

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

August 2009

Welcome to the *PharmSource ADVANTAGE Briefing!*

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Welcome to the August 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 **Kemwell's** expansion into the biologics market through a partnership with Boehringer Ingelheim. In addition, we analyze **FDA approvals** during the first half of 2009. We also profile **Azopharma** which recently completed an expansion of its cytotoxic facility. And don't miss the information on how to access our latest **white paper** on the **U.S. Foreign Corrupt Practices Act (FCPA)** on page 4.

Enjoy the issue!

Feature Story

Kemwell Partners with BI, Enters Biomanufacturing Market

Kemwell (Bangalore, India), a provider of contract development and manufacturing services, has unveiled plans to enter the biologics market in partnership with Boehringer Ingelheim (BI – Ingelheim, Germany). Kemwell will build a 15,000-square-meter biomanufacturing facility on its campus in Bangalore and will offer process development, cell culture capabilities, fermentation, purification and formulation of biologics for preclinical and clinical studies.

Kemwell plans to invest as much as USD 50 million in the new facility, which will house microbial fermentation of up to 1000 L and cell culture bioreactors up to 2000 L. In addition, the plant will include aseptic filling and lyophilization capacity, with the capability of handling fill volumes ranging from 2 mL to 20 mL, at up to 30,000 vials per batch.

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Briefing

Under the terms of the strategic collaboration, Kemwell clients will have access to BI's BI HEX expression technology. Clients will also have preferred access to BI's BI HEX expression technology. Clients will also have preferred access to BI's large-scale commercial production at its facilities in Europe. According to BI spokesperson Hans-Peter Grau, the alliance is part of BI's Production Alliance Network (PAN) Biologics, through which the company has established a network of relationships with smaller CMOs. "The partners are selected for their technology platforms compatible with our pilot plants and commercial manufacturing facilities in order to facilitate process transfers," said Grau.

Kemwell is a family-owned dedicated CMO. It has four facilities in Bangalore and one in Sweden that offer contract manufacturing services for the production of tablets, capsules, liquid orals, ointments, gels and creams. The company also provides development services including clinical manufacturing and packaging, formulation and analytical development.

What it means

The choice of Kemwell as a partner over larger, better-known Indian CMOs like Piramal Healthcare Pharma Solutions (Mumbai, India) and Dishman Pharmaceuticals & Chemicals (Ahmedabad, India) is notable.

In an interview with PharmSource, Anurag Bagaria, vice president of Kemwell, commented that Kemwell's strength lies in the fact that the company exclusively offers contract services instead of selling excess capacity. Patheon, who formed a strategic alliance with Kemwell in April, also emphasized Kemwell's status as a dedicated CMO. Bagaria also asserts that Kemwell is known for its adherence to global intellectual property norms, even before India signed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in 2005.

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
AMAG Pharmaceuticals	FDA Approval	Catalent Pharma Solutions	Feraheme	Commercial Packaging
Cumberland Pharmaceuticals	FDA Approval	Hospira One 2 One	Caldolor	Injectables Manufacturing
ImmunoGen Inc.	Development Terminated	Laureate Pharma	IMGN242	Process Development and Cell Culture
Kowa Pharmaceuticals	FDA Approval	Mipharm	Cambia	Solid Dose Manufacturing

Source: PharmSource Lead Sheet

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Business Conditions

NME Approvals Up, Total Approvals Down at FDA

The FDA's Center for Drug Evaluation and Research (CDER) approved 11 new molecular entities (NMEs) in the first half of 2009, up two from the nine approved during the first half of 2008 and three from the eight approved in the first half of 2007. The 11 NME approvals include three parenterals (all biologics), six tablets, one lotion and one ophthalmic solution. Novartis led the way with three of the NME approvals; no other company had more than one NME approval. Overall, CDER approved 36 new drug applications (NDAs) during the first six months of 2009, down from 42 approvals in the first half of 2008.

Prospects for approvals in the second half of 2009 look mildly promising. PharmSource estimates that there are more than 50 NDAs and BLAs with expected approval dates before the end of the year. We estimate that approximately half of those candidates awaiting approval will be manufactured by contract manufacturers.

