

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

July 2010

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Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the July 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 the intelligence packed into our flagship newsletters, *Bio/Pharmaceutical Outsourcing Report* and *Emerging Markets Outsourcing Report*, along with a company profile developed from our comprehensive **PharmSource ADVANTAGE** contractor database.

This month, we discuss **AMRI's** acquisition of injectables CMO **Hyaluron Contract Manufacturing**. In addition, we highlight the details of a new biotech tax credit outlined in the healthcare reform bill. We also profile **Kemwell**, which recently opened its second pharmaceutical manufacturing center in Sweden. And don't miss the information on our latest report, *The Market for Analytical Testing and Development Services* on page 2.

Enjoy the issue!

Feature Story

AMRI Buys Hyaluron

AMRI (Albany, N.Y., USA), formerly known as Albany Molecular Research, has acquired injectables CMO **Hyaluron Contract Manufacturing** (Burlington, Mass., USA). Total deal value was USD 27 million, including assumption of debt. Hyaluron had revenues of USD 13 million in 2009 and expects revenues of USD 15 million to 17 million in 2010, according to AMRI.

Hyaluron provides clinical and small-scale commercial manufacturing services for injectable drugs. It has two filling lines for prefilled syringes, with a theoretical capacity of 150,000 units per day. It also has a 36-square-foot lyophilization unit for clinical batches.

Diversification strategy

AMRI has been engaged in an effort to broaden and diversify its portfolio of revenue- and profit-generating activities, including the expansion of its contract services offerings and development of a proprietary products portfolio. The strategy has two major drivers:

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Briefing

- AMRI has been heavily dependent on the royalties it earns on a process patent for manufacture of fexofenadine, the active ingredient in the allergy drug Allegra. Those royalties accounted for 20% of revenues during the 2005-2009 period and all of the company's operating income. In fact, AMRI reported USD 164 million in royalties during the period but only USD 61 million in operating income, meaning that its contract services businesses lost money over that time.
- A major part of the profitability problem has been AMRI's large-scale manufacturing business, which manufactures APIs at commercial scale. Revenues for that business have been flat for the past five years, and its cumulative gross margin over the period has been just 3%. The discovery and development services business has performed better, with a gross margin of 22%, but even that is not sufficient to cover selling and administrative expenses.

The strategy to make the business model more self-sustaining and robust has had multiple arms:

- A portfolio of proprietary new drug candidates that can be developed internally or partnered.
- A product line of niche generic APIs, especially highly-potent APIs.
- A global network of sites offering discovery and process chemistry and manufacturing, with an emphasis on locations in emerging markets, including India, Singapore and Hungary, as well as US and European sites.
- An expanded service offering with formulation development and manufacturing capabilities added to its legacy chemistry capabilities.

AMRI is very focused on international expansion. Earlier this year it announced plans to reduce the size of its US labor force by 10% (80 staff), including the closure of a development lab near Albany, while simultaneously announcing plans to add 180 workers and complete USD 30 million in investments in its non-US operations.

Subscribers to PharmSource ADVANTAGE received our enhanced analysis of AMRI's acquisition of Hyaluron, including the challenges AMRI faces as it attempts to establish a "one-stop shop" offering as well as the future implications for bio/pharma companies and other CDMOs.

To read the full version of this article, sign-up for a free trial:

www.pharmsource.com/productsservices/pharmsource-advantage/request-pharmsource-advantage-test-drive.

PharmSource Special Report

New Study Sizes the Analytical Testing Market

PharmSource's latest report, *The Market for Analytical Testing and Development Services*, 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.

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Briefing

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/productservices/special-reports/.

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
<i>Potentially Positive Side Effects</i>				
Boehringer Ingelheim Biopharmaceuticals	Amgen	EMA and FDA approval	Prolia	Biomanufacturing
Catalent Pharma Solutions	GSK	FDA approval	Jalyn	Solid dose manufacturing
Rottendorf Pharma	GSK	FDA approval	Jalyn	Solid dose manufacturing

Source: The PharmSource Lead Sheet.

