

May 2009

In This Issue:

- Feature Story: PPD Deals
Signal Partnering Focus 1
- Side Effects 2
- Business Conditions: Funding
for Biopharma Down Sharply
in Q1 2009 2
- PharmSource ADVANTAGE
New Features 3
- Contractor Profile: Ben Venue
Laboratories 4
- PharmSource ADVANTAGE
Test-Drive Offer 8

Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the May 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 **PPD**'s compound partnering program and what it means for their CRO business. In addition, we analyze the possible implications of reduced venture capital funding on the bio/pharmaceutical industry. We also profile **Ben Venue Laboratories** as it nears completion on the construction stage of its cytotoxic injectable facility. And don't miss the latest features added to **PharmSource ADVANTAGE** on page 3.

Enjoy the issue!

Feature Story

PPD Deals Signal Partnering Focus

PPD Inc. (Wilmington, N.C., USA) announced two deals in March that indicate the company is looking beyond contract services for its future growth.

PPD announced its intention to sell its Piedmont Research Center (PRC) to **Charles River Laboratories International Inc.** (Wilmington, Mass., USA). PRC provides in vitro and in vivo discovery-stage research and evaluation of anti-cancer agents and therapies and constitutes the bulk of PPD's discovery services offering. Charles River is paying USD 46 million for PRC, which had revenues of USD 19 million in 2008.

On the same day, PPD announced that it will acquire **Magen BioSciences Inc.** (Waltham, Mass., USA) for USD 14.5 million in cash. Magen has discovery-related capabilities for screening compounds for efficacy and safety. However, the main attraction for PPD is Magen's pipeline of dermatology candidates it has in-licensed from Eli Lilly & Co. and its fit into PPD's program of acquiring rights to new drug candidates. In announcing the acquisition, PPD stated, "The acquisition expands PPD's compound partnering program into dermatology, initially in the indications of psoriasis, atopic dermatitis and acne."

Continued on next page

© 2009 PharmSource Information Services, Inc.

Tel. 703-383-4903
Fax. 703-383-4905
www.pharmsource.com
info@pharmsource.com

Briefing

Begun in 1998, PPD's compound partnering program seeks to in-license promising early-stage compounds, typically from major pharmaceutical companies that are restructuring their pipelines; take them through proof of concept; and out-license them to larger partners for late clinical testing and commercialization. PPD absorbs the early-development expense for these compounds, and revenues are generated by licensing fees, milestone payments and commercial royalties from licensees. The program has yielded about USD 33 million in the last three years from two products: dapoxetine, licensed to Johnson & Johnson for genitourinary indications; and alogliptin, licensed to Takeda for diabetes indications. Dapoxetine received its first approvals, in Europe, earlier this year, and Takeda has filed an NDA for alogliptin, but FDA review has been delayed and approval is not expected before next year.

What it means

Taken together, the two announcements suggest that PPD executives see bigger long-term opportunities in proprietary drug development than in contract R&D services, despite the higher risk. Furthermore, the two deals don't appear to have any immediate implications for PPD's customers or competitors, but they may cause competitors to rethink their own growth strategies.

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
Laboratorios Salvat	FDA approval	The Ritedose Corp.	Cetraxal	Semi-solid & liquid manufacturing
Vanda Pharmaceuticals	FDA approval	Patheon	Fanapt	Solid dose manufacturing
VeroScience	FDA approval	Patheon	Cycloset	Solid dose manufacturing

Source: PharmSource Lead Sheet

Business Conditions

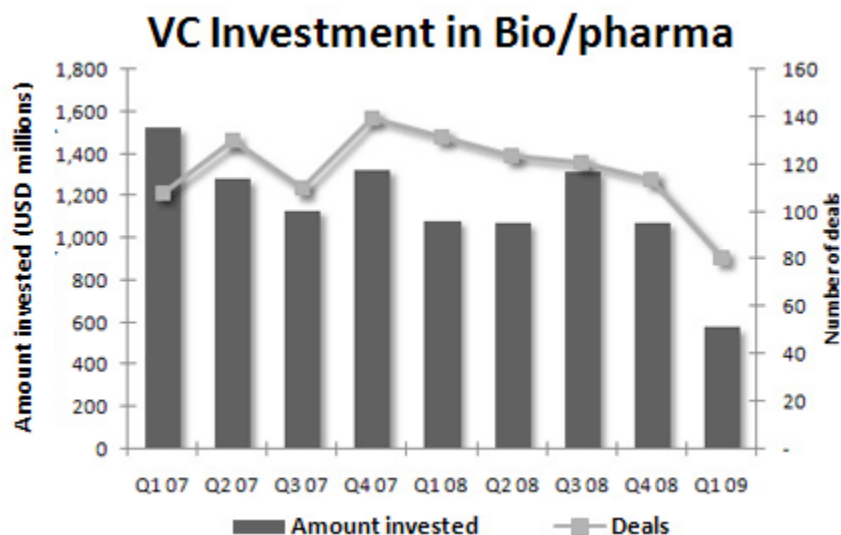
Funding for Biopharma Down Sharply in Q1 2009

