

## PharmSource ADVANTAGE: Sourcing Intelligence for Intelligent Sourcing

August 2010

Welcome to the *PharmSource ADVANTAGE Briefing!*

### In This Issue:

#### Feature Story

**Aptuit Closes on Verona Site** ..... 1

#### PharmSource Special Report:

**Top Dose CMOs by Number of NDA and BLA Approvals** ..... 2

**Side Effects** ..... 3

#### Business Conditions

**CRO Market Update: Optimism Resurges as Industry Begins to Bounce Back** ..... 3

#### Contractor Profile

**AAIPharma Services Corp.** .... 5

#### PharmSource ADVANTAGE

**Free Test-Drive Offer** ..... 8

Welcome to the August 2010 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 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 **Aptuit's** acquisition of GlaxoSmithKline's R&D site in Verona, Italy. In addition, we highlight the optimism growing throughout the CRO industry as we analyze the results of our exclusive survey conducted among exhibitors at the 2010 Drug Information Association (DIA) annual meeting in Washington, DC. We also profile **AAIPharma Services**, which recently announced a strategic alliance with CritiTech. And don't miss the information on our latest report, *Top Dose CMOs by Number of NDA and BLA Approvals*, on page 2.

*Enjoy the issue!*

### Feature Story

## Aptuit Closes on Verona Site

**Aptuit** (Greenwich, Conn., USA) completed its acquisition of GlaxoSmithKline's Verona, Italy, R&D site. GSK declared the site redundant earlier this year when it announced plans to withdraw from research in some neuroscience areas, including pain and depression.

According to CEO Tim Tyson, Aptuit received a three-year contract (with renewal options for up to eight years) from GSK for R&D services to be performed at the site. In an interview with PharmSource, Tyson said that GSK is already a major client for Aptuit, and the agreement extends that relationship.

The Verona site has a broad range of capabilities, from discovery through development. Discovery-related capabilities include medicinal chemistry, DMPK, toxicology, and biology. Development capabilities include process and analytical chemistry, formulation and clinical scale drug product manufacturing. The facility has a staff of 500.

© 2010 PharmSource Information Services, Inc.

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

*Continued on next page*

# Briefing

Tyson said that Aptuit has no plans to consolidate any of its other operations, e.g., the preclinical testing it offers from a facility in Scotland, to the Verona site. He said that utilization of its capacity at the other 18 sites in its network is “good” and there is no rationale for consolidating sites at this time.

*Subscribers to PharmSource ADVANTAGE received our enhanced analysis of the Verona site acquisition in the “What it means” section of the article, which further examines Aptuit’s positioning in the contract services industry and its integrated services strategy.*

*To read the full version of this article, sign-up for a free trial:*

[www.pharmsource.com/productsservices/pharmsource-advantage/request-pharmsource-advantage-test-drive](http://www.pharmsource.com/productsservices/pharmsource-advantage/request-pharmsource-advantage-test-drive).

## PharmSource Special Report

### New Report Highlights CMO Success

A new analysis by PharmSource documents one measure of success in the CMO industry – the number of regulatory approvals gained. The report, **Top Dose CMOs by Number of NDA and BLA Approvals**, was published as part of the *PharmSource Market Intelligence Service*.

In our analysis, we found that 200 of the 487 products receiving FDA approval (NDA and BLA) during the period 2005-2010 involved a contract dose manufacturer. Of those 200, we were able to successfully identify the CMO for 185 (92%) of them.

In total, 72 different CMOs had at least one of the 200 outsourced FDA approvals granted during the 2005-2010 period. Of those 72 CMOs, 44 (60%) received only one FDA approval during the nearly five years covered by this analysis. Nearly half of the CMOs getting approvals (34 of the 72) are selling excess capacity and are not dedicated to the CMO business. The 12 companies receiving the most approvals accounted for 105 (52%) of all approvals involving a dose CMO.

The analysis suggests that we should see more industry consolidation in the coming years. Consider that more than 60% of CMOs listed in the **PharmSource ADVANTAGE** database that claim FDA compliance received no new FDA approvals in the period, while most CMOs that did receive an approval received only one.

The report contains a list of the 72 CMOs receiving FDA approvals and the number of approvals received by dosage form.

*Individual copies of the eight-page report can be purchased by contacting Kasaundra Coleman in PharmSource customer service at 703-383-4903 or [kasaundra@pharmsource.com](mailto:kasaundra@pharmsource.com).*

*More information on The Market for Analytical Testing and Development Services is available at [www.pharmsource.com/productsservices/special-reports/](http://www.pharmsource.com/productsservices/special-reports/).*

*Continued on next page*

## 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
<b>Potentially Positive Side Effects</b>				
3M Drug Delivery Systems	Merck	FDA approval	Dulera	Inhalation dose form manufacturing
Patheon	Kowa Pharmaceuticals	Marketing alliance with Abbott	Livalo	Solid dose manufacturing
Siegfried	Arena Pharmaceuticals	Marketing alliance with Eisai	Lorcaserin	Small molecule API manufacturing
LTS Lohmann Therapie-Systeme	Purdue Pharma	FDA approval	Butrans Transdermal System CIII	Transdermal dose manufacturing
SAFC	Winston Pharmaceuticals	NDA filed	CIVANEX (civamide)	Small molecule API manufacturing
<b>Potentially Negative Side Effects</b>				
DPT Laboratories	Galderma	First Generic Competition	Differin Cream 0.1%	Semi-solid & liquid manufacturing
Catalent	Abraxis Bioscience	to be acquired by Celgene Corp.	Abraxane	Commercial packaging
Lonza Group	Alnara	to be acquired by Eli Lilly	liprotamase	Fermentation

**Source:** The PharmSource Lead Sheet.

For more information, click here: [www.pharmsource.com/productsservices/ps-leadsheet](http://www.pharmsource.com/productsservices/ps-leadsheet).

