

February 2009

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Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the February 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 analysis of the drop in VC funding in the bio/pharma industry and what it means for contract service providers. In addition, we've profiled Dow Pharmaceutical Sciences after its recent acquisition by Valeant Pharmaceuticals. We also explore recent biomanufacturing capacity expansions in India. And don't miss our analysis of the uncertain cell culture outlook on page 3.

Enjoy the Issue!

FEATURE STORY

Funding for Biopharma Down in 2008

Funding to bio/pharmaceutical companies took a sharp drop in 2008 according to data sets released by the National Venture Capital Association (NVCA) and Burrill and Company.

According to Burrill, equity investment in bio/pharmaceutical companies dropped 51% in 2008. Public equity, including initial public offerings (IPOs) and follow-on offerings, dropped 72% for the year, with IPOs drying up almost completely (1 deal for USD 6 million). Venture capital investing was down just 5.5%.

The NVCA survey reported at the end of January that venture investing in biotech dropped 8.5% for the year to USD 5 billion, from USD 5.2 billion in 2008. Q4 2008 suffered a steep decline to USD 1.0 billion, down 22% from both Q3 2008 and Q4 2007. The number of deals in life sciences dropped 20% from 2007 levels to 109.

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Briefing

What it means

The new data partially explain the decline in early development that has hit the contract services industry in the past six months (Big Pharma project delays are also part of the explanation). The decline in Q4 funding provides insight on why many CROs and CMOs did not see the drop-off coming sooner. Venture-backed companies are engaged largely in early-stage development, for which the order and project cycles are relatively short. As venture money became more difficult to obtain entering Q4, early development work slowed drastically.

The lack of funding from all sources has forced biopharma companies to restructure operations and focus resources on the most promising candidates. According to data from the *PharmSource Lead Sheet*, three times as many restructuring actions were announced by bio/pharma companies in Q4 2008 as in Q4 2007.

With no improvement in equity markets expected in the foreseeable future, the prospects for early development services are not expected to recover any time soon.

BUSINESS CONDITIONS

API – Biomanufacturing

More Biomanufacturing Capacity Planned in India

Two Indian biotechnology companies recently announced plans to build new biomanufacturing facilities, adding capacity to a small base in the area.

Panacea Biotec is building a new mammalian cell culture biomanufacturing facility with a total capacity of nearly 1500 L. The plant, expected to be operational in H1 2009, will house two 750 L reactors for clinical scale biomanufacturing and 75 L and 7 L developmental scale reactors.

Intas Biopharmaceuticals has signed a memorandum of understanding with the local government in Sanand, India to set up a biomanufacturing facility. Intas will invest INR 1600 million (USD 33 million) to set up the plant, which will have bioreactors ranging in size up to 5000 L and will exclusively produce monoclonal antibodies. The facility is expected to be fully operational by 2011.

While both companies participate in the contract market, it is unclear how much of the new capacity will be available for contract work. Both companies have their own line of products: Panacea produces vaccines, and Intas, generic biologics for the Indian market.

According to the PharmSource Advantage contractor database, the addition of Panacea brings the number of CMOs offering mammalian cell culture biomanufacturing in India to nine (Intas already offers contract biomanufacturing from an existing facility). None of the CMOs, however, are strategic players; all offer services to fill excess capacity or to develop partnerships. The current capacity is designed for small-scale production, with the largest bioreactor at just 3000 L.

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Briefing**SIDE EFFECTS**

CMOs and CROs influenced by key client events.

Pharma Company	Event	Contractor	Product	Relationship
Ferring Pharmaceuticals	FDA approval	Rentschler Biotechnologie	degarelix	Injectables manufacturing
Genzyme	FDA approval	Patheon	Mozobil	Injectables manufacturing
GTx	NDA submitted to FDA	Fermion (Orion Corp.)	toremifene 80 mg	Small molecule API manufacturing
Indevus Pharmaceuticals	to be acquired by Endo Pharmaceuticals	Helsinn Chemicals	Sanctura XR	Small Molecule API manufacturing
Indevus Pharmaceuticals	to be acquired by Endo Pharmaceuticals	Catalent Pharma Solutions	Sanctura XR	Solid dose manufacturing
Indevus Pharmaceuticals	to be acquired by Endo Pharmaceuticals	Plantex	Valstart	Small Molecule API manufacturing
Neurobiological Technologies	development discontinued	Nordmark Arzneimittel	Viprinex	Biomanufacturing
Neurobiological Technologies	development discontinued	Baxter BioPharma Solutions	Viprinex	Injectables manufacturing
Oncothyreon	manufacturing rights sold to Merck KGaA	Baxter BioPharma Solutions	Stimuvax	Injectables manufacturing
Prism Pharmaceuticals	FDA approval	Baxter BioPharma Solutions	Nexterone	Injectables manufacturing (PFS)
Prism Pharmaceuticals	FDA approval	HollisterStier Laboratories	Nexterone	Injectables manufacturing (vials)
Targanta Therapeutics	to be acquired by The Medicines Company	Catalent Pharma Solutions	oritavancin	Injectables manufacturing
Targanta Therapeutics	to be acquired by The Medicines Company	Abbott Laboratories	oritavancin	Small Molecule API manufacturing
XenoPort	resubmission of NDA to FDA	Lonza	Solzira	Small Molecule API manufacturing
XenoPort	resubmission of NDA to FDA	Patheon	Solzira	Solid dose manufacturing

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.

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Briefing

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.