Venture capital funding for bio/pharmaceutical startup companies took a nosedive in Q1 2009, according to PricewaterhouseCoopers and the National Venture Capital Association, based on data from Thomson Reuters.

Funding for biotechnology companies registered at USD 577 million for the quarter, down a whopping 46% from Q4 2008 levels and 47% from Q1 2008. Last quarter marked the first quarter where funding for biotech companies was under USD 1 billion since Q1 2006 (when USD 909 million was invested) and the least amount invested in the industry since Q3 2002 (USD 478 million).

Continued on next page

Total value of financings for companies raising venture capital for the first time fell in Q1 2009, but the average deal size held steady at USD 6.7 million (vs. USD 6.5 million, the average for the last five years). The same cannot be said of later-stage financings, where the average deal size dropped 38% to USD 7.2 million from a five-year average of USD 11.6 million.



What it means

The dramatic drop in VC investment will undoubtedly hit the early-development segment the hardest, continuing the downward trend started in H2 2008. The smaller late-stage deals are in line with what we have seen in the industry recently as investors are being more cautious with their money and forcing their portfolio companies to focus on only the most promising candidates. Thus, with the outlook for the global equity markets remaining very clouded, the prospects for providers of early development services do not look rosy.

New Capabilities on PharmSource ADVANTAGE

The **PharmSource ADVANTAGE** online service has added two new capabilities to its interactive database of more than 1,000 contract service providers. With the latest added features, subscribers can now easily acquire an overall, streamlined view of contractor relationships throughout the industry and quickly access a clear, up-to-date picture of the size of service providers in the marketplace.

Search by Client

- This new feature enables our subscribers to rapidly generate a comprehensive list of known contractor relationships for a particular bio/pharma company. To access this feature:
 - Log in to the **PharmSource ADVANTAGE** home page.
 - In the “Contract Service Providers” box, click on “Search by Client.”

Continued on next page

Compare Companies by Contract Revenue Range

- This new feature allows subscribers to select and/or rank contract service providers by the size of their contract revenue. It is designed to enhance the ability to search and compare companies by presenting a complete perspective of all companies within a certain contract revenue range. To access this feature:
 - Log in to the **PharmSource ADVANTAGE** home page.
 - In the “Contract Service Providers” box, select the service for which you would like to search (e.g., “Commercial Dose Manufacturing/Injectables Manufacturing”).
 - The “Refine Your Search” box will be displayed on your screen.
 - Use the pull-down menu for “Any or All Contract Revenue Ranges” on the left-hand side to select the revenue range for which you would like to search.
 - A list of companies matching your revenue range will be displayed alphabetically.
 - To further sort by revenue range, click on the “Contract Revenue Range” link at the top of the far right column.

If you have questions regarding these new features or would like to receive personalized training on how to use all of the tools available in a **PharmSource ADVANTAGE** subscription, please send an e-mail to info@pharmsource.com or call us at 1-703-383-4903 (ET).

PharmSource ADVANTAGE: Contractor Profile

Commercial Dose Manufacturing

Ben Venue Reaching Milestone at New Cyto Facility

Ben Venue Laboratories (Bedford, Ohio, USA) is nearing completion on the construction stage of its cytotoxic injectable facility. The 224,000-square-foot expansion of its main facility includes three new vial fill lines and nine freeze dryers with total capacity of 2250 square feet. Containment for the filling lines will use a combination of full isolator and Restricted Access Barrier Systems (RABS) technologies. Once validation is completed in mid- 2010, Ben Venue cytotoxic capabilities will expand to 3,500 sq.ft. of useable shelf space, including the 1244 sq. ft. it has currently.

