

A CenterWatch Publication

Cmed Raises \$10M to Advance EDC

U.K.-based contract research organization (CRO) Cmed has raised almost \$10 million in growth capital—funds that will be used to advance the company's electronic data capture (EDC) system and the company's brand worldwide.

The funding, from European investment firm Scottish Equity Partners (SEP), comes as an investment in Cmed shares. Cmed will have access to further funds should the company need it, according to Cmed CEO David Connelly.

Up until recently, Cmed was known simply as a CRO with EDC capabilities, and the company used profits from its CRO division to fund

the development of its Timaeus EDC platform. However, Timaeus has gained increasing interest from pharmaceutical companies as a stand-alone product.

"Interest in our Timaeus system as a next-generation system has really been starting to grow over this last 12 months," Connelly said. "We recognized that we needed to take on capital if we were going to grow the company to the next level."

Timaeus, according to the company, is the first EDC system to enable multiple types of data capture (including paper, Web, advanced wireless) within a single trial with full data

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MCRC Launches Niche Phase I Business

While the weakening economy has forced some drug companies to cancel or delay early phase projects, at least one company has seen a growing need for its niche phase I drug development services.

Dallas, Texas-based Metroplex Clinical Research Center (MCRC), which specializes in rheumatology studies, recently expanded its services to include phase I capabilities for clinical trials on patients. In the past year, the company has seen an increase in drug companies that want to conduct phase I studies on patients who are afflicted with different rheumatological diseases (e.g., rheumatoid arthritis, lupus and scleroderma) rather than

healthy patients.

"[Drug companies] want to try to begin to define the dose range of their drug and look for signals of side effects and also get a hint of efficacy. That's why they're choosing to treat patients who actually have the disease," said MCRC medical director Stanley Cohen, M.D.

Under the medical leadership of Cohen and Roy Fleischmann, M.D., MCRC has conducted more than 800 clinical studies since its founding in 1984, but the organization only began doing phase I studies last year. MCRC currently has four phase I studies in the works and an additional five coming in 2009, according to

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CWWeekly (ISSN 1528-5731)

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Industry Briefs

CROs

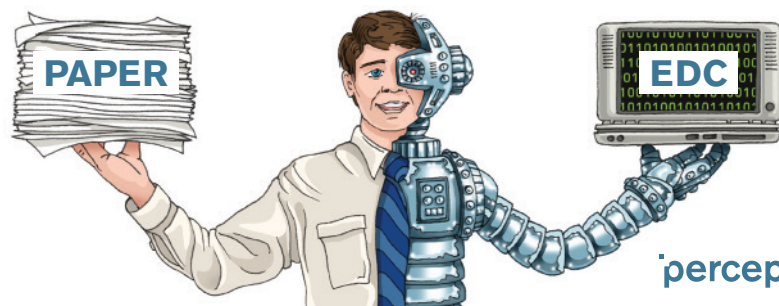
- Three years after entering the Mexico clinical trials market, Raleigh, N.C.-based contract research organization (CRO) PRA International has opened a new office in Mexico City, Mexico. The new location offers proximity to one of Mexico's largest population centers, Mexico City, as well as easy access to the Ministry of Health and the ability to oversee trials in Central America. The facility currently houses 20 clinical staff with room to expand as the demand for PRA services in the region increases. Global CRO Parexel has formed an alliance with Safe Implementation of Treatments in Stroke (SITS) International, the world's largest network of clinical sites with specialized capabilities in the area of stroke. This partnership grants Parexel access to more than 800 investigator sites (located in 40 countries), which conduct phase II to phase IV clinical trials focused on strokes. Through SITS, Parexel will provide clients with a range of stroke-related services, including clinical, post marketing, and safety studies. Global laboratory supply giant Thermo Fisher opened a new \$17-million clinical services facility in Ahmedabad, India, giving the Waltham, Mass.-based company the largest Indian presence of any company in its industry, according to a company release.

The new 150,000-square-foot facility will support growing demand for biopharma services in the region and serve as a hub for packaging, distribution and logistics management of clinical trial supplies. Thermo Fisher first located in India in 2000 and has rapidly expanded its presence there through new facilities and acquisitions.

