

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

March 2009

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Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the March 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 analyze the implications of the waning demand for early development services, formerly one of the hottest sectors in the industry. In addition, we profile **Halo Pharmaceuticals** after its recent acquisition of Abbott's plant in Whippany, N.J. We also explore **Quotient Bioscience's** acquisition of Pharmaceutical Profiles and the "roll-up" strategy. And don't miss our analysis of the uncertain cell culture outlook on page 3.

Enjoy the issue!

FEATURE STORY

Early Development CROs Hit by Demand Decline

The second half of 2008 proved to be tough on CROs that provide early development services. After nine straight quarters of double-digit growth, revenues for public CROs increased only 7% in the third quarter. Project delays and cancelations led to a decline in revenues by 4% in the fourth quarter.

- **Covance** announced that it will close two of its Phase I clinics in order to help offset reduced revenues due to delays in noncritical studies. The two clinics are located in Boise, Idaho, and San Diego, Calif., and have just 12 and 36 beds, respectively.
- **MPI Research** announced in December that it was laying off at least 200 people at its sites in Michigan. The layoffs came after MPI revealed ambitious growth plans that include investing USD 330 million to renovate former Pfizer facilities and increase staff to 3000.

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Briefing

- **Charles River Laboratories (CRL)** will cut 3% of its global workforce, mostly in its Preclinical Services segment. In addition, CRL initiated a salary freeze and announced plans to close its Redfield, Ark., animal toxicology facility and seek strategic alternatives for its Phase I clinic in Edinburgh, Scotland.

What it means

Early development has gone from one of the hottest service sectors to one of the worst-performing sectors in a matter of months. Two reasons are primarily to blame for this significant slowdown: big pharma reprioritizing its pipeline and a decrease in available funding for small companies. With funding hard to come by, small companies are cutting costs in order to protect burn rate. These cuts often include a reduction in the number of molecules being actively developed. Obviously, fewer molecules in development means fewer early-stage trials.

BUSINESS CONDITIONS

Quotient Buys Pharmaceutical Profiles

Quotient Bioscience (Cambridgeshire, UK) has acquired **Pharmaceutical Profiles** (Nottingham, UK). Pharmaceutical Profiles specializes in the formulation development of oral, intravenous and inhaled dosage forms, and manufactures clinical supplies up to Phase I scale. Pharmaceutical Profiles, which has 75 employees, will adopt the name of Quotient Biosciences' drug development unit, Quotient Bioresearch.

Quotient Bioscience was founded in 2007 and has grown by acquisition. Business units provide drug development services, drug surveillance testing services for sports and manufacture of reagents used in blood typing. Group revenues are nearly GBP 40 million. The company is backed by private equity firm **TA Associates**, which invested GBP 35 million in the company in 2008.

What it means

As we have noted before, strategies to build broad-capability drug development companies through acquisitions, known as roll-ups, continue to be popular in the industry and are a favorite vehicle of private equity firms. Other examples include Aptuit, Azopharma and Cetero Research.

We are watching carefully how the roll-up strategy fares in the difficult early development business environment. On the one hand, the reduced demand and uncertainty could put the brakes on further activity as investors wait to see when and how demand will pick up again. Alternatively, weak demand will create a pool of desperate sellers that can be acquired at very attractive prices.

