

## PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

September 2009

Welcome to the *PharmSource ADVANTAGE Briefing!*

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Welcome to the September 2009 issue of the *PharmSource ADVANTAGE Briefing*, a complimentary newsletter designed to provide actionable intelligence to bio/pharmaceutical and contract service professionals.

This month, we discuss Water Street Healthcare Partners (WSHP) acquisition of the pharmaceutical development division of **AAIPharma** and the impact that the deal may have on AAIPharma's survival in the economic downturn. In addition, we highlight some of the changes being made in India to improve the country's CRO industry. We also profile **Fisher Clinical Scientific** whose revenues were disclosed by its parent company, **ThermoFisher Scientific**. 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

## AAIPharma Sells Pharmaceutical Development Division to Private Equity Firm

**AAIPharma** (Wilmington, N.C., USA) sold its pharmaceutical development division to Water Street Healthcare Partners (WSHP), a private equity firm that focuses on the health care industry. The new company is named AAIPharma Services Corp., and the original headquarters have been retained in Wilmington, N.C., USA. L. Lee Karras, who has led the pharmaceutical development division over the past three years, has been named as the company's CEO.

AAIPharma Services will continue to provide analytical chemistry, formulation development, clinical packaging, oral drug delivery and contract manufacturing services. WSHP has committed as much as USD 75 million in equity financing to invest in additional and upgraded capabilities. WSHP has a number of investments in the health care industry, but this is its first investment in the pharmaceutical services sector.

The deal with WSHP does not include AAIPharma's early clinical and clinical development businesses, which continue to operate under the AAIPharma name for now.

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

**Briefing****What it means**

WSHP's acquisition of AAIPharma's pharmaceutical development service business comes at an interesting time. Once one of the largest CMC service providers, AAIPharma was sidetracked by its predecessor company's ill-fated diversion into proprietary products. Its resultant bankruptcy filing and subsequent ownership by a bond trader with no long-term interest in the business limited the company's ability to invest and participate in the venture-capital-fed boom of the past five years.

However, by being a latecomer to the game, WSHP has avoided the problems that face CDMOs acquired by private equity firms in mid-decade, especially the need to manage large debt loads and reduced cash flows in the face of sharply lower demand. AAIPharma has fresh capital it can invest while its competitors are hunkering down. This could prove to be a competitive advantage as the industry works its way through the current downturn and poorly capitalized competitors fight for survival.

**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
BioDelivery Sciences	FDA approval	Aveva Drug Delivery Systems	Onsolis	Transdermal dose form manufacturing
Epix Pharmaceuticals	Filed for bankruptcy	Aptuit	Multiple products	Drug product and API manufacturing and testing
Epix Pharmaceuticals	Filed for bankruptcy	Johnson Matthey Pharma Services	Multiple products	Small molecule API manufacturing
Epix Pharmaceuticals	Filed for bankruptcy	Thermo Fisher Scientific	Multiple products	Drug product manufacturing and testing
Medarex	To be acquired by Bristol-Myers Squibb	Lonza	Proteins and antibody-drug conjugates	Biomanufacturing
Oscient Pharmaceuticals	Product to be sold to Cornerstone Therapeutics	Patheon	Factive	Solid dose manufacturing
Oscient Pharmaceuticals	Product to be sold to Cornerstone Therapeutics	Anderson Packaging	Factive	Commercial packaging
United Therapeutics	FDA approval	Catalent Pharma Solutions	Tyvaso	Inhalation dose form manufacturing
Zogenix	FDA approval	Patheon	Sumavel DosePro	Injectables manufacturing
Zogenix	FDA approval	Dr. Reddy's Labs	Sumavel DosePro	Small molecule API manufacturing

Source: PharmSource Lead Sheet

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**Business Conditions****FDA Trains India Health Ministry to Conduct Site Audits**

The U.S. Food and Drug Agency (FDA) opened offices in New Delhi and Mumbai in January 2009 as part of its Beyond the Borders initiative, staffing the offices with 10 in-country officials. As one of its first initiatives, India's FDA staff gave workshops for Indian Ministry of Health officials, fulfilling its mission of helping the Indian government strengthen its regulatory institutions. The FDA has trained 24 Indian officials on how to conduct short-notice audits of clinical research sites, including how to audit internal processes and clinical trial data. These 24 officials will then train Indian state drug inspectors. India plans to conduct these audits in all regions of the country.