Associations

- The Association of Clinical Research Professionals (ACRP) has partnered with the Shanghai Clinical Research Center (SCRC) to promote ACRP training and certification throughout China. SCRC will develop multiple ACRP-approved training centers in China, launch an annual national conference and facilitate ACRP Certification Examinations throughout China. SCRC will offer ACRP Certification Exam Review courses in early 2009 in preparation for the March certification exam. The organization will also license its training course to ACRP. ACRP also appointed a new acting president and CEO this week, James Thomasell, replacing Thomas Adams who is leaving the organization after eight years as president and CEO.

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Cmed

ment capabilities.

"If you look at the competitors out there, they've either had an old CDMS—an old Clinical Data Management System—and they've tried to add on with Web electronic data capture or they've built a Web electronic data capture system and they're trying to build the system backwards to provide data management capabilities as well," Connelly said. "Our view was that you really shouldn't do that. What we decided to do was build a brand new architecture that's quite different from the current systems out there."

Founded in 1999, Cmed will continue to be a CRO, but Connelly predicts the CRO and

technology divisions will become increasingly separate as more pharmaceutical companies license the Timaeus technology.

Other CROs are beginning to express interest in Cmed's Timaeus technology, as well.

"We're not averse to providing [other CROs] the technology, because we recognize as a CRO with just under 250 people we cannot support the big global studies or meet the demands of some of the clients. In fact, some [sponsors] are suggesting to CROs that they come to us, especially for large or difficult studies," he said.

Headquartered in the UK with offices in the United States and Romania, Cmed will use the funding to promote the company's brand worldwide. Connelly said the company

has been called the "best kept secret in clinical research," but he hopes to change that in 2009.

"Because of growing interest in Africa, we are currently exploring the possibility of a presence in Africa. We have just recruited our first person in Singapore so we may well put a technical support hub in Singapore. Longer term, we have plans to expand further into Central and Eastern Europe and also into South America," Connelly said.

In 2009, the company will open up at least one additional U.S. office and plans to add to its senior management team to facilitate the company's growth.

MCRC

chief operating officer Sara Hibbard.

"Now that we have had this experience with phase I, and it has gone so well and been such a positive thing for us, we're really going to be expanding our phase I facilities," Hibbard said.

Headquartered on the campus of St. Paul Medical Center at the University of Texas Southwestern, MCRC is preparing to expand its phase I space (which currently sleeps two to four patients) in 2009. The organization will also make staffing changes to meet the increased demand for their services.

"One of the challenges for these phase I studies is that you can't plan as you do for

phase II through IV studies in terms of how you're going to recruit and how you're going to staff it because of the structure of them," Hibbard said. "[Investigators] may dose two patients and then do a safety analysis that might last a month and then they call and you have to be ready on a dime to start screening again."

MCRC has used temporary as-needed personnel while researching the best way to staff their phase I unit. Hibbard predicts that the research center will transition some split-shift staff to full-time by April 2009.

MCRC's 30-year operating history provides them with a large pool of potential clinical trial participants who are loyal to MCRC and its physicians, Hibbard said. This reduces the num-

ber of no-show and drop-out participants in any given study, making the research center's services more attractive to pharmaceutical companies conducting clinical trials.

Cohen predicts sponsors' interest in MCRC's niche phase I services will continue to grow.

"At least in our field for now—and this may change tomorrow—we are seeing a lot of activity with a plethora of new molecules as we continue to understand the immune system. The difference we're seeing over the last several years is that companies are making the go/no-go decision very critically after phase II or even mid-phase II trials," he said.

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Profile: Early Phase Contract Research Organization

Biotrial, Rennes, France

An interview with Jean-Marc Gandon, PharmD, president and CEO

How and why was Biotrial founded?

I founded the company 20 years ago on the campus of University Hospital in France to mainly focus on early stage drug development. We started with phase I first-in-man studies, and now we are one of the top five in Europe for phase I studies. This is our core business. Biotrial is an independent and privately owned CRO. We have 150 beds and a staff of 250 in several subsidiaries in France and the UK. Biotrial runs more than 80 studies per year, either in our own clinics in Paris and Rennes, or in cooperation with hospital specialists and general practitioners.

