

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

June 2010

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Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the June 2010 issue of the *PharmSource ADVANTAGE Briefing*, a complimentary newsletter designed to provide actionable intelligence to bio/pharmaceutical and contract service professionals. Inside each issue, you will find a snapshot of the intelligence packed into our flagship newsletters, *Bio/Pharmaceutical Outsourcing Report* and *Emerging Markets Outsourcing Report*, along with a company profile developed from our comprehensive **PharmSource ADVANTAGE** contractor database.

This month, we discuss **Charles River Laboratories'** bid to acquire **WuXi PharmaTech**. In addition, we highlight the Q1 2010 results for the top CDMOs and CROs. We also profile **Uman Pharma** which recently entered a strategic alliance with Antares Pharma. And don't miss the information on our latest report, *The Market for Analytical Testing and Development Services* on page 2.

Enjoy the issue!

Feature Story

Charles River Laboratories to Acquire WuXi PharmaTech

Charles River Laboratories (CRL - Wilmington, Massachusetts, USA) has agreed to acquire Shanghai-based **WuXi PharmaTech** for USD 1.6 billion in cash and stock. The purchase price represents a multiple of 25x earnings and 28% premium over WuXi's stock price immediately before the deal was announced.

WuXi has built a strong presence in medicinal and early-phase process chemistry, and has relationships with most global bio/pharmaceutical companies and many small and mid-size companies. Last year, it opened a 250,000-square-foot toxicology facility in Suzhou, China, and has also begun offering formulation services. In 2008, it acquired **Apptec Labs**, a US-based provider of analytical and manufacturing services for biopharmaceuticals. That USD 163 million acquisition has not worked out especially well for WuXi, as it came on the cusp of the financial crisis and downturn in funding for early-stage biopharmaceutical companies. WuXi ultimately shut down Apptec's mammalian cell culture manufacturing operations.

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Briefing

What it means

On the surface, the combination of CRL and WuXi could be a game-changing development. The combined companies have the potential to be a major force in the discovery-preclinical arena. Nevertheless, the deal has major risks for CRL and its shareholders. Jana Partners, a hedge fund operator known to pursue an activist investment strategy, has already launched a challenge of CRL's plan to acquire WuXi. The investor group recently acquired 4.7 million shares of CRL stock and immediately sent off a letter to management objecting to the acquisition. The letter indicated Jana's belief that the USD 1.6 billion price CRL intends to pay WuXi shareholders is too high given WuXi's declining profit margins and expected challenges in integrating the two firms.

Even though many of WuXi's executives and senior scientists have global bio/pharma experience, the cultural gaps between US-run CRL and China-based WuXi could be huge. Recent examples are not promising: WuXi's acquisition of US-based AppTec has not worked out as well as expected, and the joint venture it announced with Covance in 2008 was terminated just months after it was announced. It is rumored that the #3 US preclinical CRO, **MPI Research** (Mattawan, Mich., USA), recently terminated its own JV in China with **Medicilon** (Shanghai, China).

Retention of key staff in China could be an issue as well. No doubt the key WuXi staff have agreed to stay on for some period (WuXi founder Ge Li is to stay on to run the China operations), but they are obviously a very entrepreneurial group, and holding onto them long-term could be a challenge.

Regardless of how well CRL pulls off its merger with WuXi, the underlying notion of a combined chemistry/toxicology offering may well be valid. If so, we might expect other toxicology CROs to make a similar play, whether in North America, Europe or in emerging markets.

Subscribers to PharmSource ADVANTAGE received an enhanced analysis of the acquisition and the impact it may have throughout the industry. To learn more about PharmSource ADVANTAGE, go to www.pharmsource.com/productsservices/pharmsource-advantage.

PharmSource Special Report

New Study Sizes the Analytical Testing Market

PharmSource is pleased to announce the publication of our new report, *The Market for Analytical Testing and Development Services*. The report presents the findings of our extensive effort to model expenditures on GMP analytical development and testing in both the clinical and commercial phases and to understand the factors that will drive outsourcing of analytical activities over the next five years.

The heart of the study is our model of spending for CMC development, including API process development, formulation, CTM manufacture and associated analytical testing. We have constructed a model driven by the new product pipeline and the outsourcing behavior of the major end-customer segments. A separate model breaks down spending for analytical testing of commercial products.