NME Approvals through June 30, 2009

Company	Product	Generic Name	Approval Date	Indication
Forest Labs	Savella	Milnacipran HCl	Jan. 14	Fibromyalgia
Takeda	Uloric	Febuxostat	Feb. 13	Gout
Novartis Pharma	Afinitor	Everolimus	March 30	Oncology
Novartis Pharma	Coartem	Artemether/ Lumefantrine	April 7	Malaria
Sciele Pharma	Benzyl Alcohol	Benzyl Alcohol	April 9	Lice
Johnson & Johnson	Simponi	Golimumab	April 24	Autoimmune
Ipsen	Dysport	AbobotulinumtoxinA	April 30	Dermatology
Vanda Pharma	Fanapt	lloperidone	May 6	Schizophrenia
Otsuka	Samsca	Tolvaptan	May 19	Hyponatremia
Bausch & Lomb	Besivance	Besifloxacin	May 28	Ophthalmic
Novartis Pharma	Ilaris	Canakinumab	June 17	Cryopyrin-Associated Periodic Syndromes

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PharmSource White Paper

The U.S. Foreign Corrupt Practices Act (FCPA): How to Minimize Your Risk

We are pleased to announce the publication of our latest white paper entitled **The U.S. Foreign Corrupt Practices Act (FCPA): How to Minimize Your Risk**. This incisive resource provides guidelines on how to establish a strong FCPA compliance program that minimizes corruption risk for companies doing business throughout the world.

The U.S. is increasing the number of investigations of FCPA and financial fraud violations, particularly within the pharmaceutical sector. This has been reflected by an increase in enforcement budgets and the employment of additional personnel to improve the frequency with which investigations are conducted. Readers will find this timely publication to be a critical first step in understanding FCPA practices especially while conducting business in emerging markets.

“[After all], it is far easier to start a compliance program before commencing work overseas than it is to implement one retroactively, but it is also far more cost-effective to implement and run a compliance program than it is to be involved in any kind of FCPA investigation, which not only is costly but can have devastating effects on a company’s reputation and business.”

Leslie McCarthy
Director of Corporate Development, The STEELE Foundation

The U.S. Foreign Corrupt Practices Act (FCPA): How to Minimize Your Risk includes information on:

- Industry-specific implications of current FCPA regulations.
- Essential elements of a strong FCPA compliance program for those in the bio/pharma industry.
- Comprehensive steps to implement a solid FCPA compliance program.
- Enforcement of anti-corruption business practices in emerging markets.
- Mechanisms to avoid compliance pitfalls despite global and economic challenges.

To learn more, please go to www.pharmsource.com/white-paper.

PharmSource **ADVANTAGE**: Contractor Profile

Clinical Dose Manufacturing and Packaging

Azopharma Completes Expansion of Facilities

Azopharma Product Development Group (Hollywood, Fla., USA) completed the expansion of its cGMP cytotoxic and high-potent compound facilities with the addition of an extra 7,000 square feet of space that includes three manufacturing suites with dedicated equipment, analytical instrumentation and staff.

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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.

Azopharma Product Development Group

Headquarters: Hollywood, Fla., USA

Services:

- **Analytical Services**
 - ◆ **Analytical Chemistry and Stability**
 - ◆ **Bioanalytical Testing**
- **Clinical Dose Manufacturing and Packaging**
 - ◆ **Drug Delivery**
 - ◆ **Injectable Phase I/II CTM and Formulation**
 - ◆ **Solid, Semi-solid/Liquid Phase I/II CTM and Form**
- **Commercial Dose Manufacturing**
 - ◆ **Inhalation Dose Form Manufacturing**

Azopharma Product Development Group

Mergers/Acquisitions News & Analysis

Corporate Profile:

Address: Two Oakwood Blvd., Suite 110
Hollywood, FL 33020 USA

Voice: 954-433-7480

Fax: 954-432-9015

Website: www.azopharma.com

E-mail: pmeeks@azopharma.com

Ownership: Private: private equity or venture capital

Subsidiaries: **Cyanta Analytical Laboratories, IQsynthesis, ADMEquant Bioanalytical Services, AvivoClin Clinical Services, AniClin Preclinical Services**

Primary Business: Contract Services

Contract Business:

Business Head: Phil Meeks

Title: Chief Executive Officer

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Contract revenues: \$25-49 million
Number of employees: 251-500
Business Head contact: Phil Meeks
Voice: 954-433-7480
E-mail: pmeeks@azopharma.com
North American contact: Tina Shannon
Voice: (954) 241-4170
E-mail: tshannon@azopharma.com
European contact: Dr. Colin Crowley
Voice: 44-173-33-58791
E-mail: ccrowley@azopdogroup.com
Trade shows: AAPS Annual Meeting, BIO, Interphex