Biotrial corporate headquarters in Rennes is 5,000 square meters, including a phase I unit, located inside the University Hospital area, with intensive care monitoring equipment and laboratories for non-clinical *in vivo* studies. At Biotrial Paris, the Stell Clinic covers 1,000 square meters, including a phase I unit with intensive care monitoring equipment based on a hospital ground. We also have a safety lab for some models in preclinical studies. We don't do toxicology but we do safety pharmacology. We started in collaboration with the University team, so we immediately had a niche activity in terms of specific models in healthy volunteers and in patients.

What else differentiates Biotrial from other CROs?

One differentiator is our strong focus on early devel-

opment. From the last study on animals with specific models to proof-of-concept studies, phase IIa/b, our clients can find every competency necessary on the Biotrial team, including data management, biostatistics, central labs for interpretation of ECGs and MRIs, medical writing, non-clinical pharmacology, quality assessment and advice in regulatory affairs. Our niche approach is based on adding science for the client. For example, we don't just receive protocols and do a cost estimate and PK studies or QT studies on the basic value for the client. Biotrial has several people who have previously held senior positions at Big Pharma, so we are able—if the client needs it—to give advice and share experience. We can submit a synopsis, write a protocol, do the interpretation, etc. Thirty percent of our staff come from Big Pharma, and between 30% and 40% are not French. Eighty percent of our revenue does not come from French companies, so our team and clients are really international. We can finish the last animal study to the proof-of-concept study with the same group and the same company. That's another differentiating factor. We can help create the development plan for compounds, which is why our contracts with biotech are increasing.

What are your plans for growth?

Our growth strategy is to remain a niche early development provider and to become a global provider in terms of geography. We are opening a phase I unit

Year founded: 1989
Employees: 250
Beds: 150
Avg. # of studies per year: 80+
Contact: Anne Peron
Email: anne.peron@biotrial.com
Web site: www.biotrial.com


of about 100 beds in the U.S. on the East Coast next year. Following that, we will also go to Eastern Europe to enroll specific patient populations. And for basic studies, we will also set up a partnership in India. We believe that, especially in early development, a lot of studies are going back to the U.S., and also, in some cases, science is going back to the U.S. So, opening a U.S. phase I unit is not only a commercial activity or an opportunity in terms of site and location but also it's a way to do the best types of studies and the best job with a link between European culture for early development and clinical work and the U.S. It's not only, as in India, just a location, it really allows us to share experience and therefore to do good work. Biotrial's strategy is to follow our clients globally and anticipate what they will need, stay within our business niche of early development, and be sure that if the client is coming to us, we can offer everything the client needs for early development.

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Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Sponsor Info
Lexicon Pharmaceuticals	LX-4211	type 2 diabetes	IND filed with the FDA; phase I trials planned	(281) 863-3000 www.lexicon-genetics.com
Quintessence Biosciences	QBI-139	solid tumors	IND approved by the FDA, phase I trials planned	(608) 441-2950 www.quintbio.com
Ablynx	ALX-0681	thrombosis	phase I trials initiated enrolling 36 subjects	+32 (0)9 262 00 00 www.ablynx.com
Ablynx/Wyeth	ABX-0401	inflammatory disorders	phase I trials initiated	+32 (0)9 262 00 00 www.ablynx.com
Alkermes	ALKS 33	addiction/CNS disorders	phase I trials initiated enrolling 16 subjects	(617) 494-0171 www.alkermes.com
EntreMed	ENMD-2076	multiple myeloma	phase I trials initiated in Indiana	(240) 864-2600 www.entremed.com
GPC Biotech	RGB-286638	solid tumors	phase I trials initiated enrolling 48 subjects in the Netherlands	+49 (0)89 8565-2693 www.gpc-biotech.com
Halozyme Therapeutics	bisphosphonate + rHuPH20 enzyme	osteoporosis	phase I trials initiated enrolling 40 subjects in the U.S.	(858) 794-8889 www.halozyme.com
Memgen/Leukemia & Lymphoma Society	ISF35 vaccine	cancer	phase I trials initiated enrolling 12 subjects in the U.S.	(214) 731-3141 www.memgenbio.com
Parion Sciences	GS9411	pulmonary disease	phase I trials initiated	(919) 313-1180 www.parion.com
VentiRx Pharmaceuticals	VTX-2337	cancer	phase I trials initiated in the U.S.	(858) 436-1530 www.ventirx.com
Biocancell Therapeutics	BC-819	pancreatic cancer	IND filed with the FDA, phase I/II trials planned in the U.S. and Israel	+972-2-548-6555 www.biocancell.com
DOR BioPharma	DOR201	acute radiation enteritis	IND approved by the FDA, phase I/II trials planned in the U.S.	(305) 534-3383 www.dorbiopharma.com
KAI Pharmaceuticals	KAI-1678	post-operative pain	phase IIa trials initiated enrolling 110 subjects in New Zealand	(650) 244-1100 www.kai pharmaceuticals.com
Proteo Biotech	Elafin	allograft nephropathy/kidney transplant	phase II trials planned in Egypt	+49 431 88 88 463 www.proteo.de
Genentech/Curis	GDC-0449	ovarian cancer	phase II trials initiated enrolling 100 subjects in the U.S.	(888) 662-6728 www.gene.com
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Trial Results