Ben Venue Laboratories

Headquarters: Bedford, Ohio

Services:

- **Commercial Dose Manufacturing**
 - ◆ **Injectables Manufacturing**

The construction phase was originally scheduled to be completed by now, but Ben Venue and Boehringer Ingelheim management decided to make improvements to the facility design before sealing it up. The changes include improved air handling and the addition of controlled-not-classified corridors to allow one-way process flows of materials, product and equipment. Additionally, Ben Venue has added a new \$17 million lab office building, which includes a process development pilot laboratory, and expanded QA/QC laboratories.

Continued on next page

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.

Ben Venue Laboratories

Financials **News & Analysis** **FDA Reports** **Known Clients**

Corporate Profile:

Address: 300 Northfield Road
PO Box 46568
Bedford, OH 44146 USA

Voice: 440-232-3320

Fax: 440-439-6398

Website: www.benvenue.com

E-mail: BenVenueServices.cle@boehringer-ingelheim.com

Ownership: Unit of private company

Parent Company: Boehringer Ingelheim GmbH

Primary Business: Contract Services

Contract Business:

Business head: Thomas J. Murphy

Title: President and COO

Contract revenues: \$100-249 million

Number of employees: 1001-2500

Business Head contact: Thomas J. Murphy
Voice: 440-232-3320
Fax: 440-439-6798
E-mail: tmurphy@cle.boehringer-ingelheim.com

North American contact: Bill Conway
Voice: 440-804-6472
E-mail: Bconway@cle.boehringer-ingelheim.com

Kyle R. Armbruster
Voice: 440-232-3320 ext 3209
Fax: 440-439-6398
E-mail: karmbruster@cle.boehringer-ingelheim.com

Trade shows: AAPS Annual Meeting, Interphex

Continued on next page

Contract Services:

Commercial Dose manufacturing
 Injectables manufacturing

Ben Venue Laboratories, Inc.
Bedford - OH - USA Facility
 300 Northfield Road
 PO Box 46568
 Bedford, OH 44146 USA
 Phone: 440-232-3320 Fax: 440-439-6398
 BenVenueServices.cle@boehringer-ingelheim.com

FDA Number: 1519257/CIN
 Size: 285,000 sq. ft.

Specifications for "Injectables manufacturing"

Dosage Forms

Large volume parenterals: No
 Lyophilized: Yes
 Parenteral solutions: Yes
 Parenteral suspensions: Yes
 Pre-mix products: No
 Sterile Powders: No

Project Acceptance Criteria

Antibiotics

Carbapenem: No
 Cephalosporin: No
 Penicillin: No

Controlled substances

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

High potency and cytotoxic

Cytotoxic materials: Yes
 Hormones/steroids: Yes

Vaccines and viruses

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

Other materials

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

Continued on next page

Briefing**Viials and Ampules - Standard Potency - GMP*****Production scale***

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

Vial and ampule processing

Aseptic fill:	Yes
Aseptic formulation:	Yes
Emulsions:	Yes
Glass-lined vessels:	Yes
High viscosity materials (>50 centipoises):	Yes
Inert atmospheres:	Yes
Light sensitive:	Yes
Lipid formulations:	Yes
Non-aqueous solvents:	Yes
Oxygen sensitive:	Yes
Terminal sterilization:	Yes
Terminal sterilization technologies:	autoclave, super-heated water shower
Vacuum drying:	Yes

Lyophilization

Lyophilization capability:	Yes
Lyophilization capacity:	5412 sq. ft., 21 units
Non-aqueous solvent handling:	Yes

Vial and ampule packaging

ADD-vantage:	No
Ampules - glass:	Yes
Ampules - number of lines:	Yes
Ampules - sizes and types:	up to 20 mL
Blow-fill-seal:	No
Blow-fill-seal presentations:	No
Vials:	Yes
Vials - number of lines:	8
Vials - sizes and types:	0.5 mL to 200mL

Prefilled Syringes/Cartridges-Standard Potency-GMP***PFS and cartridge packaging***

Cartridges:	No
Pre-filled syringes:	No
Proprietary syringe device:	No
Syringe type: bulk:	No
Syringe type: pre-sterilized (SCF or other):	No

Continued on next page

Briefing**Large Volume Parenterals - GMP***LVP packaging*

LVP bags: No

LVP glass bottles: No

Processing Capabilities*Other processing capabilities*

Other processing capabilities: microspheres

Regulatory Approvals and Certifications

Canada - HPB: Yes

Europe - EMEA or constituent countries: Yes

Japan - Koseisho: Yes

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. 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.

**PharmSource ADVANTAGE Briefing is a
publication of PharmSource Information Services, Inc.**