

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

November 2009

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Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the November 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 **MDS Inc.**'s divestiture of its analytical technologies and pharmaceutical services businesses. In addition, we highlight the pros and cons of conducting clinical trials in India. We also profile **Vetter Pharma** which recently announced plans to open a new service facility in Chicago, Ill., USA. And don't miss the information on our latest report, *The Market for Analytical Testing and Development Services* on page 4.

Enjoy the issue!

Feature Story

MDS Exiting Pharma Services Business

MDS Inc. (Toronto, Ontario, Canada) announced plans to divest its analytical technologies and pharmaceutical services businesses. Once the plan is completed, the company's only business will be MDS Nordion, a manufacturer of medical isotopes.

The divestiture program is well under way. In September, MDS announced the sale of its analytical technologies business, which makes LC/MS/MS and other analytical instruments, to Danaher Corporation for USD 650 million in cash. In July, it completed the sale of its Phase II-IV clinical research business to INC Research for USD 50 million; the business had revenues of about USD 200 million and 800 employees. In November, MDS completed the sale of its central laboratory business to private equity firm Czura Thornton, which owns clinical CRO Chiltern. The early development business, which includes Phase I research sites and bioanalytical testing services, is the last piece left; its revenues are also around USD 200 million.

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MDS Pharma Services has suffered from declining revenues and market share for several years. Its once market-leading bioanalytical services business was seriously hurt by quality problems uncovered in an FDA inspection, and it never recovered. Although its revenues put it among the top 10 clinical CROs by revenue, management never figured out how to compete successfully. Case in point: In 2004, MDS Pharma Services had revenues of USD 509 million, twice those of Icon, which had USD 270 million. By 2008, Icon’s revenues of USD 865 million were 50% higher than MDS’ USD 582 million.

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
<i>Potentially Positive Side Effects</i>				
Addrenex Pharmaceuticals	FDA Approval	UPM Pharmaceuticals	Jenloga	Solid-dose manufacturing
NicOx	NDA submitted	Capsugel	naproxcinod	Solid-dose manufacturing
NicOx	NDA submitted	DSM Pharma Chemicals	naproxcinod	Small molecule API manufacturing
Sirion Therapeutics	FDA Approval	Alliance Medical Products	Zirgan	Semi-solid manufacturing

Source: PharmSource Lead Sheet

Business Conditions

Clinical Trials in India: Benefits Balance Hidden Costs

Are clinical trials really cheaper in India? Not by as much as people think, experts say. While cost savings are certainly a factor for running trials in India, especially in a time when clinical trial costs are rising very rapidly, historically India has been an attractive site for clinical trials for other reasons.

Hidden Costs Reduce Savings

“Running clinical trials in India is an ongoing cost-benefit analysis,” says Mukesh Kumar, PhD, RAC, Sr. Director, Regulatory Affairs, Amarex, LLC. While some Indian CROs quote prices much lower than what a trial would cost elsewhere, there are hidden costs to running trials in India that companies need to consider. These include:

- The cost of getting regulatory approvals in India.
- Import and export fees.

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Briefing

- Shipping costs, especially for materials that have special handling considerations.
- Patient medical expenses. With an enormous uninsured patient population in India, sponsors must often cover these for enrolled patients.
- Audit fees. The Indian regulators are now conducting site audits, and these will increase going forward.
- Storage and handling costs, especially for temperature-sensitive material.

How do companies pay for these hidden costs? Sponsors very often use the money they saved by running the trial in India to begin with and the end result can be no significant costs savings at all.

Sticker Shock

Finding out exactly how much a trial will cost in India is another problem. “Cost loading is common with some Indian CROs,” says Munish Mehra, PhD, Managing Director, Global Drug Development Experts. This is the practice of providing a low quote upfront, then “raising” the price later by charging for vendor activities or other products or services required for the trial.

So why go to India? According to recent reports, India’s draw for clinical trials has historically been, and remains today, focused on time savings and volume—the country’s ability to enroll the largest number of patients in the shortest amount of time. This results in faster trials and, ultimately, getting drugs into the market faster.

“Trial enrollment in India is fast and easy, and you have an enormous pool of treatment-naïve patients,” says Tufail Syed, M.D., Managing Director, MedPace India. However, the benefits of running trials in India extend still further. India’s second official language is English, and it is widely spoken, especially by professionals. The population is well-educated, and many professionals attend college or university overseas. And it is a democracy, with a legal system modeled on standards familiar to the West—this makes it an easier country to operate in for most Western companies, where there are similar systems of capitalism and government oversight.

Keeping Costs Down and Benefits Up

Despite the similarities, for Western companies India remains a foreign country with different laws and regulations and ways of doing business. So how to navigate the complex clinical trial landscape there? There are strategies companies can use that will help keep costs down yet enhance the country’s benefits.

