PharmSource ADVANTAGE Briefing

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

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In This Issue:

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Welcome to the *PharmSource ADVANTAGE Briefing*!

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

This month, we discuss **ResearchPoint** and its successful CRO partner model. In addition, we analyze the revenue results for the contract services industry during the fourth quarter of 2009 and highlight some signs of optimism for 2010. We also profile **Biovian** and discuss the company's expansion of its aseptic filling capacity. 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

ResearchPoint Continues to Expand Its Reach With CRO Partner Model

ResearchPoint (Austin, Texas, USA) recently welcomed **GVK Biosciences** (Hyderabad, India) as the ninth CRO affiliate in its network of like-minded CRO partners, ResearchPoint Global (RPG). The addition of GVK Biosciences serves to extend the network's presence into India, and GVK Biosciences is the first Asian-based partner to join the group. RPG has 22 offices in 17 countries and provides clinical trial services in 65 countries throughout the Americas, Europe, Africa and now Asia.

Founded in 2004, RPG was designed to help ResearchPoint and its partners offer global coverage more efficiently. "ResearchPoint President and CEO John Farinacci and the company's COO Robert Davis both worked for large CROs in the past and wanted to try a different approach with ResearchPoint. Their model was to build a strong network of companies that they know well and that have similar business practices and philosophies," explained Matt Walker, executive VP, business development and marketing at ResearchPoint.

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"This model provides ResearchPoint and its partners with the best of both worlds – global capabilities with local expertise. [Through RPG,] we provide a bigger footprint for clinical trials both individually and collectively. We all share the same global model and offer that to our customers," Walker continued.

Once a company joins RPG, it agrees to work with the group and to abide by a universal set of standard operating procedures (SOPs). In fact, each partner CRO is required to attend monthly meetings to discuss operational and business development issues. Members also sign a partnership agreement that outlines how costs and revenues will be shared.

"Partners share the administrative costs associated with conducting trials. Revenues are split according to a formula which takes into account each participant's involvement in a study, the overall revenues to the group and the relative revenues to participants in the study," explained Walker.

ResearchPoint believes that the CRO partner model allows the company and its affiliates to offer customers a "unique simplicity." With RPG, members have the reach of a large, global CRO but are able to provide the customer service found at a smaller CRO. "Through our partnerships, we offer clients several benefits, including low overhead costs and an expansive, worldwide reach for conducting trials. At the same time, although studies may be conducted in several locations throughout the world by different CRO partners, customers have a single point of contact for their study, the simplicity of one contract and the assurance of a single set of SOPs like those offered by large global companies."

Over the course of this year, ResearchPoint plans to develop RPG further into a hybrid model whereby the network will include partner CROs in addition to ResearchPoint offices throughout the world. As a part of this transition, ResearchPoint is considering the purchase of other CROs, with RPG partners as possible candidates.

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.

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/.

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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		
Anderson Packaging	Somaxon Pharmaceuticals	FDA approval	Silenor	Commercial packaging
Catalent Pharma Solutions	Intermune	MAA filed	pirfenidone	Solid dose manufacturing
Contract Pharmaceuticals Ltd. (CPL)	Medivir	US marketing agreement signed with Meda	Xerese	Semisolid manufacturing
Patheon	Somaxon Pharmaceuticals	FDA approval	Silenor	Solid dose manufacturing
Solvay (Abbott) Injectables	Watson Pharma	FDA approval	diluent for Trelstar	Injectables manufacturing
		Potentially Negative Side Effects		
3M Drug Delivery Systems	Graceway Pharmaceuticals	Generic competition (ANDA approval)	Aldara Cream	Semisolid manufacturing
Baxter BioPharma Solutions	Cadence Pharmaceuticals	Complete response letter from FDA	Acetavance	Injectables manufacturing
Ben Venue Labs	TopoTarget	Product to be acquired by SpePharm	Savene	Injectables manufacturing
Hyaluron Contract Manufacturing	Novelos Therapeutics	Development discontinued	NOV-205	Injectables manufacturing
Oregon Freeze Dry	Novelos Therapeutics	Development discontinued	NOV-205	Lyophilization services

Source: PharmSource Lead Sheet

Business Conditions

2009 Ends With Some Positive Signs for 2010

January marked the end of 2009, a bad year for all but the top contract service providers. Revenues at publicly traded CROs and CDMOs in the preclinical, API and CMC sectors declined significantly during the year due to reduced funding for startup companies and R&D cutbacks and inventory management at large bio/pharmaceutical companies. Revenues at publicly traded clinical CROs grew slightly during 2009, although that can be attributed to market share gains at a few of the top players.

