

## **Kendle to Acquire Clinical Services Business of Preclinical CRO Charles River Laboratories**

Cincinnati-based Kendle agreed to acquire the clinical services business of preclinical research powerhouse Charles River Laboratories of Wilmington, Mass. for \$215 million in cash. Charles River took on the clinical services unit when it bought Inveresk, largely a preclinical contract research organization (CRO) two years ago.

Kendle's shares fell May 10 on the news, down 12.5% to \$34.88.

The acquisition brings a little more than \$100 million in annual revenues to Kendle, which has a goal of reaching \$500 million in

annual revenue. In 2005, Kendle generated \$251 million in revenues. "We are excited by this move, which is an important component of our overall growth strategy designed to significantly enhance our global competitive position and accelerate Kendle to a \$500 million organization," said Candace Kendle, chairman and chief executive officer of Kendle.

Kendle told analysts that its acquisition of Charles River's clinical unit brings new geographic reach for Kendle in Europe and new markets such as specialty pharmaceuticals. The two companies have little overlap in cus-

page 3

## **SFBC Early Clinical Development Work Drops, Cuts Guidance for 2006**

SFBC's troubled phase I unit in Miami hurt first quarter performance for the contract research organization (CRO) as revenues fell well below expectations and the company swung to a loss. The company's shares plunged 27% to \$17.32 on May 10.

Overall, direct revenue for the first quarter increased just 4% to \$80.1 million. Total net revenue for the first quarter rose 14% to \$110.1 million, which included reimbursed out-of-pocket expenses of approximately \$30 million.

The company said that as a result of weak revenues, operating results and outlook for its Miami and Ft. Myers facilities, it recorded pre-tax, non-cash goodwill and long-lived asset

impairment charges in the first quarter of 2006 of \$7.1 million. The goodwill impairment charges of \$4.1 million include \$3.5 million for the remaining goodwill related to the company's Miami operations and \$600,000 for the goodwill related to its Ft. Myers operations. The asset impairment charge reduces the carrying value of the Miami property on the company's balance sheet to reflect the estimated fair market value of the property based on a recent appraisal.

"SFBC continues to make significant progress on the issues facing the company," said Jeffrey McMullen, president and chief executive officer of SFBC. "We are taking and will continue to take the necessary steps to

page 3

**Quintiles** launches its expanded strategic partnering group... 2

**Covance** strengthens laboratory testing... 2

### **Company Profile... 4**

An interview with Binoy Gardi, managing director

### **Veeda Clinical Research**

### **Drug & Device Pipeline News... 5**

CenterWatch has identified 19 drugs and devices that have entered new trial phase this week.

### **Trial Results... 6**

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

### **Biotech Review... 7**

Biotech briefs from *Bioworld Today*.

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**Industry Briefs****CROs**

■ **Quintiles** launched its expanded strategic partnering group under the **NovaQuest Capital**, a global investment firm with more than \$5.8 billion in equity capital. NovaQuest helps life science company's portfolios through strategic partnering solutions such as risk sharing. The group was formerly known as PharmaBio Development. TPG-Axon, led by the former head of Goldman Sachs' Principal Strategies Department, Dinakar Singh, will be NovaQuest's first-line partner for co-development and co-promotion investments. Since 2000, when Quintiles started a formal strategic partnering function, more than \$1.5 billion has been invested or committed to Quintiles' partnerships with companies of all sizes. Through its alliance with TPG-Axon, NovaQuest has access to capital to fund strategic partnerships. TPG-Axon already has committed several hundred millions of dollars to NovaQuest partnerships to date. "Customers can tap into our global development and commercialization infrastructure, deal-making expertise, and financial resources to create tailor-made solutions to their most significant strategic and financial challenges," said Quintiles chairman and chief executive officer Dennis Gillings. NovaQuest will be led by Ron Wooten, executive vice president, Corporate Development, Quintiles. Wooten has overseen the development of Quintiles' partner-

ing capabilities since joining the company in 2000. "In less than seven years, we've seen partnering grow from a promising concept to a proven strategic option," Wooten said. "NovaQuest's launch reflects the maturity of Quintiles' partnering capabilities, our record of success and increasing demand from customers. Doing business as usual isn't enough anymore. Customers need alternative growth strategies designed around their specific challenges and goals."

