

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

June/July 2009

In This Issue:

Feature Story

Charles River Labs Seeks
Second China Facility 1

Side Effects 2

Business Conditions

Q1 2009 Financial Review:
Asian Contract Revenue
Growth Halved but Still
Positive 3

PharmSource White Paper

The U.S. Foreign Corrupt
Practices Act (FCPA): How to
Minimize Your Risk 4

Contractor Profile

Ebewe Pharma 4

PharmSource ADVANTAGE

Test-Drive Offer 8

Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the June/July 2009 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 newsletter, *Bio/Pharmaceutical Outsourcing Report*, along with a company profile developed from our comprehensive **PharmSource ADVANTAGE** contractor database.

This month, we discuss **Charles River Laboratories International**'s newest facility in China and what it means for the Chinese market. In addition, we analyze the revenue growth of Asian contract service providers during the first quarter of 2009. We also profile **Ebewe Pharma** which recently entered into an agreement with Novartis to sell its generic oncology business. And don't miss the information on how to access our latest **white paper** on the **U.S. Foreign Corrupt Practices Act (FCPA)** on page 4.

Enjoy the issue!

Feature Story

Charles River Labs Seeks Second China Facility

Charles River Laboratories International (CRL - Wilmington, Mass., USA) plans to open a second facility in China, President and CEO James Foster disclosed during the company's Q1 2009 earnings conference call. CRL currently has a 60,000-square-foot preclinical facility in Shanghai that is operated by Charles River Preclinical Services Greater China, a joint venture formed between Charles River Labs and Shanghai BioExplorer. The facility was opened in October 2008.

According to Foster, CRL believes that the market in China will expand significantly over the next three to five years and that there is a need among its clients to have local facilities to provide services. The company wishes to position itself as the leading international CRO with GLP capabilities in China.

CRL's position contrasts sharply with that of **Covance** (Princeton, N.J., USA), its principal rival in the preclinical toxicology business.

© 2009 PharmSource Information Services, Inc.

Tel. 703-383-4903
Fax. 703-383-4905
www.pharmsource.com
info@pharmsource.com

Continued on next page

Briefing

Covance has taken a “wait and see” approach to the Chinese market, especially after its joint venture with WuXi PharmaTech, announced in July 2008, fell apart. That position was recently confirmed when Laurene Isip, head of Corporate Communications at Covance, responded to a PharmSource inquiry by saying that “Covance is continuing to explore opportunities to further expand” in the country.

What it means

The contrasting positions of CRL and Covance regarding the Chinese market are certainly confusing to someone trying to understand the trends in that market. However, those positions no doubt reflect specific circumstances of the companies themselves.

CRL would not comment further on its plans for China, but the planned second facility could reflect a strong sense that the toxicology market opportunity will blossom in China over the next several years and/or a desire by the company to establish a second, solely owned operation in China. At the same time, Covance’s decision to set a deliberate pace in establishing a presence in China is not likely to be less-informed than CRL’s. Covance already has a significant presence in the country. Thus, Covance has the local knowledge and financial wherewithal to establish a China operation when it sees the opportunity.

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.

Pharma Company	Event	Contractor	Product	Relationship
AP Pharma	NDA submitted	Hyaluron	APF530	Injectables manufacturing
ARCA biopharma	Complete Response Letter from FDA	Groupe Novasep	Gencaro	Small molecule API manufacturing
BioPartners GmbH	MAA application withdrawn	Recipharm	Biferonex	Cell culture; Injectables manufacturing
Cadence Pharmaceuticals	NDA submitted	Baxter Biopharma Solutions	Acetavance	Injectables manufacturing
GlaxoSmithKline	FDA approval	Eurand	Lamictal ODT	Drug delivery technology
HRA Pharma	EMA approval	Osny Pharma	Ellaone	Solid dose manufacturing
IDM Pharma	To be acquired by Takeda	Ben Venue Laboratories	Mepact	Injectables manufacturing
NeurogesX	EMA approval	LTS Lohmann Therapie-Systeme	Qutenza	Transdermal dose form manufacturing
UCB	FDA approval of new indication	Lonza	Cimzia	Biomanufacturing
Victory Pharma	To be acquired by Shionogi	Mikart	Dolgic Plus	Solid dose manufacturing

Continued on next page

Business Conditions

Q1 2009 Financial Review: Asian Contract Revenue Growth Halved but Still Positive

Asian contract service providers proved susceptible to the lower demand that crippled Western CROs and CMOs during the first quarter of 2009. Overall, the nine Indian and Chinese companies that report contract service revenue saw their revenue growth cut in half last quarter.