Endocrinology

■ **Arena Pharmaceuticals** released positive results from a phase IIb trial of **lorcaserin** for the treatment of obesity. This randomized, double-blind, placebo-controlled study enrolled 469 subjects with a Body Mass Index ranging from 30 to 45, in the United States. The subjects received lorcaserin 10mg once daily, 15mg once daily, or 10mg twice daily or placebo for 12 weeks. The primary efficacy endpoint was a reduction in weight from baseline at the end of 12 weeks. The subjects who were treated with lorcaserin achieved progressive, dose-dependent and statistically significant weight loss of 4 pounds (1.8 kg), 5.7 pounds (2.6 kg) and 7.9 pounds (3.6 kg) at daily doses of 10mg, 15mg and 20mg (10mg twice daily), respectively, compared to weight loss of 0.7 pounds (0.3 kg) for placebo ($p < 0.001$ for each group). A statistically significant percentage of subjects treated with lorcaserin who completed the study lost greater than or equal to 5% of their weight from baseline: 12.8%, 19.5% and 31.2% in the 10mg, 15mg and 20mg groups, respectively, compared to 2.3% of those on placebo. The dose with the highest degree of efficacy was 20mg, with more than 90% of subjects achieving some level of weight loss. In addition, total cholesterol and waist circumference were significantly decreased by the two highest lorcaserin doses. Phase III trials of lorcaserin are currently underway.

■ **ConjuChem** issued positive results from two phase II trials of **PC-DAC: Exendin-4** for the treatment of type 2 diabetes. The two phase II trials were randomized, double-blind, placebo-controlled, multiple-dose studies that evaluated the efficacy and safety of three months of weekly or twice-weekly injections of PC-DAC: Exendin-4 in subjects with type 2 diabetes not adequately controlled by metformin monotherapy. In the first trial, 144 subjects were randomized to one of three parallel treatment groups: a 1.5mg per week cohort; a 1.5mg per week cohort titrating to 2mg per week after one month; and a placebo cohort. In the second trial, 80 subjects were randomized to one of three parallel treatment groups: a 1.5mg twice-weekly cohort titrating to 2mg per week after one month; a 3mg (1.5mg twice per week) cohort; and a placebo cohort. The primary endpoint, reduction in HbA1c versus both baseline and placebo, was reached with significance for all active treatment groups throughout the treatment period. The most significant reduction was in the 3mg dose group, a decrease of 1.4% at the end of the treatment period (Day 85) was observed. The HbA1c reduction was 0.8% for both the 1.5mg and 2mg groups and 0.4% for the placebo groups. In addition, a weight loss of 1.2 kg was achieved in the 3mg group, with over 80% of subjects losing some weight versus a 0.4 kg reduction in the

placebo group. In the first trial, weight losses of 2.0 kg and 1.3 kg, respectively, were observed in the 1.5mg and 2mg dose groups. PC-DAC-Exendin-4 was well tolerated. Based on the results.

