

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

February 2010

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Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the February 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 analyze the acquisition of **Marken** by Apax Partners. In addition, we examine the merger and acquisition (M&A) trends occurring in the contract biomanufacturing market. We also profile **OctoPlus** and discuss the company's intention to shift its primary focus from proprietary product development to drug delivery services. And don't miss the information on our latest report, *The Market for Analytical Testing and Development Services* on page 3.

Enjoy the issue!

Feature Story

Marken Acquired by Apax Partners

Marken (London, UK), a provider of clinical supply logistics services, agreed to be acquired by Apax Partners, a private equity investment group. Financial details of the deal, which is expected to be completed by early 2010, were not disclosed; however, unconfirmed reports indicate that Apax will pay a total of USD 1.6 billion to acquire the company from Intermediate Capital Group. The private equity firm is currently raising USD 513 million of financing for the acquisition, according to press reports. Marken had revenues of GBP 70 million (USD 105 million) in 2008, with profits of GBP 29 million (USD 44 million), and revenues may have grown to GBP 90 million (USD 135 million) in 2009.

Marken provides a range of clinical trial logistics and support services to the biopharma industry, including the exportation of trial medication, vaccines and clinical trial material; cold-chain management; protocol and regulatory support; investigator liaison; and transportation of biological samples.

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Briefing

The company specializes in moving pharmaceutical products such as vaccines, trial kits and investigation drugs between clinical trials, research companies and biotechnology laboratories by using temperature-controlled containers. Its principal competitors include World Courier.

What it means

If the rumored purchase price of USD 1.6 billion is accurate, Apax is paying an enormous multiple for Marken, perhaps as high as 25x EBITDA. Clearly, the buyers are counting on Marken to maintain a very high growth rate (revenues were up 35% in 2008 over 2007) as clinical trials become more global. Still, the amount of debt that will be loaded on the company could prove to be a burden if its growth hits any bumps in the road. Apax may even pump more cash into the company, as it announced its intention to finance Marken's expansion into emerging markets.

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				
Ash Stevens	Millennium Pharmaceuticals	FDA approval of sNDA	Velcade	Small-molecule API manufacturing
Bausch & Lomb Contract Manufact.	ISTA Pharmaceuticals	sNDA filed	Xibrom (XiDay)	Sterile liquid manufacturing
Diosynth	Biodel	NDA filed	VIAject	Insulin manufacturing
Hospira One 2 One	Cumberland Pharmaceuticals	Out-licensed product for South Korean market	Caldolor	Injectables manufacturing
Lonza	Elusys Therapeutics	HHS development contract	Anthim	Biomanufacturing
Norwich Pharmaceuticals	Santarus	FDA approval	Zegerid tablet	Solid-dose manufacturing
Patheon	Kowa Pharmaceuticals	Co-promotion agreement in the US	Livalo	Solid-dose manufacturing
Potentially Negative Side Effects				
3M Drug Delivery Systems	Forest Laboratories	Product to be acquired by Acton Pharmaceuticals	Aerospan	Inhalation dose form manufacturing
Alliance Medical Products	Sirion Therapeutics	Product to be acquired by Alcon	Zirgan	Semi-solid manufacturing
Baxter Biopharma Solutions	Javelin Pharmaceuticals	To be acquired by Myriad Pharma	Dyloject	Injectables manufacturing
Ben Venue Labs.	Vion Pharmaceuticals	Filed for bankruptcy	Onrigin	Injectables manufacturing
Catalent Pharma Solutions	Sirion Therapeutics	Product to be acquired by Alcon	Durezol	Semi-solid & liquid manufacturing

Source: PharmSource Lead Sheet

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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 www.pharmsource.com/other/market-for-contract-analytical-and-development-services.

Business Conditions**Year-End Biomanufacturing M&A Spree**

The year 2009 ended with two acquisition deals involving contract biomanufacturing businesses. Do the deals represent a trend in the biomanufacturing market or was it just a coincidence that both deals were announced around the same time?

