Drug Intelligence
Melissa Nazzaro Advertising
Paul Gualdoni Production Manager
Laura Tritz Graphic Designer

Send news submissions to Steve Zisson
Tel (617) 856-5950 Fax (617) 856-5901
stephen.zisson@thomson.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) 856-5224
rick.lavallee@thomson.com



Industry Briefs

CROs

■ **Astellas Pharma Europe Limited** selected the clinical trial management system (CTMS) from Parexel's technology subsidiary **Perceptive Informatics**. In a review of 10 vendors, Astellas Pharma Europe Limited selected Perceptive's IMPACT software to replace all of its existing CTMS systems, and integrate with the company's other system applications. "Astellas Pharma Europe's implementation of Perceptive's IMPACT suite of CTMS software will enable it to manage clinical trials with even greater effectiveness and efficiency. Perceptive's IMPACT software provides a comprehensive, robust and proven solution to centrally manage the complex information, processes and functions that support all aspects of clinical trials," said Todd Joron, corporate vice president and general manager of Perceptive Informatics. Perceptive Informatics is a provider of CTMS solutions and claims the largest installation of CTMS users in the world. Perceptive's IMPACT software enables complete trial management and planning, activities monitoring, and clinical cost and supplies tracking.

■ **PRA International** has closed its previously announced acquisition of **Sterling Synergy Systems Private Limited**, a CRO based in Mumbai and Pune, India.

PRA's clinical operations in India will be based in the Mumbai office while the company will house a data management center in Pune. With the Pune center, PRA will be able to provide integrated around-the-clock data management capability, augmenting its existing facilities in Lenexa, Kansas; Victoria, British Columbia; and Swansea, Wales.

Regulatory

■ United Kingdom Health Minister Andy Burnham announced the membership of an **Expert Group** to investigate clinical trials to the House of Commons. The Chair of the group, Prof. Gordon Duff, was appointed in April following the adverse reaction of six clinical trial participants to the TeGenero drug TGN1412. "This is a complex scientific issue which raises important questions about the potential risks associated with this type of drug. That is why Secretary of State agreed to the establishment of an Expert Working Group," Burnham said. "Clinical trials in general have an excellent safety record, but monoclonal antibodies are a relatively new type of biological drug. The Expert Group will provide advice for the future authorisation of trials involving these types of products." The Expert Group is an independent scientific committee that will determine its own work program.



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Aspire

said Guidry.

Eva Pastor, BS, CIP, CIM and the current IRB manager at St. Davids HRRB, has accepted the position of director of East Coast operations and John Freeman will remain the chairman of St. Davids HRRB.

“The expertise of both organizations and their speciality in different phases of research will greatly enhance the services of Aspire IRB,” said Pastor.

Aspire IRB was founded in 2004 by four women IRB professionals with more than 25 years of combined IRB experience. It is a certified women-owned

business by the Women’s Business Enterprise National Council. St. Davids HRRB was established in 1981. Both boards meet weekly with the West Coast board meeting on Tuesdays and the East Coast board meeting on Thursdays.

Summit

quality of healthcare and promote evidence-based decision making. The agency provides clinicians, insurance providers and governmental policy makers with treatment reviews for guidance. The AHRQ is the U.S.’s closest equivalent to the UK’s National Institute for Health and Clinical Excellence (NICE), which offers similar services but also provides much needed guidance within the UK’s regulatory approval process. “There is a lot of interest in whether a model like that can be utilized in the U.S. I think the general feeling is that it wouldn’t translate exactly over here because our healthcare system is more federated and unified. There is definitely interest, but there will

be a lot of structural barriers,” said Gliklich.

During another presentation, Mathias Hukkelhoven, senior vice president and global head of regulatory affairs at Novartis, discussed the ideas to revamp the drug approval process. Given that comprehensive safety and efficacy drug data often involve long-term phase IV trials and pharmacovigilance data to gather statistically accurate results, Hukkelhoven discussed the possibility of multi-staged approval processes.

Developing a limited or “conditional” approval stage where treatments may only be marketed to a narrow range of patients could give clinicians more time to determine their value may be considered.

Post-approval studies are becoming more critical not only for pharmaceutical companies hoping to strengthen their products’ success, but for clinical practitioners, healthcare payors and drug regulators as well. Several speakers detailed the importance of phase IV trials, patient registries, pharmacovigilance and trial result transparency. An increased emphasis on risk management, advancing the development of healthcare IT systems and setting goals in standardizing outcome reporting were all discussed. A consensus-based determination of treatment value in real-world settings, including risk versus effectiveness review and cost analysis were also highlighted.

