

## PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

October 2009

### In This Issue:

#### Feature Story

Catalent Creates Development Group ..... 1

Side Effects ..... 2

#### Business Conditions

Q2 2009 Financial Review:  
Growth Slows for Asian  
Service Providers ..... 3

#### PharmSource Special Report:

The Market for Analytical  
Testing and Development  
Services ..... 4

#### Contractor Profile

The University of Iowa  
Pharmaceuticals ..... 4

#### PharmSource ADVANTAGE

Free Test-Drive Offer ..... 7

### Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the October 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 the creation of **Catalent's** development and clinical services unit. In addition, we highlight the revenue growth for contract service providers in Asia in Q2 2009. We also profile **The University of Iowa Pharmaceuticals** which recently installed new lyophilization cycle development equipment in its facility. And don't miss the information on our latest report, *The Market for Analytical Testing and Development Services* on page 4.

*Enjoy the issue!*

### Feature Story

## Catalent Creates Development Group

**Catalent Pharma Solutions** (Somerset, N.J., USA) has reorganized some of its operating units to focus on the clinical development market. The new unit, Catalent Development and Clinical Services, combines the clinical packaging operations from Catalent's packaging services group with the analytical chemistry, formulation and biomanufacturing units that have been part of its Sterile Technologies segment. Capabilities in the new group include early-phase manufacture of injectables, development and manufacture of respiratory delivery systems, and regulatory consulting and support. The new unit has 900 employees, implying revenues of USD 100 million-125 million.

Catalent appointed Scott Houlton to run the new development business. Houlton was formerly chief operating officer of **Aptuit** (Greenwich, Conn., USA), and before that he ran its clinical packaging operations.

#### *What it means*

The creation of a business unit focused on development services is a move Catalent should have made eight years ago when it bought Magellan Laboratories.

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# Briefing

It is recognition that development services are a distinct market, not just part of a clinical-to-commercial continuum. As part of their respective commercially oriented business segments, Catalent's development services were poorly promoted and lost the brand awareness that its predecessor companies had gained. It also fell behind the market leaders in some key capability areas.

Houlton will be challenged to fill some important gaps in Catalent's capabilities while building a stronger business development organization and renewed brand identity. Its size already makes the Development and Clinical Services unit one of the larger CDMOs in the industry, and operations in North America and Europe give it some global presence. The new unit can benefit when the market for development services finally starts turning around.

## 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
<b>Potentially Positive Side Effects</b>				
ISTA Pharmaceutical	FDA approval	Bausch & Lomb Contract Manufacturing	Bepreve	Sterile liquid manufacturing
Kowa Pharmaceuticals	FDA approval	Patheon	Livalo	Solid dose manufacturing
Salix Pharmaceuticals	FDA approval	Catalent Pharma Solutions	Metozolv ODT	Solid dose manufacturing
Shire	FDA approval	DSM Pharmaceuticals	Intuniv	Solid dose manufacturing
Theravance	FDA approval	Ben Venue Labs	Vibativ	Injectables manufacturing
<b>Potentially Negative Side Effects</b>				
Altus Pharmaceuticals	Trial terminated; company closing	Althea Technologies	ALTU-238	Injectables manufacturing
P&G Pharmaceuticals	To be acquired by Warner Chilcot	Norwich Pharmaceuticals	Actonel	Solid dose manufacturing
P&G Pharmaceuticals	To be acquired by Warner Chilcot	Norwich Pharmaceuticals	Didronel	Solid dose manufacturing
Peplin	To be acquired by Leo Pharma	DPT Laboratories	PEP005	Semi-solid and liquid manufacturing
SkinMedica	Product to be acquired by Bayer Healthcare	CPL	Desonate	Semi-solid and liquid manufacturing
SkinMedica	Product to be acquired by Bayer Healthcare	DPT Laboratories	NeoBenz Micro	Semi-solid and liquid manufacturing

Source: PharmSource Lead Sheet

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**Business Conditions**

**Q2 2009 Financial Review: Growth Slows for Asian Service Providers**

Revenue growth for contract service providers in Asia slowed in Q2 2009, coming in at just 10 percent for the 11 companies that report service revenues. Results varied widely among the companies, with four of the 11 reporting a loss of revenue. The Asian CROs and CMOs were hit by the same factors as their North American and European counterparts, namely inventory management by bio/pharma companies and a reduction in R&D spend.