Overall, top-line growth at the nine companies was 13%, just half of the Q4 2008 rate and well below the run rate in 2007 and 2008. Results varied widely by company, with all but one company experiencing positive growth. **Jubilant Organosys** reported a 25% growth in its CRAMS revenues, thanks in large part to new capacity at **Hollister-Stier** and the addition of revenue from last April's acquisition of **Draxis Health**. **Biocon**'s revenue jumped 47%, thanks to the initiation of a discovery and development deal with Bristol-Myers Squibb. **Torrent Pharmaceuticals** experienced 30% growth, albeit on a small base.

Piramal Healthcare Pharma Solutions registered negative growth of 2% for the quarter, due to a 40% drop in revenues from assets outside of India. Some of this drop can be attributed to Piramal's decision to shift production from Western facilities to Indian plants, as well as an overall fall in demand; the company was forced to close its Huddersfield, UK, plant after capacity utilization fell to just 35%.

WuXi PharmaTech experienced a drop in manufacturing revenues of more than 80% during Q1, but growth in both U.S.- and China-based laboratory services buoyed overall revenue growth into positive territory at 5%. Revenues at **Suven Life Sciences** grew just 4% as it continues to focus on its internal pipeline.

Q1 (ending March)	Contract Services		Total	
	Revenue (\$M)	Growth (%)	Revenue (\$M)	Growth (%)
Jubilant Organosys	99.2	25	166.5	22
Dr. Reddy's	97.0	13	392.3	50
Piramal Healthcare Pharma Solutions	59.8	(2)	168.4	9
WuXi PharmaTech	59.1	5	59.1	5
Dishman Chemical	41.8	17	57.9	21
Biocon	13.4	47	96.3	74
Suven Life Sciences	7.2	4	7.2	4
Torrent Pharmaceuticals	8.8	30	79.3	25
Vimta Labs	4.0	6	4.0	6
Total	390.4	13	1031.7	14

Continued on next page

PharmSource White Paper**The U.S. Foreign Corrupt Practices Act (FCPA):
How to Minimize Your Risk**

We are pleased to announce the publication of our latest white paper entitled **The U.S. Foreign Corrupt Practices Act (FCPA): How to Minimize Your Risk**. This incisive resource provides guidelines on how to establish a strong FCPA compliance program that minimizes corruption risk for companies doing business throughout the world.

The U.S. is increasing the number of investigations of FCPA and financial fraud violations, particularly within the pharmaceutical sector. This has been reflected by an increase in enforcement budgets and the employment of additional personnel to improve the frequency with which investigations are conducted. Readers will find this timely publication to be a critical first step in understanding FCPA practices especially while conducting business in emerging markets.

“[After all], it is far easier to start a compliance program before commencing work overseas than it is to implement one retroactively, but it is also far more cost-effective to implement and run a compliance program than it is to be involved in any kind of FCPA investigation, which not only is costly but can have devastating effects on a company’s reputation and business.”

Leslie McCarthy
Director of Corporate Development, The STEELE Foundation

The U.S. Foreign Corrupt Practices Act (FCPA): How to Minimize Your Risk includes information on:

- Industry-specific implications of current FCPA regulations.
- Essential elements of a strong FCPA compliance program for those in the bio/pharma industry.
- Comprehensive steps to implement a solid FCPA compliance program.
- Enforcement of anti-corruption business practices in emerging markets.
- Mechanisms to avoid compliance pitfalls despite global and economic challenges.

The white paper will be offered as a **free download** from **July 8 through July 21, 2009** at www.pharmsource.com/pharmsource-white-paper.

PharmSource ADVANTAGE: Contractor Profile

Commercial Dose Manufacturing

Novartis to Acquire Ebewe

Novartis (Basel, Switzerland) will acquire the generic oncology business of **Ebewe** (Unterach, Austria) and make it part of its Sandoz generics unit. In addition to offering its own generic oncology products, Ebewe has been an active participant in the contract cytotoxic injectables market.

Novartis will acquire Ebewe’s oncology assets for EUR 925 million (USD 1.2 billion), representing a multiple of nearly five times Ebewe’s 2008 revenues of EUR 188 million (USD 272 million) and 18

Continued on next page

Briefing

times its operating income of EUR 53 million (USD 77 million). Ebewe's contract manufacturing revenues were not broken out, but we do not believe they are more than 10% of revenues.

According to the **PharmSource ADVANTAGE** contractor database, Ebewe's cytotoxic manufacturing facility has a single line with capacity of 750 liters/60,000 vials per batch or about 9 million vials per year. It has no lyophilization capability. Ebewe also has standard potency manufacturing capability of 15 million vials and 100 million ampoules annually.

We contacted Norbert Hittinberger, head of contract manufacturing for Ebewe, about the future of the CM business. "I think we will be able to offer contract manufacturing for oncology products in the future," was his brief e-mail reply.