Psychiatry/Psychology

■ **Alexza** reported positive results from the phase III trial of **AZ-004** for the treatment of acute agitation in bipolar disorder. This randomized, double-blind, placebo-controlled study enrolled 314 acutely agitated patients with bipolar I disorder, in the U.S. The subjects received AZ-004 at two dose levels, 5mg and 10mg, and were eligible to receive up to three doses of AZ-004 in a 24-hour period. The primary endpoint was the change from baseline in the PANSS Excited Component score (PEC score), measured at two hours after the first dose. Both the 5mg and the 10mg dose of AZ-004 met the primary endpoint, showing a highly statistically significant improvement compared to placebo ($p < 0.0001$). The key secondary endpoint was the Clinical Global Impression-Improvement (CGI-I) score, measured at two hours after the first dose. Both the 10mg and the 5mg doses of AZ-004 showed highly statistically significant differences versus placebo ($p = < 0.0001$). AZ-004 exhibited a rapid onset of effect.



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Biotech Review

From *BioWorld Today*

- **BioSante Pharmaceuticals** has entered an agreement with **Azur Pharma** to market Elestrin (estradiol gel) in the U.S. to treat moderate-to-severe hot flashes in menopausal women, in a deal that could bring in up to \$144.5 million for BioSante plus double-digit royalties.

The deal includes an upfront payment of \$3.3 million, comprising a \$500,000 product licensing fee and \$2.8 million for transfer of the Elestrin trademark and inventories, among other items. The additional payments are contingent on BioSante achieving certain sales-based milestones. In addition, Azur has agreed to pay BioSante royalties on sales of Elestrin ranging from 10% to 20% depending on the annual sales level.

- Danish biotech firm **Zealand Pharma** partnered with Helsinn Healthcare in a potential 140 million euros (US\$176.8 million) deal to develop its early clinical stage glucagon-like peptide (GLP)-2 receptor agonist, ZP1846, in chemotherapy-induced diarrhea (CID). Under the terms, Zealand granted Helsinn worldwide rights to the compound, except for the Nordic countries, where Zealand retains marketing rights. In addition to the potential 140 million euros (the company did not disclose specific figures for upfront, development and sales milestones) the Copenhagen, Denmark-based firm also would get royalties from any future product sales if ZP1846

gains approval in CID, a condition that affects about half of patients undergoing chemotherapy treatment.

- **Arpida** said it will cut up to 60 jobs, or about three-quarters of its workforce, as it focuses on lead anti-biotic **iclaprim**. The Reinach, Switzerland-based company saw its shares fall more than 50% last month after the FDA's Anti-Infective Drugs Advisory Committee voted against iclaprim for complicated skin and skin structure infections. The FDA's decision on iclaprim is expected by Jan. 16, 2009, and the drug is under review in Europe and Canada with decisions expected around the third quarter of 2009. For **Introgen Therapeutics** nearly three months after the FDA refused to accept its biologics license application for gene therapy Advexin in the treatment of head and neck cancer, the Austin, Texas-based biotech announced plans to cut 30 jobs, or about two-thirds of its employees. Introgen reported cash, equivalents and short-term investments of just \$6.3 million as of Sept. 30 after burning through \$4.7 million during the third quarter. Accordingly, the company initiated restructuring efforts and hired Torrey Partners to explore strategic alternatives.
- San Francisco-based **Titan Pharmaceuticals** is slashing its workforce by 40% and said it expects further reductions

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"in the next several weeks." Titan ended the third quarter with \$12.2 million in cash, enough money to carry the firm through January 2009, and executives warned at the time that the firm would have to employ strategic alternatives, including the possible sale of assets or the discontinuation of development programs, if unable to secure additional funding by year-end. The company will focus its remaining staff and resources on finding a partner or licensee for its Probuphine program.

- At a time when many biotechs are reeling from the cash crunch, San Francisco-based **Catalyst Biosciences** is steadily moving ahead, thanks to a healthy Series C financing that added \$40.5 million to the company's coffers. Proceeds from its Series C round will allow Catalyst to get early proof-of-concept data for CB 813, as well as fund further development of its Alterase platform, which is designed to re-engineer proteases so that they cleave and inactivate disease-causing proteins.

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