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Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the January 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 you'll find an update on expected VC investment in the bio/pharma industry in 2009. In addition, we've profiled Cenexi and its recent management buyout. Also, be sure to read the article on changes to India's clinical trial regulations.

Enjoy the Issue!

FEATURE STORY

Bio/Pharma Could Be Spared VC Downturn

Venture capital funding for the biopharmaceutical industry is expected to hold up much better than for most industries, according to a new survey from the National Venture Capital Association (NVCA).

In a survey of its members conducted in late November and early December of 2008, the NVCA found that 92% of ventures capitalists (VCs) expect total venture investment to decrease in 2009 versus 2008. However, 58% of VCs expect investment in biotech to either grow or remain stable next year, while 42% expect it to decrease. The survey indicates that companies with products in later stages of development are most likely to receive funding, while early stage and start-up companies will have a difficult time. VCs expect opportunities for them to exit their investments to be poor in the coming year. An overwhelming majority of respondents (72%) expect the IPO market to remain closed in 2009. A smaller majority expects acquisition activity to remain the same or increase, but 87% expect transaction value to decline. Most expect returns on VC investing to decline over the next ten years.

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Briefing

Raising funds will be a problem for VCs in 2009, according to survey respondents. Most expect institutional investors to reduce their commitments to venture capital in the coming year, and expect new fundraising to be extremely difficult. There is concern that some existing limited partners will not be able to meet current commitments (known as “capital calls”).

What it means

The NVCA survey results confirm what we have been reporting (see *BPOR* October 2008) and what we are hearing from CROs and CMOs around the industry. According to data from Burrill and Company, VC funding to biopharma actually rose slightly in the third quarter of 2008, and has remained close to its USD 1 billion per quarter average of recent years. Late phase development programs are progressing but demand for early phase development services has been falling off rapidly. VCs that invest in biopharma are making sure their current portfolio companies are adequately funded to continue development of their most promising candidates but are forcing companies to shelve less advanced programs.

We expect 2009 to be a difficult year for service providers focusing on preclinical and Phase I services, especially those that are dependent on venture-backed companies and have little Big Pharma exposure. Late development services should hold up but may be impacted in later years because fewer candidates will be advancing from early development.

BUSINESS CONDITIONS

Early Development Clinical Research

Clinical Trials in India Still Awaiting Changes

Industry experts have been predicting that India’s Drug Technical Advisory Board will approve major changes to clinical trial regulations in the country, including allowing Phase I trials in India under certain circumstances and allowing Phase III data from Indian subjects gained in global trials to be used in new drug applications.

These modifications have not yet happened, however, in part due to a scandal involving as many as 49 infant deaths during trials at the All-India Institute of Medical Sciences (AIIMS). While AIIMS has launched an internal inquiry, the Uday Foundation, which exposed the deaths, is calling for an external investigation, saying two of the drugs tested had not been studied in pediatric patients.

The scandal seems to have stopped progress toward relaxing India’s clinical trial regulations, at least until next May. It is expected that over the long term, changes in clinical trials regulations will be approved and should benefit India by bringing in more significant R&D revenue. However, in the short term, the majority of trials will be done in the U.S. and Europe.

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SIDE EFFECTS

CMOs and CROs influenced by key client events.

Pharma Company	Event	Contractor	Product	Relationship
Alpharma	to be acquired by King Pharmaceuticals	Hikal	veterinary product	Small Molecule API manufacturing
Dow Pharmaceutical Sciences	FDA approval	Contract Pharmaceuticals Limited (CPL)	Acanya Gel	Semi-solid & liquid manufacturing
Duramed Pharmaceuticals	FDA approval	DPT Laboratories	Synthetic Conjugated Estrogen Cream	Semi-solid & liquid manufacturing
Omrix Biopharmaceuticals	to be acquired by Johnson & Johnson	Talecris Biotherapeutics	cryoprecipitate	Blood products and testing

Source: PharmSource Lead Sheet

SPECIAL REPORTS

Uncertain Cell Culture Outlook

While contract mammalian cell culture manufacturers are operating at near capacity, the major biopharmaceutical companies with substantial, internal cell culture capabilities are at less than 70%. In this dynamic market, arriving at the right make or buy decision requires an intimate understanding of the demand drivers and variables.

One of the biggest factors in future planning is the rate at which improved process yields are translated from the laboratory to the commercial production environment. And one key aspect of this is how quickly technological advances will translate into productivity gains. Another big wildcard in the equation is the rate of new product approval and market uptake. With at least nine pipeline products with the potential to require one ton of product within the first five years of launch, even tighter capacity conditions could develop rapidly.

