

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

December 2009

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Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the December 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 **Asymchem Laboratories'** new dedicated high potency API (HPAPI) facility in Tianjin, China and its comprehensive suite of HPAPI services. In addition, we analyze the Q3 revenue results for publically traded CROs and CMOs. We also profile **Penn Pharmaceutical 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

Asymchem Laboratories Opens Dedicated HPAPI Facility in China

Asymchem Laboratories (Morrisville, N.C., USA) recently opened a dedicated high potency API (HPAPI) facility at its site in Tianjin, China, enabling the contract manufacturer to provide its customers with a full range of HPAPI services, from API synthesis to packaging of final drug products, in one facility. "One of the things we have tried to do at Asymchem over the last several years is broaden our appeal by offering more services and one-stop shopping to those in the biotech industry," remarked David Houser, associate director of business development at Asymchem, in an interview with PharmSource. "A large portion of emphasis in the industry is on cancer and HIV treatments, both of which often consist of high potency intermediates. So this facility is designed to meet this need."

Established in 1995, Asymchem offers chemical synthesis, R&D and kilo labs, as well as pilot and bulk production of APIs and raw materials. Dr. Hao Hong, CEO of Asymchem, commented that the new HPAPI facility complements Asymchem's existing cGMP pilot plant, also located in Tianjin.

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Briefing

The company currently maintains five facilities throughout China and has two additional facilities planned.

“The core attractiveness of our HPAPI facility is that we are able to produce high potency materials from the 1 gram up to the 10 kilogram scale,” said Houser. The new facility, which provides containment for production of HPAPIs at an occupational exposure level of <math><0.1 \text{ mg/m}^3/8 \text{ hrs}</math>, offers two API manufacturing suites of 50 and 100 L with four independent breathing air lines per suite. In addition, the facility contains drug product manufacturing and packaging suites as well as analytical equipment for potent compounds. The company is able to develop and validate assays for potent compounds in both API and drug product configurations.

Asymchem’s HPAPI facility was designed to ensure worker safety and scientific standards. “The company has taken every precaution to minimize the risk of working with these potentially dangerous compounds,” Houser assured us. The facility includes a specially developed program to eliminate contamination vectors, primary decontamination stations in each API suite, and equipment for qualification and processing. Furthermore, Asymchem boosts rigorous worker training and facilities performance monitoring and cleaning.

The new HPAPI facility also includes space to expand. Houser commented that depending on how well the business venture goes, the company could go forward with expansion plans in a few years. In fact, Asymchem has room to add small-scale research and production of oral dosage form manufacturing for potent ingredients.

Houser concluded that “Asymchem is unique in offering HPAPI services as an emerging market company.” The company hopes that the opening of this facility will allow it to establish itself in the high potency marketplace and gain a jump start on the competition in 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.

Pharma Company	Event	Contractor	Product	Relationship
Potentially Positive Side Effects				
Genmab	FDA approval	Lonza	Arzerra	Biomanufacturing
Gloucester Pharmaceuticals	FDA approval	Ben Venue Labs	Istodax	Injectables manufacturing
InterMune	NDA filed	ACIC Fine Chemicals	pirfenidone	Small molecule API manufacturing
InterMune	NDA filed	Catalent Pharma Solutions	pirfenidone	Solid-dose manufacturing
Regeneron	EMA approval	Brecon Pharmaceuticals	Arcalyst	Commercial packaging

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

Another Tough Quarter for Contract Services

Revenues at publicly traded CROs and CMOs fell in Q3 2009 relative to the same period last year, continuing a year-long trend. Merger activity and funding issues lengthened sales cycles and slowed decision-making on new projects, and there was a spike in outright cancellations.