Manufacturing revenues at **WuXi PharmaTech** were down 69 percent thanks to the loss of several large contracts from 2008 that did not recur in 2009. Still, total revenues at WuXi were down only 3 percent as solid growth in China and US-based laboratory services helped mitigate losses in manufacturing.

**Piramal Pharma Solutions**, the contract arm of Piramal Healthcare, experienced a 16 percent decline in total revenues thanks largely to a 23 percent drop in revenues from assets outside of India. Revenues from facilities in India, which normally counteract any losses abroad, were up only 2 percent. Lower demand due to clients managing inventory more closely along with the closing of a facility in the UK caused the drop in revenue. Revenues at Dishman Pharmaceuticals and Chemicals were down 8 percent. Local media reports indicate that poor performance at its Swiss subsidiary Carbogen Amcis was to blame.

**Jubilant Organosys** reported 12 percent growth in CRAMS revenues; new capacity at **HollisterStier** and the recognition of revenue from a multiyear contract with Johnson & Johnson at **Draxis Pharma** helped bolster CMO revenue 59 percent, while multiple new contracts drove up revenue 20 percent at Jubilant's Drug Discovery and Development Services unit. Biocon's contract service revenues increased due to the initiation of a contract with Bristol Myers-Squibb in Q1 2009. **Celltrion**, a South Korean biomanufacturer, registered a 207 percent growth in revenues, thanks in part to new capacity and a relatively small base. Growth at Celltrion is expected to drop significantly next year as the company shifts its focus from contract manufacturing to the development of biosimilars.

Q2 (ending June)	Contract Services		Total	
	Revenue (\$M)	Growth (%)	Revenue (\$M)	Growth (%)
<b>Jubilant Organosys</b>	109	12	188	8
<b>Dr. Reddy's</b>	103	7	381	21
<b>WuXi PharmaTech</b>	67	(3)	67	(3)
<b>Piramal Healthcare</b>	40	(16)	172	16
<b>Dishman Chemical</b>	35	(8)	48	(3)
<b>Celltrion</b>	33	207	33	207
<b>Hikal</b>	18	43	27	39
<b>Biocon</b>	14	56	66	14
<b>Torrent</b>	11	34	99	22
<b>Suven Life Sciences</b>	7	(2)	7	(2)
<b>Vimta Labs</b>	5	2	5	2
<b>Total</b>	442	10	1143	17

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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 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).

**PharmSource ADVANTAGE: Contractor Profile**

*Clinical Dose Manufacturing and Packaging in Brief*

**The University of Iowa Passes Pre-approval Inspection from FDA**

**The University of Iowa Pharmaceuticals** (UIP - Iowa City, Iowa, USA) passed a pre-approval inspection conducted by the FDA to evaluate the company’s facilities and procedures in order to start manufacturing of an aseptically filled sterile compound for a client.

In addition, the company recently installed new lyophilization cycle development equipment, including Lyotherm 2 and Lyostat 2, in its facility. The equipment was manufactured by Biopharma Technology Limited.

**The University of Iowa  
 Pharmaceuticals**

Headquarters: Iowa City, IA, USA

Services:

- **Analytical Services**
  - ◆ **Analytical Chemistry and Stability**
- **Clinical Dose Manufacturing and Packaging**
  - ◆ **Clinical Packaging and Distribution**
  - ◆ **Injectable Phase I/II CTM and Formulation**
  - ◆ **Solid, Semi-solid/Liquid Phase I/II CTM and Form**

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**Briefing**

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.