The most striking was Merck's announcement that it will buy the microbial fermentation business of **Avecia** (Manchester, UK) for an undisclosed amount. The deal will include Avecia Biologics' process development and scale-up, manufacturing, quality and business support operations located in Billingham, UK.

Merck plans to maintain the facility and its staff as well as honor all of Avecia's current contractual commitments. However, Merck's statement that it plans to discuss with customer their "ongoing and future biological process development and manufacturing requirements" suggests that they will not pursue additional contract work. According to the **PharmSource ADVANTAGE** contractor database, Avecia's commercial clients include Dyax, for which it makes Kalbitor.

Recipharm to Acquire Cobra

Also in December 2009, **Recipharm** (Haninge, Sweden) announced its intention to acquire **Cobra Biomanufacturing** (Staffordshire, UK). The acquisition will more than double Recipharm's biomanufacturing capacity and allow it to offer one-stop-shopping biologics capabilities.

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Briefing

Cobra Biomanufacturing has facilities in Oxford and Keele, UK, where it offers process development and small scale GMP manufacturing for both microbial fermentation and mammalian cell culture.

What is means

If the two acquisitions have anything in common, it is that they both represent rescues of companies that have struggled financially over the years. Both companies have consistently sustained operating losses in recent years, and the industry downturn in the past 2 years has been particularly painful.

Merck's acquisition of the Avecia biologics business looks to be primarily a case of preserving an important commercial supply source, but it also adds to Merck's growing biomanufacturing capabilities. In 2006, it acquired GlycoFi's manufacturing technologies for producing glycosylated proteins in yeast. In February 2009, it bought Insmed, acquiring its portfolio of biosimilar candidates and its 50,000 square feet of biologics process development analytical laboratory and commercial manufacturing facilities. Merck has created a business unit for biosimilars called Merck Bioventures.

For Recipharm, the Cobra acquisition is an opportunity to add another piece to its rapidly-expanding biomanufacturing capabilities. In January 2009, Recipharm Biotech, a subsidiary of Recipharm, entered a 12-year agreement with AstraZeneca to lease AstraZeneca's Swedish biomanufacturing facility, thereby adding mammalian recombinant protein and monoclonal antibody development and production capabilities to its biopharmaceutical services. In 2008, it acquired the clinical-scale injectables manufacturing assets and development capabilities of **Inotech** (Basel, Switzerland), which gave it lyophilization expertise.

As the accompanying table illustrates, acquisitions of small biologics manufacturing operations have been fairly common in recent years. Generally, it is a story of larger companies looking to acquire technology and entry-level manufacturing assets in expectation of greater opportunities ahead.

As the share of biologics in the pipeline continues to grow, we might expect more acquisitions to take place, although the most attractive candidates like **CMC Biologics** (Copenhagen, Denmark) and **Laureate Pharma** (Princeton, N.J., USA) aren't in need of rescuing like Avecia and Cobra.

Year	Acquirer	Target	Location	Technology
2009	Merck	Avecia	UK	Microbial
2009	Recipharm	Cobra Biomanufacturing	UK	Mammalian & microbial
2009	Recipharm	AstraZeneca facility	Sweden	Mammalian
2009	Group Novasep	Henogen	Belgium	Mammalian & microbial
2008	Wuxi PharmaTech	Apptec	US	Mammalian
2007	CMC	ICOS	US	Mammalian
2007	Gedeon Richter & Helm AG	Strathmann Biotec	Germany	Microbial
2007	SAFC	Molecular Medicine BioServices	US	Viral vaccines & vectors

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PharmSource ADVANTAGE: Contractor Profile

Clinical Dose Manufacturing and Packaging

OctoPlus to Focus on Contract Services, Raises Equity

OctoPlus (Leiden, Netherlands) announced an equity raising of EUR 4 million (USD 5.6 million) through a private placement of ordinary shares with investors. The company also received a new credit facility of up to EUR 2 million (USD 2.8 million) from the Fortis Bank Nederland. OctoPlus will use the funds to move out of proprietary product development and renew its focus on drug delivery services.