India's Central Drug Authority has submitted a new bill proposing these compulsory audits. The need for the short-notice audits arises out of growing concerns that some clinical trials in the country are not following required ethical guidelines or standard operating procedures. The Indian government conducted its first-ever audit of trial sites last fall after the death of an infant during Wyeth's clinical trial of a pediatric vaccine. (All but one of the sites has now been cleared to continue the trial.)

India has struggled for some time with controversies over alleged illegal and unethical clinical trials and trial practices. The proposed compulsory audit regulation is part of the country's effort to standardize and enforce appropriate oversight for clinical trials and CROs, something that will challenge cultural norms. Ashwini Kumar, drugs controller general of India, notes that the country "does not have a culture of policing doctors." However, with the clinical research market in India expected to reach USD 1 billion in 2010, the country is working quickly to bring itself up to appropriate international standards by pushing change where needed.

**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 merging competition from Asia.

More information on *The Market for Analytical Testing and Development Services* is available from Jim Miller at [jim.miller@pharmsource.com](mailto:jim.miller@pharmsource.com).

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**PharmSource ADVANTAGE: Contractor Profile**

*Clinical Dose Manufacturing and Packaging*

**ThermoFisher Unveils Fisher Clinical**

**ThermoFisher Scientific** (Waltham, Mass., USA) has revealed revenue figures for its pharmaceutical services businesses, **Fisher Clinical** and Lancaster Laboratories.

In its May presentation to Wall Street analysts, the company reported that its Biopharma Services unit had revenues of USD 700 million in 2008. “Logistics Services for Clinical Trials” accounted for 87% of the total, about USD 610 million, while the other USD 90 million was from “Analytical Services.” No profitability data were provided.

“Logistics Services for Clinical Trials” includes Fisher Clinical, the clinical packaging and logistic business, and Fisher Bioservices, which provides storage services for biological specimens, especially for US government agencies. Part of Fisher Clinical’s revenue comes from the Priority Solutions business, which Fisher Clinical acquired in 2007. Priority Solutions provides distribution and logistics services for distributing drugs and samples to physician offices. It had revenues of USD 95 million in 2006, the year before Fisher Clinical bought it.

Based on available data, we estimate Fisher Clinical’s clinical supplies packaging and distribution revenues at USD 400 – 450 million. It has multiple facilities in the US and Europe and has been in Singapore since 2001. In 2008, it opened facilities in China, India and Brazil.

<p><b>Fisher Clinical Services</b></p> <p><b>Headquarters: Allentown, PA, USA</b></p> <p><b>Services:</b></p> <ul style="list-style-type: none"> <li>• <b>Analytical Services</b> <ul style="list-style-type: none"> <li>◆ <b>Analytical Chemistry and Stability</b></li> </ul> </li> <li>• <b>Clinical Dose Manufacturing and Packaging</b> <ul style="list-style-type: none"> <li>◆ <b>Clinical Labels</b></li> <li>◆ <b>Clinical Packaging and Distribution</b></li> <li>◆ <b>Comparator Sourcing</b></li> </ul> </li> <li>• <b>Commercial Packaging</b> <ul style="list-style-type: none"> <li>◆ <b>Logistics and Shipping</b></li> <li>◆ <b>Commercial Packaging</b></li> </ul> </li> </ul>
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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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## Fisher Clinical Services, Inc.