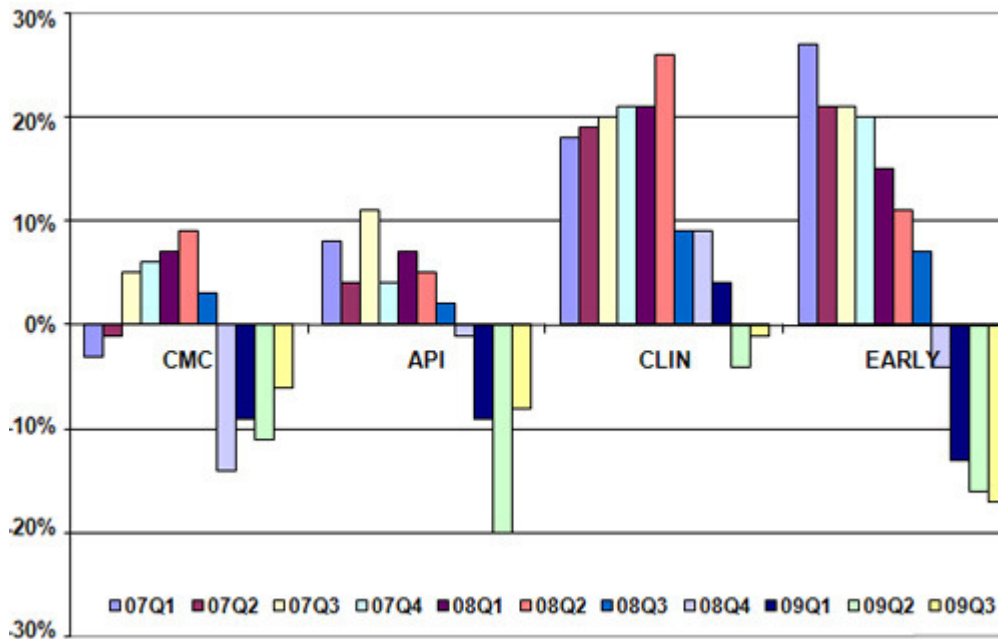
The quarter's most striking announcement came from Lonza. On their quarterly update call (Lonza only reports numbers on a half-yearly basis but provides quarterly business updates), management cut 2009 guidance by 14% and announced cost cutting initiatives that includes significant job cuts. Lonza, the leader in both chemical and biologic API development and manufacturing, cited unprecedented delays and cancellations at the end of the third quarter as new approvals were delayed and major pharmaceutical companies reduced inventories of commercial products. Most commercial manufacturers have had similar experiences this year. Lonza management expects order volatility to characterize their commercial business for several years.

A worrisome indicator was the decline in new business signings at the clinical CROs. Most of them had book-to-bill ratios (net new contracts signed divided by booked revenue) below 1.0, meaning their backlog declined in the quarter. The ratio has declined for three straight quarters, and a continued soft market will be felt throughout the industry, including manufacturers and packagers of clinical trial materials. Continued softness in early development services is also worrisome, as it suggests less activity in later phases in 1-2 years.

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Briefing

Positive news was scarce. Public company CEOs and exhibitors at the recent AAPS meeting talked of improved RFP flow in recent weeks, but not much has turned into new business as of yet. Even an expected windfall for injectables CMOs has been slow to materialize because of delays in producing the H1N1 flu vaccine.



PharmSource ADVANTAGE: Contractor Profile

Clinical Dose Manufacturing and Packaging in Brief

Penn Pharma Completes First Phase of Expansion

Penn Pharmaceutical Services (Gwent, UK) completed the first phase of its GBP 12 million (USD 17.6 million) expansion project at its facility in the UK. Phase I of the project included a 2,400-square-meter addition and the reorganization of the company’s transport and delivery infrastructure. Penn also purchased and installed a new GBP 350,000 (USD 587,000) inventory management system at the facility, which enables clients to track products and inventory remotely.

Penn Pharmaceutical Services

Headquarters: Gwent, U.K.

Services:

- **Analytical Services**
 - ◆ Analytical Chemistry and Stability
 - ◆ Microbiology
- **API—Small Molecule Manufacturing**
 - ◆ Process Development
- **Clinical Dose Manufacturing and Packaging**
 - ◆ Clinical Packaging and Distribution
 - ◆ Solid, Semi-solid/Liquid Phase I/II CTM
- **Commercial Dose Manufacturing**
 - ◆ Semi-solid & liquid manufacturing
 - ◆ Solid dose manufacturing
- **Commercial Packaging**

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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.