Just in time to support your 2009 planning process, a report on *Cell Culture Manufacturing Capacity: Trends and Outlook Through 2013* is being release. This report is brought to you by BioProcess Technology Consultants, the industry's foremost experts on cell culture manufacturing, and PharmSource, bio/pharma's preeminent market intelligence resource. Beyond a simple market overview, this publication offers the strategic insight and analyses you need to make the right tactical decisions for your business.

To download an information brochure, please click here:
<http://www.pharmsource.com/about/company-news/special-report-cell-culture-manufacturing-capacity-trends-outlook-through-2013/>

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PharmSource ADVANTAGE: CONTRACTOR PROFILE

Contract Dose Manufacturing

Cenexi Acquired in a Management Buyout

Cenexi (Fontenay-Sous-Bois, France) has been acquired from Roche in a management buyout. Chequers Capital and Indigo Capital provided funding for the acquisition, and Chequers will take a majority stake in the CMO. Cenexi has approximately 485 employees and has been operated as an independent unit for about five years.

<p>Cenexi</p> <p>Headquarters: Fontenay-Sous-Bois, France</p> <p>Services:</p> <ul style="list-style-type: none"> • Commercial Dose Manufacturing <ul style="list-style-type: none"> ◆ Injectables manufacturing ◆ Semi-solid and 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.

Cenexi
 News & Analysis

Corporate Profile:

Address: 52, rue Marcel et Jacques Gaucher
 94120 Fontenay-Sous-Bois, France

Voice: +33 (0)1 43 94 89 91

Fax: +33 (0)1 43 94 89 50

Website: www.cenexi.com

E-mail: cenexi.contact@roche.com

Ownership: Private: private equity or venture capital

Primary Business: Contract Services

Contract Business:

Business head: Philippe Mouglin

Title: General Manager

Annual revenues: \$100-249 million

Number of employees: 251-500

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European contact: Guillaume Gardan
Voice: 33 1 43 94 89 44
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Trade shows: CPhI Worldwide

Contract Services:

Commercial Dose Manufacturing

Injectables manufacturing
 Semi-solid and liquid manufacturing
 Solid dose manufacturing

Cenexi

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Size: 15,000 m²

Specifications for "Injectables manufacturing"

Injectable dosage forms

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

Project acceptance criteria

Antibiotics

Cephalosporin: No
Penicillin: No

Controlled substances

DEA schedule II: No
DEA schedule III, IV, V: No

High potency and cytotoxic

Cytotoxic materials: No
Hormones/steroids: No

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Vaccines and viruses

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

Other materials

Allergenic extracts: No
Proteins & peptides: Yes
Radiopharmaceuticals: No
Vitamins & nutritionals: Yes

Vials and Ampules - Standard Potency - GMP

Production scale

Clinical (10,000-50,000 unit batch size): No
Commercial (>50,000 unit batch size): Yes
Early clinical (<10,000 units, GMP): No

Vial and ampule processing

Aseptic fill: Yes
Terminal sterilization: Yes
Terminal sterilization technologies: Autoclave

Lyophilization

Lyophilization capability: No
Non-aqueous solvent: No

Vial and ampule packaging

ADD-vantage: No
Ampules - glass: Yes
Ampules - number of lines: 300 million units per year capacity
Ampules - sizes and types: 1, 2, 3, 5, 6, 10, 20 ml
Blow-fill-seal: No
Vials: No

Prefilled Syringes/Cartridges-Standard Potency-GMP

PFS and cartridge packaging

Cartridges: No
Pre-filled syringes: No

Large Volume Parenterals - GMP

LVP packaging

LVP bags: No
LVP glass bottles: No

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Briefing**High containment capabilities****Cytotoxics**

Dedicated cytotoxic aseptic fill: No

Dedicated cytotoxic lyophilization units: No

Dedicated cytotoxic suite(s): No

High potency (not cytotoxic)

Dedicated high potency aseptic fill: No

Dedicated high potency lyophilization unit(s): No

Dedicated high potency suite(s): No

Live viruses

Dedicated live virus aseptic fill: No

Dedicated live virus lyophilization unit(s): No

Dedicated live virus suite(s): No

Cephalosporins

Dedicated cephalosporin aseptic fill: No

Dedicated cephalosporin lyophilization unit(s): No

Dedicated cephalosporin suite(s): No

Penicillins

Dedicated penicillin aseptic fill: No

Dedicated penicillin lyophilization unit(s): No

Dedicated penicillin suite(s): No

Regulatory approvals and certifications

Europe - EMEA or constituent countries: 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.

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