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Briefing**SIDE EFFECTS**

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

Pharma Company	Event	Contractor	Product	Relationship
Akesis Pharmaceuticals	Development discontinued	Quintiles Transnational Corp	AKP-020	Clinical Data Management
Akesis Pharmaceuticals	Development discontinued	Cetero Research	AKP-020	Clinical Pharmacology (Phase I/IIa)
Altus Pharmaceuticals	Development discontinued	Lonza	Trizyte (ALTU-135)	Biomanufacturing
Altus Pharmaceuticals	Development discontinued	Patheon	Trizyte (ALTU-135)	Solid Dose Manufacturing
Panacos Pharmaceuticals	Product sold to Myriad Pharma	Boehringer Ingelheim Chemicals	Bevirimat	Small Molecule API Manufacturing
Acorda Therapeutics	NDA filed	Patheon	Fampridine-SR	Solid Dose Manufacturing (2nd source)
GTC Biotherapeutics	FDA approval	Lonza	Atryn	Purification Only
GTC Biotherapeutics	FDA approval	MedImmune Pharma B.V.	Atryn	Injectables Manufacturing
Ovation Pharmaceuticals	to be acquired by Lundbeck	Catalent Pharma Solutions	Panhematin	Injectables Manufacturing
Ovation Pharmaceuticals	to be acquired by Lundbeck	Hospira	Nembutal	Injectables Manufacturing
Vion Pharmaceuticals	NDA filed	Ben Venue Laboratories	Onrigin	Injectables Manufacturing
Vion Pharmaceuticals	NDA filed	SAFC	Onrigin	Small Molecule API Manufacturing
Wyeth	to be acquired by Pfizer	Baxter Biopharma Solutions	Prevnar	Injectables Manufacturing
Wyeth	to be acquired by Pfizer	Henogen	HIV Type 1 vaccine	Biomanufacturing
Wyeth	to be acquired by Pfizer	Catalent Pharma Solutions	Prevnar	Commercial Packaging

Source: PharmSource Lead Sheet

SPECIAL REPORTS**Uncertain Cell Culture Outlook**

While contract mammalian cell culture manufacturers are operating at near capacity, the major biopharmaceutical companies with substantial, internal cell culture capabilities are at less than 70%. In this dynamic market, arriving at the right make or buy decision requires an intimate understanding of the demand drivers and variables.

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Briefing

One of the biggest factors in future planning is the rate at which improved process yields are translated from the laboratory to the commercial production environment. And one key aspect of this is how quickly technological advances will translate into productivity gains. Another big wildcard in the equation is the rate of new product approval and market uptake. With at least nine pipeline products that have the potential to require one ton of product within the first five years of launch, even tighter capacity conditions could develop rapidly.

To support your 2009 planning process, a report on *Cell Culture Manufacturing Capacity: Trends and Outlook Through 2013* has been released. This report is brought to you by BioProcess Technology Consultants, the industry's foremost experts on cell culture manufacturing, and PharmSource, bio/pharma's preeminent market intelligence resource. Beyond a simple market overview, this publication offers the strategic insight and analyses you need to make the right tactical decisions for your business.

To download an information brochure, please click here:

<http://www.pharmsource.com/about/company-news/special-report-cell-culture-manufacturing-capacity-trends-outlook-through-2013/>

PharmSource ADVANTAGE: CONTRACTOR PROFILE

Contract Dose Manufacturing

Halo Latest Entry to Dose Manufacturing

Halo Pharmaceuticals (Whippany, N.J., USA) has acquired a manufacturing and research facility in Whippany, N.J., from **Abbott Laboratories**. The 200,000 sq. ft. facility has capabilities to manufacture sterile and non-sterile semi-solids and liquids as well as solid dosage forms and has laboratory space for formulation development services. The facility also includes an API manufacturing unit capable of handling DEA Schedule 2-5 controlled substances. Eighty Abbott employees transferred to Halo. In addition to manufacturing legacy products for Abbott, Halo inherited contracts for a number of other pharmaceutical companies.

Halo is privately owned and describes itself as a specialty pharmaceutical company. Its strategy is to operate as a contract manufacturer while building a portfolio of proprietary products through acquisition or in-licensing.

What it means

Acquiring redundant facilities from major pharmaceutical companies has been the most common route for new entrants into the contract manufacturing industry, but new owners are facing growing challenges. Acquired facilities generally have low utilization, and owners carry the burden of finding

Halo Pharmaceuticals

Headquarters: Whippany, NJ

Services:

- **Analytical Services**
 - ◆ **Analytical Chemistry and Stability**
 - ◆ **Microbiology**
- **Clinical Dose Manufacturing and Packaging**
 - ◆ **Clinical Packaging and Distribution**
- **Commercial Dose Manufacturing**
 - ◆ **Semi-Solid & Liquid Manufacturing**
 - ◆ **Solid Dose Manufacturing**
- **Commercial Packaging**
 - ◆ **Logistics and Shipping**
 - ◆ **Packaging Validation**
 - ◆ **Commercial Packaging**

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Briefing

new customers to improve utilization and replace legacy products as the initial contracts expire. Some of these new entrants have proven to be undercapitalized, as well. Prospective clients, especially the major pharmaceutical companies, are increasingly looking to consolidate their contract relationships into a smaller number of experienced and well-financed service providers, raising the barrier for these new entrants.

