

PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

May 2010

In This Issue:

Feature Story

**Azopharma Falls into
Bankruptcy** 1

PharmSource Special Report:

**The Market for Analytical
Testing and Development
Services** 2

Side Effects 3

Business Conditions

**Russian Federation Set to
Overhaul Country's
Pharmaceutical Industry** 4

Contractor Profile

**Advanced BioScience
Laboratories, Inc.** 5

PharmSource ADVANTAGE

Free Test-Drive Offer 8

Welcome to the *PharmSource ADVANTAGE Briefing!*

Welcome to the May 2010 issue of the *PharmSource ADVANTAGE Briefing*, a 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 **Azopharma's** bankruptcy and the vulnerabilities of the one-stop model. In addition, we highlight the Russian government's new development strategy for its pharmaceutical industry. We also profile **Advanced BioScience Laboratories**, which recently relocated and expanded its headquarters. 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

Azopharma Falls into Bankruptcy

Azopharma Contract Pharmaceutical Services (Hollywood, Fla., USA) and its sister companies have been pushed into Chapter 7 bankruptcy. Bank of America filed bankruptcy proceedings against Azopharma and its sister companies in the US District Court of Eastern Missouri (St. Louis) on April 1, 2010. The complaint stated that the companies owed Bank of America USD 26.5 million in principal and accrued interest, most of which was personally guaranteed by Shri Thanedar, the founder and owner of Azopharma.

The complaint was filed against all of the companies established by Thanedar, including Azopharma, **AvivoClin Clinical Services** (Phase I clinical research), and **AniClin Preclinical Services** (preclinical toxicology). It also includes Thanedar's companies that provided analytical testing for industries outside bio/pharmaceuticals, **Chemir Analytical Services** (St. Louis, Mo., USA) and **CAS-MI Laboratories** (Ypsilanti, Mich., USA).

According to various accounts, a private equity firm was ready to make an investment in Azopharma that would have kept the firm operating, but the deal fell through at the last minute. The closing of

Continued on next page

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Briefing

the facilities was rather sudden, and clients will suffer from interrupted projects and stability studies, and the loss of dedicated equipment for which they had paid. We understand that animal studies at AniClin are being maintained, and that arrangements were being made to return stability samples to clients.

What it means

The Azopharma story is a lot like the Oread story of 10 years ago: an entrepreneur tries to assemble a one-stop CMC development shop through acquisition and investment, spends heavily on advertising and promotion to build brand recognition, then runs out of cash and is forced to shut down.

Experience is teaching that the one-stop model is vulnerable in several regards:

- It appeals largely to venture-backed early stage companies with precarious funding and small pipelines. Client acquisition costs are high and changes in the funding environment, such as what occurred during the recent financial crisis, can quickly erode demand.
- The multi-service offering is only as strong its weakest link. Typically, one-stop shops are technically strong and profitable in some service disciplines but technically weak and poorly-utilized in others. The quality and negative cash flow problems in the weaker services can pull down the entire operation.

The one-stop model is being tested in other segments of the contract services industry. Those efforts differ from the Azopharma situation, however, because the one-stop model is being embraced by the global bio/pharmaceutical companies.

Subscribers to PharmSource ADVANTAGE received an enhanced analysis of the one-stop model and how it is being implemented throughout the contract services industry. To learn more about PharmSource ADVANTAGE, go to www.pharmsource.com/productsservices/pharmsource-advantage

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.

Continued on next page

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 <http://www.pharmsource.com/productsservices/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
Potentially Positive Side Effects				
3M Drug Delivery Systems	Graceway Pharmaceuticals	FDA approval	Zyclara	Semi-solid manufacturing
Catalent Pharma Solutions	Strativa Pharmaceuticals	FDA approval	Oravig	Solid-dose manufacturing
Chemi SpA	Orexigen Therapeutics	NDA filed	Contrave	Small-molecule API manufacturing
Lonza	Genmab/GSK	Conditional EMA approval	Arzerra	Biomanufacturing
Nordmark Arzneimittel	Johnson & Johnson	FDA approval	Pancreaze	Solid-dose manufacturing
Patheon	DepoMed	NDA filed	DM-1796	Solid-dose manufacturing
Patheon	Orexigen Therapeutics	NDA filed	Contrave	Solid-dose manufacturing
Patheon	Salix Pharmaceuticals	FDA approval	Xifaxan	Solid-dose manufacturing
Pharma Packaging Solutions	Salix Pharmaceuticals	FDA approval	Xifaxan	Commercial packaging
Potentially Negative Side Effects				
Baxter Biopharma Solutions	Javelin Pharmaceuticals	to be acquired by Hospira	Dyloject	Injectables manufacturing
Penn Pharma Services	Prostrakan Group	Complete response letter from FDA	Rectogesic	Semi-solid manufacturing

Source: PharmSource Lead Sheet

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Business Conditions**Russian Federation Set to Overhaul Country's Pharmaceutical Industry**

The Russian government recently laid out its development strategy to revamp the pharmaceutical industry in the country. Titled *Pharma 2020*, the plan is set to change the landscape of Russia's pharmaceutical industry by the year 2020, with the implementation of the program divided into three phases. Phase I, 2009-2012, is designed to increase the number of manufacturing facilities for small molecule APIs and biologics and to bolster drug development in the country. Phase II, 2012-2017, will be an attempt to grow the percentage of domestically produced drugs used in the market. And in Phase III, 2018-2020, the program will try to intensify the number of drugs exported from Russia to international markets.