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Briefing

Based on our model, PharmSource estimates industry spending for CMC development services at about USD 9.3 billion, divided almost equally among process and formulation development, analytical development and testing, and CTM manufacture. We estimate that as much as two-thirds of that spending is already outsourced, either to CDMOs or dedicated contract labs. Growth in the market will be constrained by a likely shrinkage in the development pipeline, and North American and European contractors will be challenged by emerging competition from Asia.

More information on *The Market for Analytical Testing and Development Services* is available at <http://www.pharmsource.com/productsservices/special-reports/>.

Side Effects

Side Effects identifies CMOs and CROs that might be impacted by key events affecting their clients, including company acquisitions, product acquisitions and licenses, product approvals, late clinical product terminations, and FDA rejections.

Contractor	Pharma Company	Event	Product	Relationship
Potentially Positive Side Effects				
Abbott Labs	Stiefel Labs/GSK	FDA approval	Hyphanox	Intermediate manufacturing
Aveva Drug Delivery Systems	Meda/Valeant Pharmaceuticals	Health Canada approval	Onsolis	Transdermal dose form manufacturing
Baxter Biopharma Solutions	Cadence Pharmaceuticals	Resubmitted NDA	Ofirmev	Injectables manufacturing
Diosynth	Dendreon	FDA approval	Provenge	Cell culture
Patheon	Pozen/ AstraZeneca	FDA approval	Vimovo	Solid dose manufacturing
Sanico	Stiefel Labs/GSK	FDA approval	Hyphanox	Solid dose manufacturing
Potentially Negative Side Effects				
Almac Group	MiddleBrook Pharmaceuticals	To be acquired by Victory Pharma	Moxatag	Commercial packaging
Catalent Pharma Solutions	Intermune	Response letter from FDA	Esbriet (pirfenidone)	Solid dose manufacturing
Dipharma	OSI Pharmaceuticals	To be acquired by Shionogi	Tarceva	Small molecule API manufacturing
DSM Pharma Products	MiddleBrook Pharmaceuticals	To be acquired by Victory Pharma	Keflex	Small molecule API manufacturing
Schwarz Pharma Manufacturing	OSI Pharmaceuticals	To be acquired by Shionogi	Tarceva	Solid dose manufacturing
Stada Arzneimittel	MiddleBrook Pharmaceuticals	To be acquired by Victory Pharma	Moxatag	Solid dose manufacturing

Source: PharmSource Lead Sheet.

For more information, go to www.pharmsource.com/productsservices/ps-leadsheet.

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Business Conditions**Q1 2010 Review: Demand Begins to Pick Up**

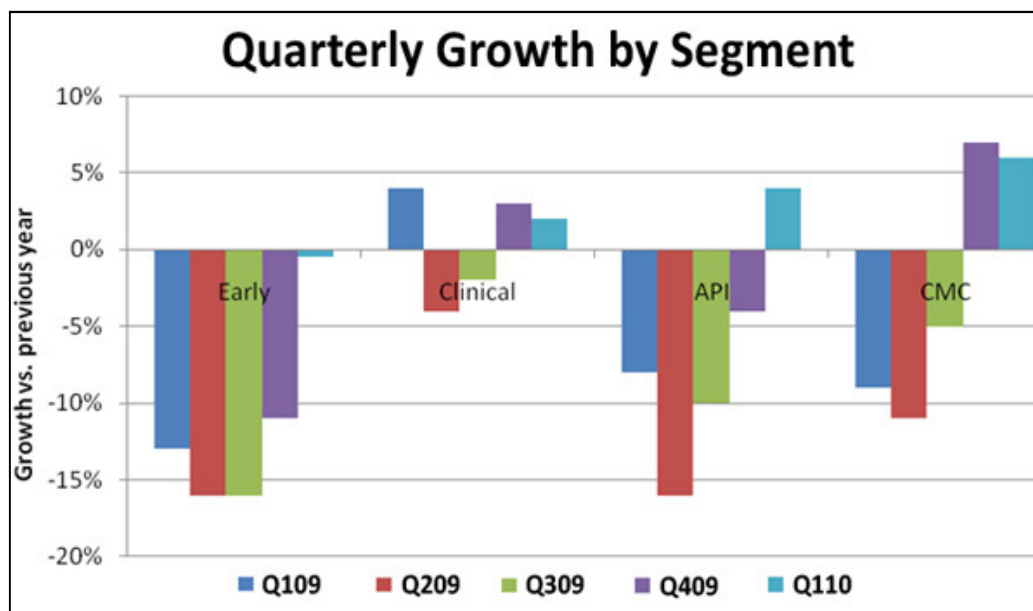
Revenues at most of the top CDMOs and CROs increased in Q1 2010 vs. the previous year, as the top clinical CROs took market share and commercial demand picked up. However, demand for early development services, which include preclinical toxicology and early-stage API process and dosage formulation development, remained weak.