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Profile: Investigative Site

Stamford Therapeutics Consortium, Stamford, Conn.

An interview with Tom Grotta, president

What is Stamford Therapeutics Consortium's background?

Stamford Therapeutics Consortium was founded 12 years ago by Dr. Paul Dalgin, a rheumatologist passionate about research. Unfortunately, seven years ago, he passed away and his wife Judith continued the business. I became involved in September of last year. Everyone who is involved is passionate about research, including me. One of the reasons I became interested in clinical research was because I had worked for the Cystic Fibrosis Foundation and actually have cystic fibrosis myself. Before working at Stamford Therapeutics Consortium, I had participated in clinical trials. I became very passionate about the fact that without clinical trials we would not move forward with new medications that have helped me and others similar to me so much. In the past, we traditionally did rheumatoid arthritis (RA) and osteoarthritis (OA) clinical studies, as Dr. Dalgin was a rheumatologist. Today, we are associated with a multi-specialty group of physicians and a general internist, which has allowed us to continue doing RA and OA studies along with multiple studies in the areas of cardiology, endocrinology, gastroenterology, internal medicine and pain management. We were a big part of

the Lyme vaccine study several years ago, and we'll do more vaccine studies in the future.

What differentiates your site from others?

We have been in business for 12 years and have a great reputation with sponsors and CROs [contract research organizations]. In addition, we work with multiple principal investigators, therefore we have different physicians with diverse specialties overseeing our studies. Our site is dedicated solely to research. We are very aware of sponsors' needs and make sure we handle the non-medical side with efficiency—we employ a regulatory specialist. On the medical side, our mission is to meet or exceed recruitment goals and at the same time produce quality data.

What challenges do you face?

Recruitment always presents a challenge as we pride ourselves on over-enrolling and patient retention. We continue to look for ways to improve our business and put most of our resources into our patients and the quality of data for each study.

Year founded: 1994
PIs: 5
CRCs: 3
Active trials: 6
Telephone: 203-325-8529
Email: tgrotta@snet.net

What are your plans for growth?

We look to stay focused on the studies we have traditionally done well with, i.e., obesity, cholesterol, OA, RA, fibromyalgia, hypertension, diabetes, pain management, dyspepsia, IBS, vaccine studies and health preventive studies. This will enable us to utilize our database effectively and offer sponsors and CROs a track record of success in these therapeutic areas. One of our near-term goals is to build awareness in our community. There is a ton of opportunity to educate the public and provide people with a resource for clinical studies and general health information. In addition to the public, we plan to build awareness among the local physicians that have also expressed an interest in clinical studies. With our latest marketing initiatives we have had quite a positive response from new physicians looking to get involved with clinical research. Lastly, over the next couple of years we hope to branch out into new therapeutic areas. As we continue to build relationships with local physicians and, based on our experience and success with other trials, we look forward to new opportunities from sponsors.