According to the Russian Federation, the country currently has approximately 350 pharmaceutical companies, which account for less than 20% of the domestic market. Most drugs are imported and the prices of these remain high. On the other hand, drugs produced domestically cannot be readily exported, due to the lack of GMP standards. *Pharma 2020* was, therefore, designed to address several disparities in the Russian market. The goals of the government's strategy are as follows:

- Increase the number of domestically manufactured medicines purchased by the Russian government so that these drugs make up more than half of its total supply. The government plans to shift to long-term contracts with Russian manufacturers to supply medicines to government, municipal and corporate hospitals and clinics as well as to medical centers affiliated with the Russian Academy of Medical Sciences. The hope is that the profits gained from these contracts will be used by Russian manufacturers to upgrade production facilities and install new technologies. Additional tariffs will also be levied on imported drugs.
- Provide for a greater number of medicines to be domestically manufactured through licensed production and generics. The Federation plans to compile a list of important and essential medicines and then promote their domestic manufacture through development institutions.
- Prevent the sale of counterfeit medicines and medicines that have already expired.
- Establish a plan to implement GMP standards, increasing the international competitiveness of the Russian pharmaceutical industry. The Russian government will no longer purchase medicines produced under non-GMP conditions.
- Integrate R&D with manufacture. The plan calls for RUB 700 million (USD 24 million) in low-interest loans to domestic pharmaceutical companies to upgrade their technologies and facilities.
- Ensure that government development institutions support the research and development of novel medicines, the movement of these medicines into production, and the promotion of the Russian pharmaceutical industry in foreign markets, especially in developing countries.
- Create a quality control system to improve the registration process of novel drugs and speed up their approval by lifting bureaucratic barriers.

Continued on next page

Briefing

- Restrain abuses by foreign pharmaceutical companies, including unfair advertising, bonuses to doctors who prescribe certain medications, lobbying by pharmaceutical representatives in medical institutions, and conflict of interests arising from medical professionals being paid by manufacturers to serve on expert boards for the approval of new medicines.
- Offer improved educational programs to increase the number of pharmaceutical graduates.

Through the implementation of *Pharma 2020*, the Russian government estimates that it will increase the consumption of domestically manufactured drugs by 50% compared with 2008, increase the share of novel pharmaceuticals to 60% of the entire domestic industry's output, increase the volume of export by up to eight times compared with 2008, and increase the supply of important and essential medicines manufactured in Russia to 85%.

PharmSource ADVANTAGE: Contractor Profile

API – Biomanufacturing

Advanced BioScience Laboratories Announces Relocation

Advanced BioScience Laboratories (ABL – Kensington, Md., USA) announced the relocation and expansion of its corporate headquarters to a 72,000-square-foot facility in Rockville, Md., USA, that will also house the company's R&D laboratories and cGMP manufacturing space. The company plans to invest USD 10 million in renovating the new facility. In addition, ABL announced its plans to add more than 10,000 square feet to the company's vivarium, bringing the total size of this facility to 35,000 square feet.

Advanced BioScience Laboratories, Inc.

Headquarters: Kensington, Md., USA.

Services:

- **API - Biomanufacturing**
 - ◆ Cell culture
- **Clinical Dose Manufacturing and Packaging**
 - ◆ **Injectable Phase I/II CTM and Formulation**
- **Early Development (Preclinical Phase I)**
 - ◆ Toxicology

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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Advanced BioScience Laboratories, Inc.

News & Analysis Known Clients

Corporate Profile:

Address: 5510 Nicholson Lane
Kensington, MD 20895 USA
Voice: 301-816-5200
Fax: 301-816-5438
Website: www.ablinc.com
E-mail: info@ablinc.com
Ownership: Private: management owned
Primary Business: Contract Services

Contract Business:

Business head: Thomas VanCott
Title: President and Chief Executive Officer
Contract revenues: \$0-24 million
Business Head contact: Thomas VanCott
Voice: (301) 774-2462
Email: thomas.vancott@ablinc.com
Field Sales contact: Tim Keen
Voice: (301) 816-5459
E-mail: tim.keen@ablinc.com
Trade shows: BIO

Contract Services:

API - Biomanufacturing
Cell culture
Clinical Dose Manufacturing and Packaging
Injectable Phase I/II CTM and Formulation
Early Development (Preclinical/Phase I)
Toxicology

Advanced BioScience Laboratories, Inc.
Kensington - MD - USA Facility
5510 Nicholson Lane
Kensington, MD 20895 USA
Phone: 301-816-5200 Fax: 301-816-5438
info@ablinc.com

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Briefing**Specifications for "Injectable Phase I/II CTM and Formulation"****Injectable dosage forms**

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

Project acceptance criteria**Antibiotics**

Cephalosporin:	No
Penicillin:	No

Other materials

Proteins & peptides:	Yes
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Vials and Ampules - Standard Potency - GMP**Production scale**

Clinical (10,000-50,000 unit batch size):	No
Clinical batch size-vials:	1500 vials
Early clinical (<10,000 units, GMP):	Yes
Hand fills (GMP):	Yes
Number of compounding suites:	1
Number of GMP clinical fill suites:	1

Vial and ampule processing

Aseptic fill:	Yes
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Lyophilization

Lyophilization capability:	No
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Vial and ampule packaging

Ampules - glass:	No
Ampules-plastic:	No
Vials:	Yes

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

Regulatory approvals and certifications

USA - FDA:	Yes
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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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