For more information, go to www.pharmsource.com/productservices/ps-leadsheet.

Business Conditions

Tax Credit Provides Unique Opportunity for CROs and CMOs

Due to a provision in the health care reform bill recently signed by President Barack Obama, many biotech firms may benefit from an infusion of cash from the federal government over the next several months. Section 6023 of the bill was designed to provide funding for qualifying therapeutic discovery projects in order to counterbalance the downturn in investments being made in biotech research. The provision includes tax credits for biotech firms equal to 50% of their expenses for discovery research during tax years 2009 and 2010 or tax-free grants for the same amount. This would enable these companies to either cut their tax bills in half or receive a nontaxable lump sum of money.

“The purpose of this legislation was to provide an opportunity for smaller, research-oriented life sciences companies to receive federal funding for their products. And it is fairly generous, since the

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Briefing

companies can actually receive a tax grant or credit at up to 50% of their qualifying costs incurred during 2009 and 2010,” explained David Green, US Leader, Life Sciences Industry Practice for Deloitte Tax, LLP.

“The bad news is that there is only USD 1 billion available and there is a tight window to apply. Formal applications will be available on June 21, 2010, and companies will have until July 21, 2010, to submit their completed applications. Note, this is a very hard deadline and there will be no extensions. However, the good news is that the companies selected should receive checks as soon as Halloween. The announcement timetable is October 29, 2010, and checks will go out immediately thereafter,” continued Green.

The statute specifies that the funds must be used for expenditures related to therapeutic development activities and cannot be used for facility maintenance, administrative expenses or interest payments. In addition, funds will be distributed only to qualifying small or midsize companies – specifically those with 250 or fewer employees, and this includes any related party with more than 50% common ownership.

Who’s Eligible?

Eligible companies can run the gauntlet of biomedical research; however, there are specific criteria that must be satisfied. “In order for companies to take advantage of this grant, there are two tiers of criteria that must be met. The first set of criteria determines whether a company qualifies for the grant, and they are fairly broad. Companies must be engaged in research and their therapeutic discovery has to qualify based on one of four types of research criteria. Meeting one of these four criteria enables them to then move ahead to the second set of criteria, which has to do with the quality of the project,” explained Green.

Biotech firms applying for the grant must first ensure that projects fulfill one of the following initial criteria:

- The project is designed to develop a new drug or biologic that either treats or prevents a disease or condition and is being evaluated through preclinical research and clinical trials.
- The project is designed to develop a product that can be used to diagnose a disease or condition.
- The project is designed to determine molecular factors related to a disease or condition that can be used to help make therapeutic decisions.
- The project is designed to develop a product, process or technology to further the delivery of a therapeutic.

Once the initial research criteria have been demonstrated, companies must meet at least one of several criteria relating to the medical benefit of projects. “Is the product likely to result in a new therapy? Will it advance medical science in some way? Will the product meet an area of current unmet medical need, or result in a new therapy to prevent, detect or treat a chronic disease or condition? Will the product reduce long-term health care cost in the US? Is the project likely to significantly advance the goal of curing cancer in the next 30 years?” said Green when outlining the basis for determining medical benefit.

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Briefing

Preferential treatment will be given to projects that improve US competitiveness in the life, medical and biological sciences as well as those that will create jobs in the US. However, there will be no special consideration for certain disease categories or projects in late vs. early stages of development.

Companies interested in being considered for the credit should submit completed applications to the Department of the Treasury.

Subscribers to PharmSource ADVANTAGE received the complete version of this article which contains helpful tips on maneuvering through the tax credit application process. The full article also included insight for CROs and CMOs that wish to help their clients take full advantage of this opportunity.

To read the full version of this article, sign-up for a free trial:

www.pharmsource.com/productsservices/pharmsource-advantage/request-pharmsource-advantage-test-drive.