To support your 2009 planning process, a report on *Cell Culture Manufacturing Capacity: Trends and Outlook Through 2013* has been released. 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/>

PharmSource ADVANTAGE: CONTRACTOR PROFILE

Contract Dose Manufacturing

Valeant to Acquire Dow Pharmaceutical Sciences

Valeant Pharmaceuticals International has agreed to acquire **Dow Pharmaceutical Sciences, Inc.** (Petaluma, Calif., USA) for USD 285 million. In addition to providing contract formulation and small-scale manufacturing for dermatological products, Dow has developed its own products, including the recently approved Acanya and five pipeline candidates. Valeant indicated that Acanya, Dow's pipeline and its expertise in formulation development were the main targets of the acquisition. The DPS service business will continue to be led by Gordon Dow, Dow's founder, and Valeant will use revenues from the service business to help fund internal R&D projects.

According to Valeant, Dow will have revenues in 2008 of USD 45 million, including USD 20 million in royalty payments and USD 25 million in services revenues. Approximately 80% of Dow's clients are small bio/pharma companies, with the remaining 20% coming from mid-size and large pharma companies that utilize Dow's services primarily when they have hard-to-formulate products.

Dow Pharmaceutical Sciences

Headquarters: Petaluma, Calif.

Services:

- **Analytical Services**
 - ◆ **Analytical Chemistry and Stability**
- **Clinical Dose Manufacturing and Packaging**
 - ◆ **Clinical Labels**
 - ◆ **Clinical Packaging and Distribution**
 - ◆ **Solid, Semi-solid and Liquid Phase I/II CTM and Formulation**
- **Consulting Services**
 - ◆ **Regulatory, Validation and QA Services**
- **Phase II-IV Clinical Services**
 - ◆ **Clinical research services**
 - ◆ **Clinical site**
 - ◆ **Data management**
 - ◆ **Institutional Review Board (IRB)**
 - ◆ **Central laboratory services**

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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.

Dow Pharmaceutical Sciences

Mergers/Acquisitions **News & Analysis** **Known Clients**

Corporate Profile:

Address: 1330 Redwood Way
Petaluma, CA 94954-6542 USA

Voice: 707-793-2600

Fax: 707-793-0145

Website: www.dowpharmsci.com

E-mail: ssmith@dowpharmsci.com

Ownership: Unit of public company

Parent Company: Valeant Pharmaceuticals

Primary Business: Contract Services

Contract Business:

Business head: Steve Smith

Title: VP, Marketing & Business Development

Annual revenues: \$50-99 million

Number of employees: 101-250

Corporate Head contact: Bhaskar Chaudhuri
Voice: 707.793.2600
Fax: 707.793.0145

Business Head contact: Steve Smith
Voice: 707-665-4672
E-mail: ssmith@dowpharmsci.com

Field Sales contact: Karen Chu
Voice: (650) 373-7304
Fax: (650) 373-7701
E-mail: kchu@dowpharmsci.com

Trade shows: AAPS Annual Meeting, BIO, DIA, Interphex

Contract Services:**Analytical Services**

Analytical chemistry and stability

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Briefing**Clinical Dose Manufacturing and Packaging**

Clinical Labels
 Clinical Packaging and Distribution
 Solid, Semi-solid/Liquid Phase I/II CTM and Formulation

Consulting Services

Regulatory, Validation and QA Services

Phase II - IV Clinical Services

Clinical research services
 Clinical site
 Data management
 Institutional Review Board (IRB)
 Central laboratory services

Dow Pharmaceutical Sciences

1330 Redwood Way
 Petaluma, CA 94954-6542 USA
 Phone: 707-793-2600 Fax: 707-793-0145

FDA Number: 2950819/SAN
 Size: 43,000 sq. ft.

**Specifications for "Solid, Semi-solid/Liquid Phase I/II
CTM and Formulation"****Processing Capabilities**

Granulation

Non-aqueous solvents: Yes

Dosage Forms

Aerosol: Yes

Gum : No

Liquids—non-sterile: Yes

Metered dose inhalers: Yes

Proprietary technologies: Yes

Semi-solids: Yes

Softgel capsules: No

Solid dose: No

Transdermal: No

Project acceptance criteria

Antibiotics

Cephalosporin: No

Penicillin: No

Controlled substances

DEA schedule II: Yes

DEA schedule III, IV, V: Yes

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Briefing**High potency and cytotoxic**

Cytotoxic materials: No

Hormones/steroids: No

Vaccines and viruses

Vaccines-killed: No

Vaccines-live/attenuated: No

Vaccines-recombinant: No

Other materials

Proteins & peptides: Yes

Radiopharmaceuticals: No

Vitamins & nutritionals: Yes

Staffing

Staff with MS/PhD degrees: 58

Total staff: 135

Development capabilities

GMP: Yes

Particle coating

Fluid bed: No

Microencapsulation: No

Drying

Fluid bed: No

Microwave: No

Tray: No

Particle sizing

Cone: No

Hammer: No

Jet: No

Micronization: No

Oscillation: No

Granulation

Extrusion: No

Fluid bed: No

High-shear: No

Low-shear: No

Roller compaction: No

Spheronization: No

Blending

Cone-type: No

Conical screw: No

Planetary: No

V-type: No

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Sizing

Particle sizing - mechanical: No

Particle sizing-manual: No

Tableting/encapsulation

Bilayer tablets: No

Instrumented press: No

Overencapsulation: No

Tablet coating - Hi-coater No

type

Tablet coating - pan: No

Tablet in a tablet: No

Semi-solids

Counter-directional blending: Yes

Filling capabilities: Tube; Jar; Pouch

High shear blending: Yes

Jacketed vessels: Yes

Vacuum vessels: Yes

Regulatory approvals and certifications

Europe - EMEA or constituent countries: Yes

Other Agencies: Swedish regulatory authorities

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.

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