OctoPlus specializes in the development of long-acting, controlled-release versions of protein therapeutics, drugs and vaccines using its proprietary drug delivery technologies. The company also provides drug formulation and clinical scale manufacturing services. In July 2009, OctoPlus doubled its manufacturing capacity, by opening a new facility in Leiden, and expanded its service offerings to include the production of clinical scale and small-scale commercial supplies of injectable pharmaceutical products and other complex formulations.

OctoPlus

Headquarters: Leiden, The Netherlands

Services:

- **Clinical Dose Manufacturing and Packaging**
 - ◆ **Drug Delivery**
 - ◆ **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.

OctoPlus

Financials Mergers/Acquisitions News & Analysis Known Clients

Corporate Profile:

Address: Zernikedreef 12
 2333 CL Leiden, The Netherlands

Voice: +31 71 524 4044

Fax: +31 71 524 4043

Website: www.octoplus.nl

E-mail: octoplus@octoplus.nl

Ownership: Public company

Primary Business: Contract Services

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Contract Business:

Corporate Head: Gerben Moolhuizen
Title: Chief Business Officer
Contract revenues: \$0-24 million
Number of employees: 101-250
Corporate Head contact: Dr. Joost J.M. Holthuis
Voice: +31 71 524 4044
Fax: +31 71 524 4043
Business Head contact: Gerben Moolhuizen
Voice: +31 71 524 4044
Fax: +31 71 524 4043
North American contact: Michael Lodder
Voice: 617-225-2527
E-mail: lodder@octoplus-inc.com
Trade shows: AAPS Annual Meeting, BIO, CPhI Worldwide

Contract Services:

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

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2333 CL Leiden, The Netherlands
Phone: +31 71 524 4044 Fax: +31 71 524 4043
octoplus@octoplus.nl

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

Injectable dosage forms

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

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

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Briefing

	High potency - not specified:	No
	Hormones/steroids:	No
<i>Vaccines and viruses</i>	Vaccines-killed:	Yes
	Vaccines-live/attenuated:	No
	Vaccines-recombinant:	Yes
<i>Other materials</i>	Proteins & peptides:	Yes
	Radiopharmaceuticals:	No
Development capabilities		
	Formulation development (non-GMP):	Yes
	Lyophilization cycle development:	Yes
Vials and Ampules - Standard Potency - GMP		
<i>Production scale</i>	Clinical (10,000-50,000 unit batch size):	No
	Clinical batch size-vials:	up to 10,000
	Early clinical (<10,000 units, GMP):	Yes
	Hand fills (GMP):	Yes
	Number of compounding suites:	1
	Number of GMP clinical fill suites:	1
<i>Vial and ampule processing</i>	Aseptic fill:	Yes
	Inert atmospheres:	No
	Light sensitive:	No
	Lipid formulations:	Yes
	Oxygen sensitive:	No
	Terminal sterilization:	Yes
	Vacuum drying:	No
<i>Lyophilization</i>	Lyophilization capability:	Yes
	Lyophilization capacity:	2.5 sq. m, 5 sq. m
<i>Vial and ampule packaging</i>	Ampules - glass:	No
	Ampules-plastic:	No
	Vials:	Yes
	Vials - sizes and types:	USP type I: 3, 6, 10, 20, 50, 100
Prefilled Syringes/Cartridges-Standard Potency-GMP		
<i>PFS and cartridge packaging</i>	Cartridges:	No
	Pre-filled syringes:	No
Large Volume Parenterals - GMP		
<i>LVP packaging</i>	LVP bags:	No
	LVP glass bottles:	No

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Briefing**High containment capabilities****Cytotoxics**

Dedicated cytotoxic aseptic fill:	No
Dedicated cytotoxic lyophilization units:	No

Regulatory approvals and certifications

Canada - HPB:	No
Europe - EMEA or constituent countries:	Yes
ISO certification:	No
Japan - Koseisho:	No
Other agencies:	Dutch authorities
UK - MHRA:	No
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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