PharmSource ADVANTAGE: Contractor Profile

Commercial Dose Manufacturing in Brief

Kemwell Opens Swedish Facility

Kemwell (Bangalore, India) announced the opening of its second pharmaceutical manufacturing center in Sweden. The facility, located in Uppsala, will double the company's production capacity from 16,000 to 31,000 square meters.

Kemwell Pvt. Ltd.

Headquarters:

- **Bangalore, India**

Services:

- **API - Small Molecule**
 - ◆ **Small Molecule API Manufacturing**
- **Commercial Dose Manufacturing**
 - ◆ **Semi-solid & liquid manufacturing**
 - ◆ **Solid Dose Manufacturing**

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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Kemwell Pvt. Ltd.

Mergers/Acquisitions

News & Analysis

Known Clients

Corporate Profile:

Address: 11, Tumkur Road
560 022 Bangalore, India
Voice: 91-80-39286200
Fax: 91-80-23379152
Website: www.kemwellindia.com
E-mail: kemwell@kemwellpharma.com

Primary Business: Contract Services

Contract Business:

Business head: Perake Oldentoft
Title: Managing Director, Kemwell Sweden
Contract revenues: \$25-49 million
Number of employees: 251-500
Business Head contact: S. K. Raman
Katarina Segetorp
Perake Oldentoft
Email: perake@oldentoft.se
Global contact: Anurag Bagaria
E-mail: anurag.bagaria@kemwellpharma.com

Contract Services:

API - Small Molecule

Small Molecule API Manufacturing

Uppsala Facility

Commercial Dose Manufacturing

Semi-solid & liquid manufacturing

Bangalore Facility
Uppsala Facility

Solid dose manufacturing

Bangalore Facility
Uppsala Facility

Kemwell Pvt. Ltd.

Bangalore - - India Facility
11, Tumkur Road
560 022 Bangalore, India
Phone: 91-80-39286200 Fax: 91-80-23379152
kemwell@kemwellpharma.com

Specifications for "Solid dose manufacturing"

Solid dosage forms

Effervescent tablets/powders: Yes
Gelcaps: No

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Briefing

Granules:	Yes
Hard capsules:	Yes
Liquid-filled hard capsules:	Yes
Pellets/beads:	Yes
Powders:	Yes
Tablets:	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:	No
High potency - not specified:	No
Hormones/steroids:	No

Other materials

Veterinary products:	Yes
Vitamins & nutritionals:	Yes

Processing Capabilities**Production scale**

Clinical (< 200 kg batch size):	Yes
Large commercial (>1000 kg batch size):	Yes
Maximum batch size:	1200 kg
Small commercial (200-1000 kg batch size):	Yes

Particle sizing

Micronization:	No
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Granulation

Extrusion:	No
Fluid bed:	Yes
Fluid bed equipment:	GLATT/ADAM
High shear:	Yes
High shear granulation equipment:	ADAM
Non-aqueous solvents:	Yes
Other granulation:	GLATT
Roller compaction:	No
Spheronization:	No

Solubility enhancement

Hot melt extrusion:	No
Spray drying:	No

Particle coating

Microencapsulation:	Yes
Microencapsulation technologies:	GLATT
Wurster column fluid bed coating:	No

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Briefing**Drying**

Fluid bed drying:	Yes
Microwave drying:	No
Tray drying:	Yes

Tablet Coating

Coating equipment:	NEOCOTA
Film:	Yes
Non-aqueous:	Yes
Sugar:	Yes
Sustained Release:	Yes

Other processing capabilities

Capsule banding:	No
Explosion-proof:	Yes
Other capabilities:	CAPSULATION

Packaging Capabilities

Blisters:	Yes
Bottles:	Yes
Custom packaging:	Yes
Pellet-filling:	No
Powder filling:	Yes
Sachet:	Yes

Regulatory approvals and certifications

Canada - HPB:	No
Europe - EMEA or constituent countries:	Yes
ISO certification:	No
Other agencies:	WHO GMP Certification
UK - MHRA:	No
USA - FDA:	No

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 Kasaundra Coleman at **703-383-4903** (ET) or write to her at kasaundra@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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