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.

Halo Pharmaceuticals

Mergers/Acquisitions News & Analysis

Corporate Profile:

Address: 30 N Jefferson Rd Petaluma,
Whippany, NJ 07981 USA

Voice: 973-428-4087

Fax: 973-428-4017

Website: www.halopharma.com

E-mail: info@halopharma.com

Ownership: Private: management owned

Primary Business: Contract Services

Contract Business:

Business head: Douglas K. Kollmorgen

Title: President

Annual revenues: \$25-49 million

Number of employees: 51-100

Corporate Head contact: Douglas K. Kollmorgen

Voice: 973-428-4011

E-mail: dkollmorgen@halopharma.com

North American contact: Allen M. Rosenston

Voice: 973-428-4087

E-mail: arosenston@halopharma.com

Trade shows: AAPS Annual Meeting, Interphex

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Contract Services:

Analytical Services

Analytical Chemistry and Stability
 Microbiology

Clinical Dose Manufacturing and Packaging

Clinical Packaging and Distribution

Commercial Dose manufacturing

Semi-solid & liquid manufacturing
 Solid dose manufacturing

Commercial Packaging

Logistics and shipping
 Packaging validation
 Commercial packaging

Halo Pharmaceuticals

30 N Jefferson Rd.
 Whippany, NJ 07981 USA
 Phone: 973-428-4087 Fax: 973-428-4017
 services@halopharma.com

Size: 230,000 sq. ft.

Specifications for "Solid dose manufacturing"

Dosage Forms

Effervescent tablets/powders: No
Gelcaps: No
Granules: Yes
Hard capsules: Yes
Liquid-filled hard capsules: No
Pellets/beads: No
Powders: Yes
Tablets: Yes

Project Acceptance Criteria

Antibiotics

Cephalosporin: No
Penicillin: No

Controlled substances

DEA schedule II: Yes
DEA schedule III, IV, V: Yes

High potency and cytotoxic

Cytotoxic materials: No
Hormones/steroids: No

Other materials

Veterinary products: Case by case
Vitamins & nutritionals: Case by case

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Briefing**Processing Capabilities*****Production scale***

Clinical (< 200 kg batch size): Yes

Large commercial (>1000 kg batch size): Yes

Maximum batch size: 1300 kg

Small commercial (200-1000 kg batch size): Yes

Particle formation and sizing

Micronization: No

Spray drying: No

Granulation

Extrusion: No

Fluid bed: Yes

Fluid bed equipment: Glatt

High shear: Yes

High shear granulation equipment: Lodige

Hot melt extrusion: No

Non-aqueous solvents: Yes

Roller compaction: No

Spheronization: No

Drying

Fluid bed drying: Yes

Microwave drying: No

Tray drying: Yes

Particle coating

Microencapsulation: No

Wurster column fluid bed coating: No

Coating capabilities

Coating equipment: Thomas

Film: Yes

Non-aqueous: No

Sugar: No

Sustained Release: No

Other processing capabilities

Capsule banding: No

Explosion-proof: Yes

Low humidity (<25%): No

High Containment Capabilities***Cytotoxics***

Dedicated cytotoxic blend/fill/tablet/encap: Yes

Dedicated cytotoxic processing suite(s): Yes

High potency (not cytotoxic)

Dedicated high potency blend/fill/tablet/encap: Yes

Dedicated high potency suite(s): No

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Briefing

Cephalosporins	No
Dedicated cephalosporin blend/fill/tablet/encap:	No
Penicillins	No
Dedicated penicillin blend/fill/tablet/encap:	No
Dedicated penicillin suite(s):	No

Packaging Capabilities

Blisters:	Yes
Bottles:	Yes
Custom packaging:	Yes
Pellet-filling:	No
Powder filling:	Yes
Sachet:	No

Regulatory Approvals and Certifications

USA - FDA:	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. 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.

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