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Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Sponsor Info
GeoVax	HIV DNA Prime/ Boost vaccine	HIV prevention	Clinical trials initiated enrolling 72 subjects	(404) 727-0971 www.geovax.com
Tanox	TNX-650	Hodgkin's lymphoma	Phase I trials initiated at two U.S. sites	(713) 578-4000 www.tanox.com
Elite Pharmaceuticals✓	ELI-154	chronic pain	Phase I trials initiated	(201) 750-2646 www.elitepharma.com
Altea Therapeutics	AT3022	chronic pain	Phase I trials initiated	(678) 495-3100 www.alteatherapeutics.com
BioLineRx/Gevys	BL-3010	pain	Phase I/II trials planned	+972 2 548-9100 www.biolinerx.com
VioQuest 20 subjects	VQD-002	solid tumors	Phase I/II trials initiated enrolling	(908) 766-4400 www.vioquestpharm.com
Schering	ZK-EPO	ovarian cancer	Phase I/II trials initiated across 30 sites in North America	+49 30 468 11 11 www.schering.de
Synta	apilimod mesylate (STA-5326)	rheumatoid arthritis	Phase IIa trials initiated	(781) 274-8200 www.synta.com
Synta	apilimod mesylate (STA-5326)	common variable immunodeficiency	Phase IIa trials initiated	(781) 274-8200 www.synta.com
Microbia	linaclotide acetate (MD-1100)	irritable bowel syndrome/constipation	Phase II trials planned	(617) 621-7722 www.microbia.com
Vertex	VX-950	hepatitis C infections	Phase II trials initiated enrolling 260 subjects in the U.S.	(617) 444-6100 www.vrtx.com
Schering	ZK-EPO	breast cancer	Phase II trials initiated across 20 sites in North America	+49 30 468 11 11 www.schering.de
Antipodean	MitoQ (mitoquinone)	Parkinson's disease	Phase II trials initiated across 10 sites in Australia and New Zealand	(415) 692-0610 www.antipodeanpharma.com
Vion	Cloretazine (VNP40101M)	acute myelogenous leukemia	Phase II trials initiated enrolling 85 subjects across 20 sites	(203) 498-4210 www.vionpharm.com
Topigen/NicOx	TPI-1020	chronic obstructive pulmonary disorders	Phase II trials initiated enrolling 30 subjects	(514) 868-0077 www.topigen.com
Nabi Biopharmaceuticals	NicVax	smoking cessation	Phase IIb trials initiated enrolling 300 subjects	(561) 989-5800 www.nabi.com
Ocera Therapeutics	AST-120	fistulizing Crohn's disease	Phase III trials initiated	(858) 436-3900 www.oceratherapeutics.com
Nektar	ABIP	pulmonary fungal infections	Fast Track status granted by the FDA	(650) 631-3100 www.nektar.com
Hana Biosciences	talotrexin (PT-523)	acute lymphoblastic leukemia	Orphan Drug status granted by the FDA	(650) 588-6404 www.hanabiosciences.com

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Trial Results

Infectious Diseases

- **SciClone** has issued negative final results of their second phase III trial of **Zadaxin** for the treatment of hepatitis C (HCV) infections. Trial data indicated that the addition of Zadaxin to a standard regimen of pegylated interferon alpha did not significantly improve sustained viral response at 72 weeks compared to pegylated interferon alpha alone, the trial's primary endpoint. Treatment with the drug was generally well tolerated. This randomized, controlled study enrolled HCV patients across sites in the U.S., who received either 1.6 mg Zadaxin or placebo twice weekly, in combination with a standard regimen of 180 mcg pegylated interferon alpha once weekly. Based on these results, the company announced no further plans to develop Zadaxin for the treatment of HCV, opting instead to support its development for the treatment of malignant melanoma.

Neurology

- **Indevus** announced positive results of a phase II trial of **pagoclone** for the treatment of persistent developmental stuttering. Results from the study met their primary efficacy endpoints, significantly improving scores on the SSI-3 diagnostic scale at weeks 4 and 8 ($p=0.02$), and the SSS severity sub-score at weeks 2 ($p=0.004$) and 4 ($p=0.05$), with an additional trend towards improvement at week

8 ($p=0.08$), compared to placebo. Numerical, non-significant superiority was also noted on the SEV diagnostic scale at weeks 2, 4 and 8 ($p=0.18$). This placebo-controlled, double-blind, multi-center study enrolled 132 subjects, who received escalating doses of the drug (0.3 mg to 0.6 mg) or placebo daily for eight weeks.

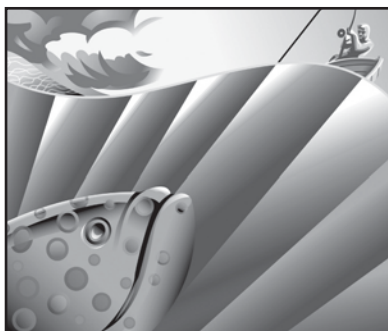
Gastroenterology

- **PDL BioPharma** announced positive results of a phase I trial of **Nuvion (visilizumab)**, for the treatment of Crohn's disease (CD), at the 2006 Digestive Disease Week (DDW) annual meeting. This multi-center open-label study enrolled 14 patients with moderate to severe non-penetrating CD, who received two doses of 10 mcg/kg Nuvion via IV bolus injection. Preliminary data yielded evidence of efficacy, with 10 of 14 subjects demonstrating clinical response (>100 point decrease) on the CDAI diagnostic scale. Five subjects achieved complete remission (total CDAI score <150 points) during the treatment period. Nuvion-responsive patients included five subjects who had relapsed on infliximab, and two subjects whose disease never responded. No lymphoproliferative, malignant or life-threatening adverse events were reported.
- **Microbia** issued positive results of a phase Ib trial of **linaclotide**, for the treat-

ment of constipation-predominant irritable bowel syndrome (IBS-C) and chronic constipation (CC), at the DDW annual meeting. Preliminary data yielded evidence of pharmacodynamic activity in the gastrointestinal tract, as measured by markers of intestinal transit, stool consistency, stool weight and time to first bowel movement. No evidence of systemic exposure was observed, and treatment was safe and well tolerated. Based on these data, the company announced plans to initiate phase II trials of the drug in the near future.