Penn Pharmaceutical Services Ltd.

[Mergers/Acquisitions](#)
[News & Analysis](#)
[Known Clients](#)

Corporate Profile:

Address: Tafarnaubach Industrial Estate, Tredegar
Gwent, NP22 3AA UK

Voice: +44 1495 713607

Fax: +44 1495 711225

Website: www.pennpharm.co.uk

E-mail: penn@pennpharm.co.uk

Ownership: Private: private equity or venture capital

Parent Company: Lloyds Development Capital with management

Primary Business: Contract Services

Contract Business:

Corporate Head contact: Craig Rennie

Business Head contact: Peter George
E-mail: Peter.George@pennpharm.com

North American contact: Britton Jimenez
Voice: 925-945-8118
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Trade shows: AAPS Annual Meeting, CPhI Worldwide, DIA

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Contract Services:

- Analytical Services**
 - Analytical chemistry and stability
 - Microbiology
- API - Small Molecule**
 - Process development-small molecule
- Clinical Dose Manufacturing and Packaging**
 - Clinical Packaging and Distribution
 - Solid, Semi-solid/Liquid Phase I/II CTM and Formulation
- Commercial Dose Manufacturing**
 - Semi-solid & liquid manufacturing
 - Solid dose manufacturing
- Commercial Packaging**
 - Commercial packaging
- Consulting Services**
 - Regulatory, Validation and QA Services

Penn Pharmaceutical Services Ltd.
 Gwent - - UK Facility
 Tafarnaubach Industrial Estate, Tredegar
 Gwent, NP22 3AA UK
 Phone: +44 1495 713607 Fax: +44 1495 711225
 penn@pennpharm.co.uk
 Size: 800 sq. m.

Specifications for "Semi-solid & liquid manufacturing"

Semi-solid and liquid dosage forms

<i>Liquids</i>	Emulsions:	No
	Lozenges:	Yes
	Solutions:	Yes
	Suspensions:	Yes
<i>Semi-solids</i>	Creams:	Yes
	Gels:	Yes
	Gum:	No
	Lotions:	Yes
	Ointments - non-sterile:	Yes
	Ointments-sterile:	No
	Suppositories:	Yes

Project acceptance criteria

<i>Antibiotics</i>	Cephalosporin:	No
	Penicillin:	No
<i>Controlled substances</i>	DEA schedule II:	Yes
	DEA schedule III, IV, V:	Yes

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Briefing**High potency and cytotoxic**

High potency - not specified: Yes

Hormones/steroids: No

Other materials

Non-pharmaceutical products: Yes

Proteins & peptides: No

Veterinary products: Yes

Vitamins & nutritionals: Yes

Processing Capabilities

Counter-rotation: No

Heated fill: Yes

High-shear agitation: Yes

Jacketed vessels: Yes

Pressurized vessels: Yes

Vacuum vessels: Yes

Production scale

Clinical: Yes

Commercial: Yes

Maximum batch size: 1000 L liquid, 200 L semi-solid

Granulation

Non-aqueous solvents: Yes

Other processing capabilities

Explosion-proof: Yes

Sterile: No

High containment capabilities**Cytotoxics**

Dedicated cytotoxic blend/fill/tablet/encap: No

Dedicated cytotoxic suite(s): No

High potency (not cytotoxic)

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

Dedicated high potency suite(s): Yes

Cephalosporins

Dedicated cephalosporin blend/fill/tablet/encap: No

Dedicated cephalosporin suite(s): No

Penicillins

Dedicated penicillin blend/fill/tablet/encap: No

Dedicated penicillin suite(s): No

Packaging Capabilities

Blow-fill-seal presentations: No

Bottles/jars: Yes

Bottles/jars - types/sizes: 1 ml to 25 l

Custom packaging: Yes

Pre-filled applicators: Yes

Suppositories: Yes

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Briefing**Tubes:** Yes**Tubes - types/sizes:** 1 g to 50 g**Regulatory approvals and certifications****Canada - HPB:** No**Europe - EMEA or constituent countries:** No**Japan - Koseisho:** No**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.

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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