- Ask Indian CROs for a total trial cost estimate.
- Avoid running small trials in India that won’t produce any cost savings.
- Collaborate with Indian companies.
- Look beyond the visible costs reflected in CRO payments and remember to figure intangible costs into the equation.

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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 merging competition from Asia.

More information on *The Market for Analytical Testing and Development Services* is available from Jim Miller at jim.miller@pharmsource.com.

PharmSource ADVANTAGE: Contractor Profile

Clinical Dose Manufacturing and Packaging

Vetter Pharma Unveils Vetter Development Services (VDS)

Vetter Pharma (Ravensburg, Germany) plans to open a new service facility in Chicago, Ill., USA, called Vetter Development Services (VDS). VDS will provide aseptic filling services of small product quantities for the company’s North American clients.

The company will fill vials and syringes for Phase I-II trials. Its facility will offer semi-automated filling by the end of 2010, and a fully automated line will be operational by mid-2011.

<p style="text-align: center;">Vetter Pharma</p> <p>Headquarters: Ravensburg, Germany</p> <p>Services:</p> <ul style="list-style-type: none"> • Clinical Dose Manufacturing and Packaging <ul style="list-style-type: none"> ◆ Injectable Phase I/II CTM and Formulation • Commercial Dose Manufacturing <ul style="list-style-type: none"> ◆ Injectables manufacturing
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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.

Vetter Pharma — Fertigung GmbH & Co. KG

Mergers/Acquisitions

News & Analysis

Known Clients

Corporate Profile:

Address: Schuetzenstrasse 87
88212 Ravensburg, Germany

Voice: +49-751-3700-0

Fax: +49-751-3700-4000

Website: www.vetter-pharma.com

E-mail: info@vetter-pharma.com

Ownership: Private: management owned

Primary Business: Contract Services

Contract Business:

Contract revenues: \$250 - 499 million

Number of employees: 1001-2500

Corporate Head contact: Peter Soelkner
Voice: +49 751 3700 0
Fax: +49 751 3700 4000
E-mail: info@vetter-pharma.com

Max Horn
Voice: +49 751 3700 0
Fax: +49 751 3700 4000
E-mail: info@vetter-pharma.com

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Voice: +49 751 3700 0
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Contract Services:

Clinical Dose Manufacturing and Packaging
Injectable Phase I/II CTM and Formulation

Commercial Dose Manufacturing
Injectables Manufacturing

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Briefing**Vetter Pharma**

Ravensburg - - Germany Facility
 Schuetzenstrasse 87
 88212 Ravensburg, Germany
 Phone: +49-751-3700-0 Fax: +49-751-3700-4000
 info@vetter-pharma.com

Specifications for "Injectables manufacturing"**Injectable dosage forms**

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

Project acceptance criteria***Antibiotics***

Carbapenem: No
 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: Yes

Vaccines and viruses

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

Other materials

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

Vials 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): Yes

Vial and ampule processing

Aseptic fill: Yes
 Glass-lined vessels: No
 High viscosity materials (>50 centipoises): Yes
 Inert atmospheres: Yes
 Light sensitive: Yes

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	Lipid formulations:	Yes
	Oxygen sensitive:	Yes
	Terminal sterilization:	Yes
	Vacuum drying:	No
Lyophilization		
	Lyophilization capability:	Yes
	Non-aqueous solvent handling:	No
Vial and ampule packaging		
	ADD-vantage:	No
	Ampules - glass:	No
	Blow-fill-seal:	No
	Vials:	Yes
	Vials - number of lines:	2
	Vials - sizes and types:	2--30mL

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

	Cartridges:	Yes
	Cartridges - types:	0.5 ml--5.0 mL
	Pre-filled syringes:	Yes
	Pre-filled syringes - sizes and types:	0.5 - 10.0 mL w/wt staked needles
	Proprietary syringe device:	Yes
	Proprietary syringe device description:	Lyo-Ject dual chamber syringe for lyophilized products
	Syringe type: bulk:	Yes
	Syringe type: pre-sterilized (SCF or other):	Yes

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

	LVP bags:	No
	LVP glass bottles:	No

Processing Capabilities***Production scale***

	Maximum batch size:	None specified
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Regulatory approvals and certifications

	Brazil - ANVISA:	Yes
	Canada - HPB:	Yes
	Europe - EMEA or constituent countries:	Yes
	ISO certification:	No
	Japan - Koseisho:	Yes
	Other agencies:	Saudia Arabia: Mott of SA; Russia: Mott of R; Germany: Regierungspraesidium; Mexico: Mott Mexico
	UK - MHRA:	No
	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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