Oncology

- **Cell Genesys** reported interim results of a phase I trial of **CG0070**, their investigational oncolytic virus under investigation for the treatment of bladder cancer, at the 2006 Annual Meeting of the American Urological Association in Atlanta. This open-label dose-escalation study had enrolled nine patients to date who had failed previous therapy with BCG; subjects received single administrations of the drug. Results from the study indicated preliminary evidence of efficacy, with complete response noted on follow-up cystoscopy in three of nine subjects (response lasted for three+, six and nine months). No serious adverse events or dose-limiting toxicities were reported to date; overall adverse events included local bladder toxicities.



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Biotech Review

From *BioWorld Today*

- **AstraZeneca** is buying **Cambridge Antibody Technology (CAT) Group**, the UK's largest biotech, in an agreed cash deal that will cost AstraZeneca £567 million, and values CAT at £702 million (U.S. \$1.3 billion). Previously, AstraZeneca paid £75 million for a 19.2% stake in CAT when they agreed to a research and development collaboration in November 2004. At £13.20 per share, the price is a 67% premium on CAT's closing price of £7.96 per share, or £420 million in total, May 12. CAT had net cash of £152 million at the end of 2005 and made an operating loss of £9.3 million in the year to September 2005.
- **Threshold Pharmaceuticals** stock fell after news that the FDA had put the phase II program with TH-070 (lonidamine) for benign prostatic hypoplasia on partial clinical hold because of liver enzyme abnormalities, and Threshold, of Redwood City, Calif., stopped dosing in the European phase III trial, as well. Its shares (NASDAQ:THLD) closed May 12 at \$3.44, down \$10.56. The abnormalities include three serious adverse events observed after three months of dosing in the phase III European/Canadian trial and three more cases of elevated liver enzymes that occurred in other ongoing trials.
- **Oxford BioMedica** is ready to begin a phase III trial of TroVax in renal cell carcinoma, which is envisioned as a fairly quick route to registration for a product with broad possibilities. The study's protocol has been agreed to through the FDA's special protocol assessment. The company, of Oxford, UK, plans to start the study in the second half of the year. The trial is designed to test whether adding the immunotherapy to first-line standard of care prolongs the survival of patients with locally advanced or metastatic clear cell renal adenocarcinoma. TroVax, which targets the tumor antigen 5T4, is made of a pox virus (MVA) gene transfer system that delivers the gene for 5T4 and stimulates a patient's body to produce an anti-5T4 immune response to destroy tumor cells carrying it. Oxford BioMedica plans to seek orphan drug designation in the U.S. and Europe.
- Just as stem cell company **Osiris Therapeutics**, of Baltimore, filed for an \$80 million initial public offering, tissue regeneration company **BioMimetic Therapeutics** priced its IPO for \$36.8 million, selling 4.6 million shares. Franklin, Tenn.-based BioMimetic sold the shares at \$8 apiece. The company was seeking \$50 million when it filed for the IPO in February.
- **Novogen** formed a licensing agreement that gives its majority-owned subsidiary, **Marshall Edwards**, development and commercialization rights to two more oncology compounds. The first candidate, NV-196, is an oral formulation in phase I safety testing, and is designed to treat pancreatic and bile duct cancer. The second drug, NV-143, is in preclinical studies as an oral formulation targeted to melanoma. Terms of the agreement include an up-front payment to Novogen of \$1 million, and undisclosed milestone payments for each compound as they move through clinical testing and the filing of a new drug application. Novogen also is entitled to a 5% royalty on sales. In addition to funding the ongoing clinical programs, Washington-based Marshall Edwards will cover commercial development costs. Novogen, of Sydney, Australia, formed Marshall Edwards in 2001 to focus on a new family of cancer drugs.

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