Publicly reporting providers of CMC services posted a 6% increase in collective revenues last quarter, driven by strong results in commercial manufacturing. **Catalent's** Oral Technologies segment grew revenues almost 9% last quarter, and strong results at **Patheon's** European operations helped drive its commercial revenue up more than 8%.

Results at API developers and manufacturers varied widely. Positive results at **SAFC** and **Ampac Fine Chemicals** helped the group grow collective revenues 4% last quarter. Demand for specialty capabilities such as DEA controlled substances and high potency APIs helped drive gains.

Clinical CROs grew revenues 2% vs. the previous year. It appears, however, that most of the growth was due to market share gains at the top companies as Big Pharma continues to narrow its vendor list to the truly global CROs. Double-digit growth at **Covance's** late-stage unit, **Parexel** and **Research Pharmaceutical Services** helped offset double-digit declines at **Kendle**, **Omnicare** and many of the smaller players.

Demand for development services still remains weak. Preclinical services providers were the only group to post negative revenue growth vs. the previous year, and CMC/API developers are still struggling to win business. **Dow Pharma Sciences** experienced a 25% drop in revenues, while **Patheon's** development segment posted a 9% drop. In addition, **Lonza** saw its pipeline of early-stage chemical and biological projects decline vs. the end of 2009.



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Briefing

What it means

The outlook for the year ahead continues to be mixed. On the positive side, preclinical toxicology providers and many clinical CROs saw an increase in RFP flow. In addition, book-to-bill ratios – the value of new contracts signed less cancellations – at the top five public CROs jumped 15% vs. Q4 2009. Another positive sign for the industry is the sustained level of investment in the bio/pharma industry. However, despite the positive signs, many companies are still expecting poor performance for the rest of 2010.

Subscribers to PharmSource ADVANTAGE and Market Intelligence Service received an enhanced analysis of the Q1 results and the outlook for the rest of 2010, including prospects by provider segments. To learn more about PharmSource ADVANTAGE, go to www.pharmsource.com/productsservices/pharmsource-advantage.

PharmSource ADVANTAGE: Contractor Profile

Commercial Dose Manufacturing

Uman Enters Strategic Alliance With Antares Pharma

Uman Pharma (Candiac, Québec, Canada) entered into a strategic alliance with Antares Pharma. The two companies will work together to develop and commercialize Antares' VIBEX MTX, a pressure-assisted injection device containing methotrexate for the treatment of rheumatoid arthritis and other related autoimmune conditions. Under the terms of the agreement, Antares will be responsible for the clinical development program and FDA regulatory submissions, while Uman will perform formulation development and manufacturing activities to support the registration of VIBEX MTX and supply methotrexate in prefilled syringes to Antares for the U.S. market. Uman received an exclusive license to commercialize VIBEX MTX in Canada, and Antares will have the rights to commercialize VIBEX MTX outside of Canada.

Uman Pharma Inc.

Headquarters:

- **Candiac, Quebec Canada**

Services:

- **Commercial Dose Manufacturing**
 - ◆ **Injectables Manufacturing**
 - ◆ **Solid Dose Manufacturing**

Below is a part of an actual profile from the **PharmSource ADVANTAGE** database of contract service providers. The database provides detailed information about contractor capabilities in dose and API manufacturing, packaging services, formulation and more. Qualified companies are listed in PharmSource's contractor database **free of charge**, based on their relevance to our data sets. Along with each profile, you'll find information about known clients, mergers/acquisitions/alliances, company financials and our comprehensive archive of proprietary articles.

The **PharmSource ADVANTAGE** database of contract service providers can be used to create a shortlist of contractor candidates, or for benchmarking. It can help you save weeks of searching, researching and due diligence.

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Uman Pharma Inc.