## The University of Iowa Pharmaceuticals

**News & Analysis**      **Known Clients**

### Corporate Profile:

**Address:** 115 S. Grand Avenue G-20  
Iowa City, IA 52242-1112 USA

**Voice:** 319-335-8674

**Fax:** 319-335-9418

**Website:** [www.pharmacy.uiowa.edu/uip/](http://www.pharmacy.uiowa.edu/uip/)

**E-mail:** [mickey-wells@uiowa.edu](mailto:mickey-wells@uiowa.edu)

**Ownership:** University

**Parent Company:** **University of Iowa**

**Primary Business:** Contract Services

### Contract Business:

**Business Head:** Mickey L. Wells, PhD

**Title:** Director, Div. of Pharmaceutical Svcs.

**Contract revenues:** \$25-49 million

**Number of employees:** 51-100

**Business Head contact:** Mickey L. Wells, PhD  
Voice: (319) 335-8674  
Fax: (319) 335-9418  
E-mail: [mickey-wells@uiowa.edu](mailto:mickey-wells@uiowa.edu)

**North American contact:** Randy R. Yeates  
Voice: (319) 335-8674  
Fax: (319) 335-9418  
E-mail: [randhall-yeates@uiowa.edu](mailto:randhall-yeates@uiowa.edu)

**Trade shows:** AAPS Annual Meeting

### Contract Services:

#### Analytical Services

Analytical chemistry and stability

#### Clinical Dose Manufacturing and Packaging

Clinical packaging and distribution

Injectable Phase I/II CTM and Formulation

Solid, Semi-solid/Liquid Phase I/II CTM and Formulation

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**The University of Iowa Pharmaceuticals**

Iowa City - IA - USA Facility  
 115 S. Grand Avenue G-20  
 Iowa City, IA 52242-1112 USA  
 Phone: 319-335-8674 Fax: 319-335-9418  
 mickey-wells@uiowa.edu

FDA Number: 1918751 Size: 24,000 sq. ft.

**Specifications for "Injectable Phase I/II CTM & Formulation"**

**Injectable dosage forms**

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

**Vaccines and viruses**

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

**Other materials**

Proteins & peptides: Yes  
 Radiopharmaceuticals: No

**Development capabilities**

Formulation development (non-GMP): Yes  
 Lyophilization cycle development: Yes  
 Package/closure testing: Yes  
 Preformulation studies: Yes

**Vials and Ampules - Standard Potency - GMP**

**Production scale**

Clinical (10,000-50,000 unit batch size): No  
 Clinical batch size-vials: 5,000 vials  
 Early clinical (<10,000 units, GMP): Yes  
 Number of GMP clinical fill suites: 2

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**Briefing****Vial and ampule processing**

<b>Inert atmospheres:</b>	Yes
<b>Terminal sterilization:</b>	Yes
<b>Terminal sterilization technologies:</b>	Autoclave
<b>Vacuum drying:</b>	Yes

**Lyophilization**

<b>Lyophilization capability:</b>	Yes
<b>Lyophilization capacity:</b>	48 sq. ft.

**Vial and ampule packaging**

<b>Ampules - glass:</b>	Yes
<b>Ampules-plastic:</b>	No
<b>Vials:</b>	Yes

**Prefilled Syringes/Cartridges-Standard Potency-GMP**

<b>Are PFS suites same as vial suites?:</b>	Yes
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**PFS and cartridge packaging**

<b>Cartridges:</b>	No
<b>Pre-filled syringes:</b>	Yes

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

<b>LVP bags:</b>	No
<b>LVP glass bottles:</b>	No

**Related services**

<b>Clinical packaging and labeling:</b>	No
<b>Stability testing and storage:</b>	Yes

**Regulatory approvals and certifications**

<b>USA - FDA:</b>	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](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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