Financials

Mergers/Acquisitions

News & Analysis

Known Clients

### Corporate Profile:

**Address:** 7554 Schantz Rd  
 Allentown, Pennsylvania 18106 USA

**Voice:** (610) 391-0800

**Fax:** (610) 391-0801

**Website:** [www.fisherclinicalservices.com](http://www.fisherclinicalservices.com)

**E-mail:** [fcsinfo@fishersci.com](mailto:fcsinfo@fishersci.com)

**Ownership:** Unit of public company

**Parent Company:** **Thermo Fisher Scientific Inc.**

**Subsidiaries:** **Acculogix LLC**

**Primary Business:** Contract Services

### Contract Business:

**Business Head:** Michael Ivers

**Title:** General Manager-North America

**Contract revenues:** \$250 - 499 million

**Number of employees:** 501-1000

**Business Head contact:** Michael Ivers  
**Voice:** 610-391-0800  
**E-mail:** [michael.ivers@fishersci.com](mailto:michael.ivers@fishersci.com)

**North American contact:** B. Jeff Hallquist  
**Voice:** 610-871-8399  
**Fax:** 610-871-8599  
**E-mail:** [jeff.hallquist@fishersci.com](mailto:jeff.hallquist@fishersci.com)

**European contact:** Steve Savage  
**Voice:** +44 (0) 1403 212 700  
**Fax:** +44 (0) 1403 212712  
**E-mail:** [stephen.savage@fishersci.com](mailto:stephen.savage@fishersci.com)

**Field Sales contact:** Frank DiStefano  
**Voice:** 610-871-8399  
**E-mail:** [frank.distefano@fishersci.com](mailto:frank.distefano@fishersci.com)

**Trade shows:** AAPS Annual Meeting, DIA, Interphex, ISPE

### Contract Services:

#### Analytical Services

Analytical chemistry and stability

#### Clinical Dose Manufacturing and Packaging

Clinical labels

Clinical packaging and distribution

Comparator sourcing

#### Commercial Dose manufacturing

Logistics and shipping

Commercial packaging

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**Briefing****Fisher Clinical Services, Inc.**

Allentown - Pennsylvania - USA Facility  
 7554 Schantz Rd  
 Allentown, PA 18106 USA  
 Phone: (610) 391-0800 Fax: (610) 391-0801  
 fcsinfo@fishersci.com

Size: 300,000 sq. ft.

**Specifications for "Clinical Packaging and Distribution"****Primary Packaging*****Special Materials***

**Cephalosporins:** Yes  
**Cytotoxic materials:** Yes  
**DEA schedule II:** Yes  
**DEA schedule III, IV, V:** Yes  
**High potency:** Yes  
**Penicillins:** Yes  
**Veterinary products:** Yes  
**Vitamins & nutritionals:** Yes

***Facilities***

**Dedicated air rooms:** Yes  
**Low humidity rooms (<25%):** Yes

***Solid dose***

**Blisters - cold-form:** Yes  
**Blisters - thermoform:** Yes  
**Bottle:** Yes  
**Powders-bottle:** Yes  
**Powders-sachet:** No

***Semi-solids and liquids***

**Bottle:** No  
**Sachet/pouch:** No  
**Tube:** No

**Secondary Packaging**

**Assembly:** Yes  
**Blister carding:** Yes  
**Package design:** Yes  
**Proprietary technologies:** Global distribution software; drug management services software

***Labelling***

**Labels - double-blind:** Yes  
**Labels - non-English:** Yes  
**Labels - open:** Yes

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**Briefing****Clinical supplies manufacturing**

Overencapsulation:	Yes
Placebo manufacture - capsule:	Yes
Placebo manufacture - tablet:	No

**Ancillary clinical supplies services**

Analytical testing:	No
Comparative agent procurement:	Yes
Distribution/fulfillment:	Yes
Packaging validation:	Yes
Returned drug destruction:	Sub-contracted
Returned drug reconciliation:	Yes
Stability storage:	No
Stability storage conditions:	Room temp, refrigerated

**Warehousing and storage**

Freezer storage:	Yes
Freezer storage temperature:	-10° to -20° C; -70°
Refrigerated storage:	Yes
Refrigerated storage temperature:	-20°-8° C

**Regulatory approvals and certifications**

Canada - HPB:	Yes
ISO certification:	Yes
Other agencies:	Germany & Sweden QP
UK - MHRA:	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](mailto: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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