The fourth quarter of 2009 turned out to be the best quarter of the year even though many companies and the entire preclinical sector still experienced a down quarter. Many of the largest contractors, however, performed well.

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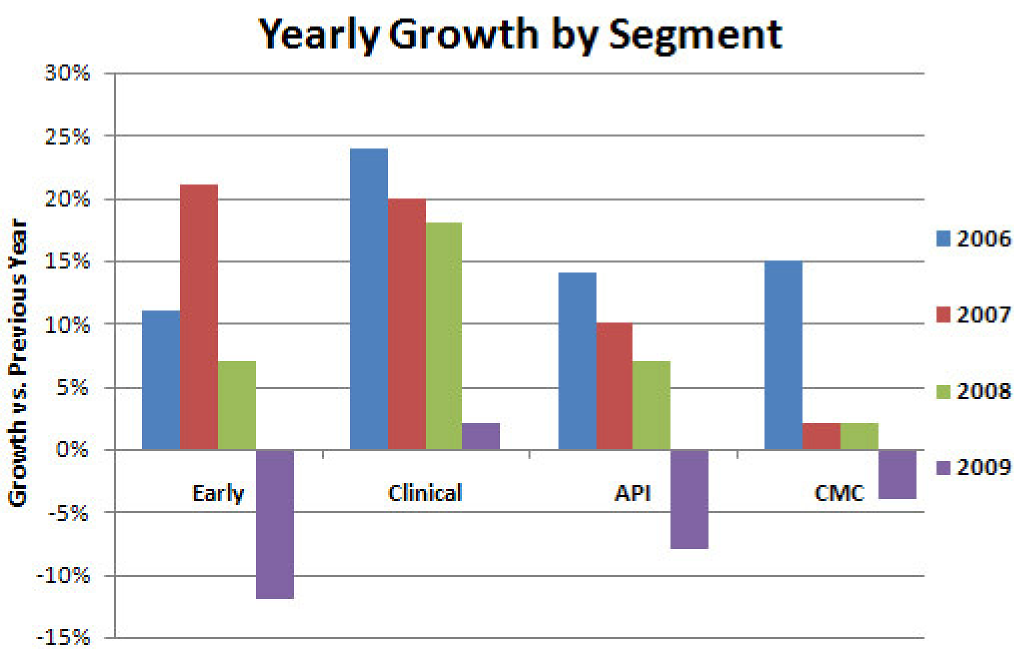
Revenues for CMC services grew by 7% during Q4 2009, mainly bolstered by strong results in Patheon, Catalent and Hollister-Stier's commercial manufacturing divisions. Multiple providers of injectables manufacturing and packaging services reported a boost during H2 2009 due to H1N1 influenza orders.

Demand for clinical CROs with global capabilities helped Covance's late-stage division, Parexel and Icon (the second- through fourth-largest public CROs) lead the clinical sector to positive growth in Q4 2009, even though the largest public CRO (PPD) posted a decline in revenues.

Demand for development services was still down significantly during Q4 2009 as evidenced by lower revenues almost across the board for preclinical CROs and process development and formulation CDMOs.



What it means

The early indicators for 2010 provide some reason for optimism. New business signings at clinical CROs picked up in Q4 2009 after hitting a low in the third quarter. Book-to-bill ratios – the value of new contracts signed less cancellations – at the five biggest public clinical CROs grew 8% over Q3 2009 to 1.1, a figure that is still well below the boom years of 2007 and 2008, when book-to-bill ratios of 1.4 to 1.5 were common. While some of the pickup is certainly due to vendor consolidation, it is also a sign that large bio/pharmaceutical companies are returning their focus to R&D efforts after completing megamergers and pipeline reorganizations last year.

Project pipelines at many CDMOs are also growing. Sigma-Aldrich reported that the pipeline of projects at its SAFC unit grew significantly in 2009 and has approximately doubled since 2006 to almost 450 projects. Most of the growth in recent years has come from early development candidates (preclinical and Phase I), although late development projects (Phase II/III) swelled to almost 140 at the end of 2009. Hollister-Stier and Draxis Pharma's combined pipeline grew 20% in Q4 2009 vs. the previous quarter, with the addition of three new projects in both Phase I and Phase II and two new Phase III projects.