■ **Covance** announced several developments that further strengthen the laboratory testing capabilities provided by its Covance Central Laboratory Services unit in the Asia Pacific region. First, Covance announced that its own dedicated laboratory in Singapore and its laboratory service provider in Shanghai, China—Huashan Hospital Center of Laboratory Medicine—have both achieved certification by the College of American Pathologists (CAP). Second, Covance signed agreements whereby Japan's two largest central laboratories—Mitsubishi Kagaku Bio-Clinical Laboratories and SRL Medisearch—will service its clients' clinical trials in Japan, through its Covance Virtual Central Laboratory service. Finally, Covance expanded kit production facilities in Sydney, Australia, and a quadrupling of its laboratory testing facilities in Singapore, including expanded quantitative PCR testing.

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**Features** (continued from page 1)

**Kendle**

tomers with only one of the top 10 clients in common, Kendle said.

Kendle said the acquisition, which will be complete in the third quarter, would make the company the fourth-largest CRO in the phase II-IV arena.

Charles River executives had said in the

past two years that they planned to hold onto the former clinical business of Inveresk.

The acquired operations will operate under the Kendle name. The agreement provides for the purchase of 100% of the phase II-IV Clinical Services business for \$215 million in cash. This amount is subject to working capital adjustments to be determined at closing.

Kendle intends to finance the transaction

with a combination of cash on hand and debt. Kendle has obtained a commitment for financing necessary to complete the acquisition from UBS Investment Bank, which is also acting as Kendle's financial advisor in connection with the transaction.

**SFBC**

address these issues, including the implementation of a new structure for the early clinical development segment that better aligns SFBC's leadership team with our strategic, operational and financial goals. The time and resources necessary to fully address these issues have significantly exceeded our original expectations. In addition, we experienced weaker-than-expected performance in our early clinical development segment in the first quarter of 2006."

McMullen told analysts that SFBC has been inspected several times in the past few months and received just one "483" notice and those problems have already been addressed. A warning letter, or 483, is issued by the Food and Drug Administration after an on-site audit and lists deficiencies. SFBC came under regulatory scrutiny early this year after *Bloomberg* published a series of reports critical of its patient recruitment efforts, particularly at its Miami phase I facility.

SFBC's loss from operations for the first quarter was \$3.3 million compared with earnings from operations of \$11.7 million for the first quarter of 2005. The net loss for the first quarter of 2006 was \$4.1 million compared with net earnings for the first quarter of 2005 of \$5 million. The net loss for the first quarter of 2006 was \$0.23 per basic and diluted share compared with net earnings for the first quarter of 2005 of \$0.32 per basic share and \$0.30 per fully diluted share.

For its Early Clinical Development segment, SFBC recorded direct revenue, which does not include reimbursed out-of-pocket expenses of \$33 million, or 41% of total direct revenue, in the first quarter compared with \$41.3 million, or 53%, in the first quarter 2005. The loss from operations for Early Clinical Development was \$5.6 million. For the Late Clinical Development segment, SFBC reported direct revenue of \$47.1 million, or 59% of total direct revenue, in the first quarter compared with \$36 million, or 47%, in the first quarter 2005. Earnings from operations for Late

Clinical Development were \$7.5 million, representing a 15.9% operating margin on direct revenue.

At March 31, 2006, backlog for SFBC was \$336.3 million, a decrease of 7%, from \$360.9 million at December 31, 2005. SFBC reported an increase of \$15.1 million in cash to \$53.9 million at March 31, 2006, from \$38.8 million at December 31, 2005.

For 2006, SFBC cut its guidance based upon its current business outlook, greater than previously anticipated decrease in revenues at its Miami facility, greater than previously anticipated legal and related expenses pertaining to recent issues and a lower than previously anticipated outlook for SFBC Anapharm in Quebec City, Quebec. The company now anticipates its direct revenue in 2006 will be \$308 million to \$324 million, down from \$332 million to \$347 million. SFBC now sees 2006 adjusted earnings of 73 cents to 85 cents a share, about half of its previous guidance of \$1.44 to \$1.58 a share.