What it means

Regardless of whether Ebewe withdraws from contract manufacturing, the impact on the European cytotoxic injectable contract manufacturing market will be marginal. With its single line and lack of lyophilization capacity, Ebewe has been at a competitive disadvantage over other European manufacturers with more capacity and capability, and there are plenty of competitors in the market.

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.

Ebewe Pharma

Known Clients **News & Analysis**

Corporate Profile:

Address: Mondseestrasse 11
A-4866 Unterach am Attersee, Austria

Voice: +43 7665 8123 585

Fax: +43 7665 8123 11

Website: www.ebewe.com

E-mail: office@ebewe.com

Primary Business: Contract Services

Ebewe Pharma

Headquarters:

Unterach am Attersee, Austria

Services:

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

Continued on next page

Contract Business:

Contract revenues: \$0-24 million
Number of employees: 501-1000
European contact: Norbert Hittenberger
Voice: +43 7665 8123 585
Fax: +43 7665 8123 11
E-mail: norbert.hittenberger@ebewe.com

 Julia Abraham
Voice: +43 (7665) 8123-585
E-mail: julia.abraham@ebewe.com

Trade shows: CPhI Worldwide

Contract Services:

Commercial Dose manufacturing
 Injectables manufacturing

Ebewe Pharma
 Unterach am Attersee — Austria Facility
 Mondseestrasse 11
 A-4866 Unterach am Attersee, Austria

 Phone: +43 7665 8123 585 Fax: +43 7665 8123 11
office@ebewe.com

Specifications for "Injectables manufacturing"

Dosage Forms

Large volume parenterals: Yes
Lyophilized: No
Parenteral solutions: Yes
Parenteral suspensions: No
Sterile Powders: No

Project Acceptance Criteria

Antibiotics
Carbapenem: No
Cephalosporin: No
Penicillin: No

Controlled substances
DEA schedule II: No
DEA schedule III, IV, V: No

High potency and cytotoxic
Cytotoxic materials: Yes
Hormones/steroids: Yes

Vaccines and viruses
Vaccines-killed: Yes
Vaccines-live/attenuated: No

Continued on next page

<i>Other materials</i>	Vaccines-recombinant:	Yes
	Allergenic extracts:	No
	Proteins & peptides:	Yes
	Radiopharmaceuticals:	No
	Veterinary products:	Yes
	Vitamins & nutritionals:	No

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

Vial and ampule processing

Aseptic fill:	Yes
Glass-lined vessels:	No
High viscosity materials (>50 centipoises):	Yes
Inert atmospheres:	Yes
Light sensitive:	Yes
Lipid formulations:	Yes
Oxygen sensitive:	Yes
Terminal sterilization:	Yes

Lyophilization

Lyophilization capability:	No
Non-aqueous solvent handling:	Yes

Vial and ampule packaging

ADD-vantage:	No
Ampules - glass:	Yes
Ampules - number of lines:	>100 mil units annually
Ampules - sizes and types:	1 ml - 20 ml
Blow-fill-seal:	No
Vials:	Yes
Vials - number of lines:	> 15 mil units annually
Vials - sizes and types:	1 ml to 100 ml

Prefilled Syringes/Cartridges-Standard Potency-GMP

PFS and cartridge packaging

Cartridges:	No
Cartridges—types:	No
Pre-filled syringes:	Yes
Pre-filled syringes—sizes and types:	1-20ml; >2mil. annually

Continued on next page

Briefing**Large Volume Parenterals - GMP****LVP packaging**

LVP bags: No

LVP glass bottles Yes

LVP glass bottles—sizes and types: Max 400L

High containment capabilities**Cytotoxics**

Dedicated cytotoxic aseptic fill: Yes

Dedicated cytotoxic lyophilization units: No

Dedicated cytotoxic suite(s): Yes

Number of cyto fill lines:

Single line with capacity of 750 liters/ 60,000 vials per batch (9 million vials annually)

High potency (not cytotoxic)

Dedicated high potency aseptic fill: Yes

Dedicated high potency suite(s): Yes

Regulatory Approvals and Certifications

Canada - HPB: Yes

Europe - EMEA or constituent countries: Yes

ISO certification: Yes

ISO certification type: ISO 9001

Japan - Koseisho: Yes

UK - MHRA: Yes

USA - FDA: Yes

USA - Last FDA inspection: 2006

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. This service allows users to search for vendors by company, capability, geography, compliance and more. Unique, user-friendly tools provide side-by-side company comparisons, key contact information and due diligence directly from your desktop. In addition, qualified test-drive participants are provided with complimentary issues of our respected industry newsletters, *Bio/Pharmaceutical Outsourcing Report* and *Emerging Markets Outsourcing Report*.

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.

**PharmSource ADVANTAGE Briefing is a
publication of PharmSource Information Services, Inc.**