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In addition, funding has picked up for small bio/pharmaceutical companies. According to the *PharmSource Lead Sheet*, venture capital investments in US-based startups climbed back over USD 1 billion in Q4 2009, the first quarter above that mark in at least two years. And the public market spout has opened again; the *PharmSource Lead Sheet* counted more than USD 3 billion raised via IPOs, secondary offerings and PIPEs last quarter.

Order volatility due to inventory management by bio/pharmaceutical companies is one issue that could continue to plague commercial suppliers in 2010. Many CMOs, most notably Lonza, were hit hard by delayed and canceled orders last year. Although analysis of inventory turns (a measure of inventory efficiency) reveals that both large and mid-size bio/pharmaceutical companies made some progress in 2009, there is still much room for improvement.

PharmSource ADVANTAGE: Contractor Profile

Clinical Dose Manufacturing and Packaging

Bovian Expands Filling Capacity

Biovian (Turku, Finland) expanded its aseptic filling capacity with the addition of two stand-alone automated filling lines. The first line is designed for aseptic filling of small batches of cytotoxic and other hazardous compounds in vials. The second accommodates a higher capacity and will be used for the aseptic filling of recombinant proteins or antibody products in vials. Vial sizes range from 2 ml to 15 ml. Lyophilization and sterile manufacturing services are both offered in addition to dilution, formulation, QC testing, labeling, color coding, packaging and warehousing, as well as QP release and delivery.

Biovian

Headquarters: Turku, Finland

Services:
- **API - Biomanufacturing**
  - ♦ **Cell culture**
- **Clinical Dose Manufacturing and Packaging**
  - ♦ **Injectable Phase I/II CTM and Formulation**

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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Biovian

Mergers/Acquisitions **News & Analysis** **Known Clients**

Corporate Profile:	
Address:	Tykistökatu 6 B FIN-20520 Turku, Finland
Voice:	358 (0)2 274 8840
Fax:	358 (0)2 274 8841
Website:	www.biovian.com
E-mail:	contact@biovian.com
Ownership:	Private: management owned
Primary Business:	Contract Services
Contract Business:	
Business head:	Sakari Heyno
Contract revenues:	$0-24 million
Corporate Head contact:	**Sakari Heyno** Voice: 358-40-5093210 E-mail: sakari.heyno@biovian.com
European contact:	**Knut Ringbom** Voice: 358-40-5171217 E-mail: knut.ringbom@biovian.com

Contract Services:

API - Biomanufacturing
- Cell culture

Clinical Dose Manufacturing and Packaging
- Injectable Phase I/II CTM and Formulation

Biovian
Turku Facility
Tykistökatu 6 B
FIN-20520 Turku, Finland
Phone: 358 (0)2 274 8840 Fax: 358 (0)2 274 8841
contact@biovian.com

Size: 1600 sq. meters

Specifications for "Injectable Phase I/II CTM and Formulation"

Injectable dosage forms	
Large volume parenterals:	No
Lyophilized:	Yes
Parenteral solutions:	Yes
Sterile Powders:	No

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Project acceptance criteria

Antibiotics

Cephalosporin:	No
Penicillin:	No

Controlled substances

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

High potency and cytotoxic

Cytotoxic materials:	No
Hormones/steroids:	No

Vaccines and viruses

Vaccines-killed:	Yes
Vaccines-live/attenuated:	No
Vaccines-recombinant:	Yes

Other materials

Proteins & peptides:	Yes
Radiopharmaceuticals:	No

Vials and Ampules - Standard Potency - GMP

Production scale

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

Vial and ampule processing

Aseptic fill:	Yes
Terminal sterilization:	Yes

Lyophilization

Lyophilization capability:	Yes

Vial and ampule packaging

Ampules - glass:	No
Vials:	Yes

Prefilled Syringes/Cartridges-Standard Potency-GMP

PFS and cartridge packaging

Cartridges:	No
Pre-filled syringes:	No

Large Volume Parenterals - GMP

LVP packaging

LVP bags:	No
LVP glass bottles:	No

Regulatory approvals and certifications

Europe - EMEA or constituent countries:	Yes

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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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