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## Profile: Phase I Contract Research Organization

### Veeda Clinical Research, Plymouth, England; Ahmedabad, India

An interview with Binoy Gardi, managing director

#### Tell me about Veeda's background.

Veeda officially started in October last year. It's an amalgamation of two companies—one called Phase I Clinical Trials Unit, based in the UK, was founded 18 years ago, and the other was a phase I unit based in India called Clinsearch, founded about two years ago. The two companies merged and became Veeda Clinical Research. Apurva Shah and I founded Clinsearch and designed the unit from scratch. There's a huge amount of interest in India but it also has a lot of perception problems—lack of experience, poor quality data, poor regulatory environment, etc. We thought we would address this issue by acquiring a high quality, long established European CRO, which is why Phase I CTU was acquired. Having a European 'shop window' is advantageous for both companies. It gives the UK unit the ability to access the power of India, and India to access the experience and expertise of the UK.

#### How can Veeda offer phase I studies in India?

Phase I first-in-man studies are not allowed to be done in India unless the molecule is discovered in India; however, you can do phase I studies if the first into man has

occurred outside India in a recognized developed country, which means you can do the multiple dose, single-dose escalations, drug-drug interactions in India. At Veeda CR, because we have a phase I unit in the UK and in India this will allow us to do the first-in-man studies in our unit in the UK and, should the drug proceed, we could do the multiple dose and subsequent studies in India. This would not only save our sponsors cost but also time. We've done over 200 phase I studies in the UK, many first-in-man studies. We use our experience in the UK to conduct studies in India where they can get not only cost savings but speed of patient recruitment. The quality levels are going to be what they're used to in the UK because we take our senior people from the UK over to India—our project managers, study coordinators, principal investigators—for the duration of the study, so they work with the same people all the way through. India has a lot to offer, but the question is how? We feel this is a great model, where you can offer India, but in the right way.

#### How has the phase I industry in India changed?

This year there's been a surge with our top 10 global pharma clients. They seem to have

**Year founded:** 2005

**Employees:** UK 100; India, 130

**Active studies:** UK 5, India 7

**Therapeutic areas:** Oncology, diabetes, cardiovascular and renal

**Beds:** UK, 60; India, 125

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a stronger pipeline with more things coming through phase I. And there's been a huge surge within India as well. With the patent law change, more of the larger domestic pharmas in India have started to invest in true R&D and so we've got more NCE inquiries from India. We've signed a contract with one of the large domestic pharmas for a full drug development program. From an Indian pharma perspective, there isn't anyone who can do phase I studies within India, you have to go outside. They get the cost benefit and geographically we're next door. After phase IIa, they'll probably outlicense their drug, make some money and invest more. So the industry in terms of R&D will grow hugely in India.

#### What are Veeda's plans for growth?

We're looking to grow through further acquisitions in the West. We want to enter the U.S. market next year through a formal acquisition. We're identifying opportunities this year. We will also expand our service offerings to phases II through IV.