Mergers/Acquisitions

News & Analysis

Known Clients

Corporate Profile:

Address: 100, de l'Industrie Boulevard
Candiac, Quebec J5R 1J1 Canada

Voice: (450) 444-9989

Fax: (450) 444-8100

Website: www.umanpharma.com

E-mail: info@umanpharma.com

Ownership: Private: private equity or venture capital

Primary Business: Contract Services

Contract Business:

Business head: Sylvain Duvernay

Title: CEO

Contract revenues: \$0-24 million

Business Head contact: Sylvain Duvernay
Voice: 877-444-9989 ext. 5000
Email: sylvain.duvernay@umanpharma.com

Alain Hubert
Voice: 877-444-9989, ext. 5003
Email: alain.hubert@umanpharma.com

North American contact: Peter Wares
Voice: 519-991-7751
E-mail: peter.wares@umanpharma.com

Michel Charbonneau
Voice: 877-444-9989, ext. 5002
E-mail: michel.charbonneau@umanpharma.com

Contract Services:

Commercial Dose Manufacturing

Injectables manufacturing
Solid dose manufacturing

Candiac, Quebec Facility
Candiac, Quebec Facility

Uman Pharma Inc.

Candiac - Quebec - Canada Facility
100, de l'Industrie Boulevard
Candiac, Quebec J5R 1J1 Canada
Phone: (450) 444-9989 Fax: (450) 444-8100
info@umanpharma.com

Size: 127,000 sq. ft.

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Briefing**Specifications for "Injectable Phase I/II CTM and Formulation"****Comments**

Capabilities: Cytotoxic injectables only

Injectable dosage forms

Lyophilized: Yes

Parenteral solutions: Yes

Project acceptance criteria**Antibiotics**

Carbapenem: No

Cephalosporin: No

Penicillin: No

Other materials

Cytotoxic materials: Yes

High potency - not specified: Yes

Vials and Ampules - Standard Potency - GMP**Production scale**

Clinical (10,000-50,000 unit batch size): Yes

Commercial (>50,000 unit batch size): Yes

Early clinical (<10,000 units, GMP): Yes

Lyophilization capability: Yes

Lyophilization capacity: 120 sq. ft.

Vial and ampule packaging

Ampules - glass: Yes

Ampules - number of lines: 3 million annual capacity

Ampules - sizes and types: 3 to 20 ml

Vials: Yes

Vials - number of lines: 10 million annual capacity

Vials - sizes and types: 1 to 100 ml

Prefilled Syringes/Cartridges-Standard Potency-GMP**PFS and cartridge packaging**

Pre-filled syringes: Yes

Pre-filled syringes - sizes and types: 0.5 to 20 ml

Processing Capabilities**Storage conditions**

Refrigerated 2°-8° C walk-in: Yes

High containment capabilities**Cytotoxics**

Cyto lyo capacity (units and size): 120 sq. ft.

Dedicated cytotoxic lyophilization units: Yes

Dedicated cytotoxic suite(s): Yes

High potency (not cytotoxic)

Dedicated high potency lyophilization unit(s): Yes

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Briefing

	Dedicated high potency suite(s):	Yes
Live viruses	Dedicated live virus aseptic fill:	No
	Dedicated live virus lyophilization unit(s):	No
	Dedicated live virus suite(s):	No
Cephalosporins	Dedicated cephalosporin aseptic fill:	No
	Dedicated cephalosporin lyophilization unit(s):	No
	Dedicated cephalosporin suite(s):	No
Penicillins	Dedicated penicillin aseptic fill:	No
	Dedicated penicillin lyophilization unit(s):	No
	Dedicated penicillin suite(s):	No

Regulatory approvals and certifications

	Canada - HPB:	Yes
	Europe - EMEA or constituent countries:	Yes
	USA - FDA:	Yes

PharmSource ADVANTAGE TEST-DRIVE

We invite you to take a **complimentary test-drive** of **PharmSource ADVANTAGE** online service, the bio/pharma industry's most insightful sourcing intelligence resource. Unique, user-friendly tools provide side-by-side company comparisons, key contact information and due diligence directly from your desktop.

To schedule your **free test-drive**, please call Michael Kaufman at **703-383-4903** ext. **104** (ET) or write to him at michael.kaufman@pharmsource.com.

For a limited time only, we are offering new subscribers a 15% discount when you subscribe within 10 days of your test-drive.

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