Contract Services:

Analytical Services

Analytical chemistry and stability
 Bioanalytical testing

Clinical Dose Manufacturing and Packaging

Drug delivery
 Injectable Phase I/II CTM and Formulation
 Solid, Semi-solid/Liquid Phase I/II CTM and Form

Commercial Dose manufacturing

Inhalation dose form manufacturing

Azopharma Product Development Group

Hollywood - FL - USA Facility
 Two Oakwood Blvd., Suite 110
 Hollywood, FL 33020 USA

Phone: 954-433-7480 Fax: 954-432-9015

Size: 18,000 sq. ft.

Specifications for "Analytical chemistry and stability"

Services

Chemistry

Cleaning validation: Yes
Dosage forms: Yes
Environmental testing: No
Lot release testing: Yes
Methods development: Yes
Packaging materials: Yes
Preformulation studies: Yes
Process water: Yes
Qualified Person (EU countries): Yes
Raw materials: Yes

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Raw materials: Yes
 Stability storage: Yes
 Stability studies: Yes

Project acceptance criteria

Antibiotics

Cephalosporin: Yes
 Penicillin: Yes

Controlled substances

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

High potency and cytotoxic

Cytotoxic materials: Yes

Compliance

GLP: Yes
 GMP: Yes

High potency and cytotoxic

Hormones/steroids: Yes

Vaccines and viruses

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

Dosage form experience

Aerosols: Yes
 Metered-dose inhalers: Yes

Other materials

Radiopharmaceuticals: No

Dosage form experience

Semi-solids and liquids: Yes
 Solid dose - extended release: Yes
 Solid dose - immediate release: Yes
 Sterile liquids & parenterals: Yes
 Transdermals: Yes

Other materials

Vitamins & nutritionals: Yes

Compendial experience

American Chemical Society (ACS): Yes
 British Pharmacopoeia (BP): Yes
 European Pharmacopoeia (EP): Yes
 Food-Chemical Codex (FCC): Yes
 Japan Pharmacopoeia (JP): Yes
 US Pharmacopoeia (USP): Yes

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Briefing**Stability storage**

Automated monitoring/mapping: Yes

Out-of-limits warning system: Yes

ICH conditions

-20° C freezer: Yes

-70° C freezer: Yes

2-8° C refrigeration: Yes

25° C/ 60% RH: Yes

30° C/ 60% RH: Yes

40° C/ 75% RH: Yes

Light chamber: Yes

Light chamber conditions: ICH Option 1 & 2

Chemical testing

Atomic absorption spectrophotometry: Yes

Differential Scanning Calorimeter (DSC): Yes

Dissolution: Yes

Elemental analysis-CHN: Yes

FT-IR: Yes

Karl Fischer-Coulometric: Yes

Karl Fischer-Volumetric: Yes

Thermal Gravimetric Analyzer (TGA): Yes

Total Organic Carbon (TOC): Yes

UV-VIS spectroscopy: Yes

Mass spectrometry

Desorption chemical ionization/MS: Yes

Fast Atom Bombardment: Yes

GC/MS-Chemical ionization: Yes

GC/MS-Dynamic head space: Yes

GC/MS-Electron ionization: Yes

ICP: Yes

LC/MS-APCI: Yes

LC/MS-Electrospray: Yes

LC/MS/MS: Yes

Liquid secondary Ion (LSIMS): Yes

Chromatography

Capillary electrophoresis: Yes

Chiral HPLC: Yes

GC: Yes

GC Head space: Yes

HPLC - gradient: Yes

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HPLC - isocratic: Yes
 Ion: Yes
 Size exclusion (SEC or GPC): Yes
 Thin layer (TLC): Yes

Structural chemistry

NMR: No
 X-ray diffraction: No
 X-ray fluorescence: No

Staffing

Fulltime QA staff: 4
 Staff in development group: 11
 Staff with MS/PhD degrees: 5
 Total staff: 21

Regulatory Approvals and Certifications

Canada - HPB: Yes
 Europe - EMEA or constituent countries: Yes
 ISO certification: 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. 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.