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## Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Sponsor Info
Cytogen	CYT-500	prostate cancer	IND accepted; phase I trials planned at one U.S. site	(609) 750-8200 www.cytogen.com
Eisai	E2012	Alzheimer's disease	Phase I trials planned	(201) 692-1100 www.eisai.com
Incyte	INCB9471	HIV infections	Phase I trials initiated; phase IIa trials planned	(302) 498-6700 www.incyte.com
NeoRx	picoplatin	colorectal cancer	Phase I/II trials initiated	(206) 281-7001 www.neorx.com
Phosphagenics	TPM-01/morphine	pain	Phase IIa trials initiated enrolling 48 subjects at one site in Australia	+61 3 9605 5900 www.phosphagenics.com
Prana Biotechnology	PBT2	Alzheimer's disease	Phase II trials planned	+61 3 9349 4906 www.pranabio.com
Protalex	PRTX-100	idiopathic thrombocytopenic purpura	Phase II trials planned	(215) 862-9720 www.protalex.com
Celtic Pharma	TA-NIC	nicotine addiction	Phase II trials initiated enrolling 400 subjects in Europe	+44 (0)20 7786 5550 www.celticpharma.com
Cardiome	RSD1235	atrial fibrillation	Phase IIb trials planned	(604) 677-6905 www.cardiome.com
Inflazyme	IPL512,602	asthma	Phase IIb trials initiated enrolling 200 subjects	(604) 279-8511 www.inflazyme.com
Depomed	gabapentin GR	post-herpetic neuralgia	Phase III trials planned enrolling 400 subjects across 75 U.S. sites	(650) 462-5900 www.depomedinc.com
Eurand	EUR-1008	exocrine pancreatic insufficiency	Phase III trials initiated at 10 U.S. sites	(937) 898-9669 www.eurand.com
Durect	Remoxy	pain	Phase III trials initiated across 20 U.S. sites	(408) 777-1417 www.durect.com
GenVec	Biobypass	coronary artery disease	Phase II trials halted due to economic concerns	(240) 632-0740 www.genvec.com
Hana Biosciences (ondansetron)	Zensana	chemotherapy-induced nausea and vomiting	NDA submission planned	(650) 588-6404 www.hanabiosciences.com
Pharmacyclics	Xcytrin (motexafin gadolinium)	non-small cell lung cancer	NDA submission planned	(408) 774-0330 www.pharmacyclics.com
Adeza	Gestiva	preterm birth	NDA submitted	(408) 745-0975 www.adeza.com
Pfizer	Chantix (varenicline)	nicotine addiction	FDA approved	(212) 733-2323 www.pfizer.com
Medicis	Solodyn (minocycline)	acne	FDA approved	(602) 808-8800 www.medicis.com

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## Trial Results

### Neurology

- **Prana Biotechnology** reported pooled results from their phase I development program for **PBT2** for the treatment of Alzheimer's disease (AD). These trials enrolled 55 young male volunteers and 32 older male and female volunteers; they were designed to investigate the safety, tolerability and pharmacokinetics of single and multiple oral doses of the drug. Preliminary data yielded a positive tolerability profile for doses up to 800 mg, with no significant differences in rates of adverse events (most common events included headache, gastrointestinal disturbance and somnolence). Maximum tolerated dose was not reached. Pharmacokinetic data indicated a rapid absorption profile, with peak plasma concentrations achieved within three hours of administration, a linear absorption profile following single doses of the drug, and little drug accumulation in multiple-dose regimens.

### Gastrointestinal

- **Tranzyme** reported positive results of a phase I trial of **TZP-101**, for the treatment of gastrointestinal motility disorders including post-operative ileus. This placebo-controlled single-ascending dose study enrolled 48 healthy volunteers, who

received one of six doses of the drug or placebo via 30-minute intravenous infusion. Trial data indicated that treatment was safe and generally well tolerated, with no serious adverse events reported. Pharmacokinetic data were supportive of further clinical development. Based on these results, the company announced plans to initiate both a multiple-dose safety and pharmacokinetic study of the drug in healthy volunteers and a single-dose study in type 1 diabetes patients suffering from poor GI motility in the near future.

### Cardiovascular

- **Cardiome** issued additional results of a phase I trial of an oral formulation of **RSD1235**, for the treatment of atrial arrhythmia; preliminary results were announced in August 2005. The additional data concerned the drug's effects on QT interval: subjects receiving a 300 mg twice daily dose of the drug had a baseline QT interval of 396 +/- 25 msec, and a value at maximum plasma concentration (Cmax) of 394 +/- 13 msec; the 600 mg twice daily group had a baseline QT of 402 +/- 19 msec, and a Cmax value of 405 +/- 18 msec; and the 900 mg twice daily dose had a baseline QT of 413 +/- 19 msec and a Cmax value of 408 +/- 25 msec. Prolongation of QT interval is a frequent

complication of antiarrhythmic therapy, and Cardiome was encouraged by the lack of this complication. The company announced plans to initiate a phase IIb trial of oral RSD1235 in the second half of 2006.

- **Scios** issued positive results of a phase II trial, dubbed NAPA (Nesiritide Administered Peri-Anesthesia in Patients Undergoing Cardiac Surgery) of **nesiritide** for the maintenance of post-operative renal function following coronary artery bypass graft (CABG). These results were announced at the 7th Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke meeting in Washington, DC. Trial data yielded significant improvements in both maximum mean increase in serum creatinine from baseline (0.15 +/- 0.29 mg/dl for nesiritide, vs. 0.34 +/- 0.48 mg/dl for placebo;  $p < 0.001$ ), and in maximum decrease in glomerular filtration rate from baseline (-10.8 mL/min/1.73 m<sup>2</sup> vs. -17.2 mL/min/1.73 m<sup>2</sup>;  $p = 0.001$ ). This prospective, multi-center, randomized, double-blind pilot study enrolled 279 heart failure patients scheduled for CABG surgery across 54 sites, who received an infusion of the drug or placebo after induction of anesthesia, with subsequent 14-day follow-up.



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## Biotech Review

### From *BioWorld Today*

- On the heels of a potential \$92 million deal with **Ilypsa** for Ilypsa's phase I phosphate binder, Tokyo-based **Astellas Pharma** has licensed early stage, oral anemia compounds from FibroGen Inc. in a pact worth \$300 million up front plus milestones totaling as much as \$465 million. Astellas is also buying \$50 million worth of FibroGen's stock in order to license FG-2216, FG-4592 and other inhibitors of prolyl hydroxylase, an enzyme that mediates degradation of hypoxia-inducible factor, critical for the body's production of endogenous erythropoietin.
- The FDA-approved Cambridge, Mass.-based **Genzyme's** Myozyme (alglucosidase alfa), an enzyme replacement therapy for Pompe disease, making it the first product cleared for the rare and often fatal muscle disorder. Its label is broad, allowing for use in all patients with the inherited disorder, which is caused by a deficiency of the enzyme acid alpha-glucosidase. While the approval was based largely on data from a pivotal trial that enrolled 18 infantile-onset Pompe disease patients, a fully enrolled study is further establishing Myozyme's profile in older patients, as well.
- At the same time that **Acuity Pharmaceuticals**, of Philadelphia, fin-

ished enrolling patients in a second phase II trial for its lead RNAi-based drug in wet age-related macular degeneration and diabetic macular edema, the company licensed an early stage anti-inflammatory siRNA from **ZaBeCor Pharmaceutical**, also of Philadelphia. **Acuity** entered a license option agreement with **ZaBeCor** for exclusive development and commercialization rights to the product in ocular settings, in exchange for an up-front payment, milestones and royalties.

- **CardioKine**, just two years old, is ready to move its lead product, Lixivaptan, into phase III trials, and it raised \$50 million to do so. The Series B preferred share financing will cover the costs of three phase III trials to begin this summer testing the compound in hyponatremia in patients with heart failure, cirrhosis and syndrome of inappropriate antidiuretic hormone (SIADH). Founded in March 2004, Philadelphia-based CardioKine raised \$37 million shortly after being launched, and its total raised to date is \$87 million. It currently has 16 employees, but that should increase to 20 by the end of the year, and 25 by the end of 2007—about the time the phase III trials are completed.
- The cancer company **NeoPharm** is cutting about a fourth of its work force as part of

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a money-saving measure. Called a "cost rationalization program" by the company, it is expected to reduce total expenses by about \$7 million on an annualized basis, nearly half of which is likely to be realized this year. The layoffs, which are affecting 23% of the biopharmaceutical firm's staff, are projected to contribute about \$3 million in payroll savings to the estimated \$7 million in total savings.

- Preclinical data from **Vical** gave strength to the theory that a universal vaccine could protect against several flu strains, including those feared to cause a deadly pandemic, and the company's stock was lifted by 30.7%. Shares (NASDAQ:VICL) shot up \$1.69 May 2 to close at \$7.19, after the company reported that its lead three-component influenza DNA vaccine candidate provided full protection in mice and ferrets against lethal challenges with a highly virulent H5N1 avian influenza virus.



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