## Business Conditions

### CRO Market Update: Optimism Resurges as Industry Begins to Bounce Back

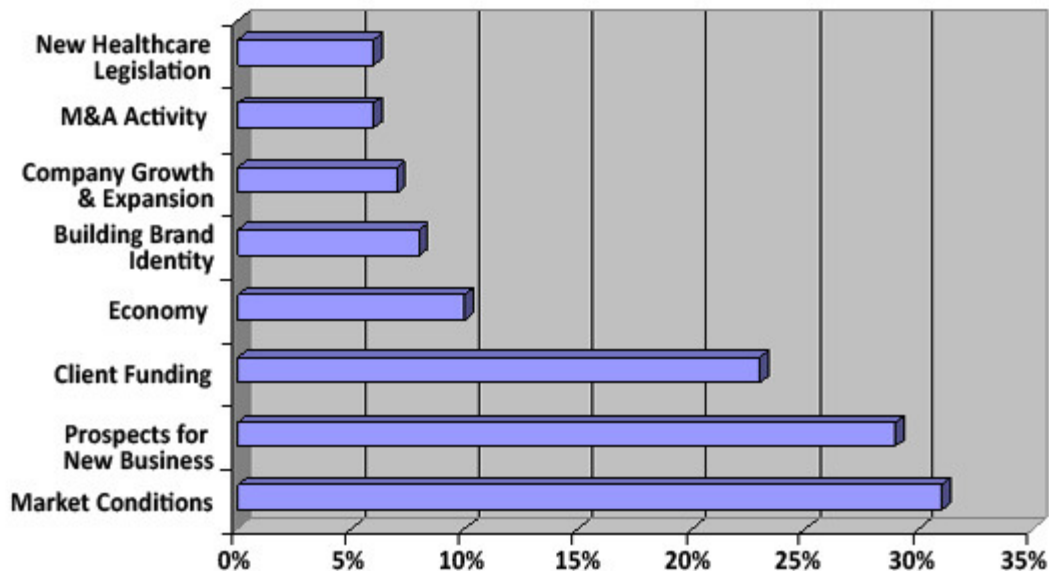
Optimism is rising in the CRO industry as buyers return to the market, according to exhibitors at last month's 2010 Drug Information Association (DIA) annual meeting in Washington, DC. DIA exhibitors are primarily CROs and other companies that support clinical trials.

In this year's PharmSource survey of DIA exhibitors, 74% of the survey participants responded that they are more optimistic about the state of the industry compared to one year ago. This is in sharp contrast with the 2009 survey, in which CROs were overwhelmingly anxious about the market in light of the faltering economic climate. The primary reasons cited for this rosier outlook included improved market conditions, growing prospects for new business and a better funding climate for clients.

*Continued on next page*

# Briefing

## Top Reasons for Optimism Regarding the CRO Market



Source: 2010 PharmSource DIA Survey

Overwhelmingly, participants commented that business is growing. Over half (58%) of the respondents cited an increased rate of RFP activity in H1 2010 compared to a year ago, and 51% revealed that the rate of new contract awards in H1 2010 relative to a year ago had also improved.

Interestingly, a closer look at the survey results by company size revealed that small companies (< 50 employees) remain more apprehensive than midsize (51-500 employees) and large (> 501 employees) companies. In fact, smaller companies had a less rosy outlook overall and were least likely to be optimistic about the state of the industry.

With economic conditions improving, CROs are addressing new challenges. This year, respondents cited competition and building brand identity as the primary challenges facing CROs in today's market. In addition, while competition grows, so does the importance of building brand identity for CROs – potential clients must know who they are and what they are able to offer.

*Subscribers to PharmSource ADVANTAGE received the complete version of this article which contains an in-depth analysis of the survey results, with a focus on the new challenges facing CROs and the growing apprehension among smaller service providers.*

*To read the full version of this article, sign-up for a free trial:*

[www.pharmsource.com/productsservices/pharmsource-advantage/request-pharmsource-advantage-test-drive](http://www.pharmsource.com/productsservices/pharmsource-advantage/request-pharmsource-advantage-test-drive).

Continued on next page

**PharmSource ADVANTAGE: Contractor Profile**

*Clinical Dose Manufacturing and Packaging in Brief*

## **AAIPharma Forms Strategic Alliance with CritiTech**

**AAIPharma Services** (Wilmington, N.C., USA) announced a strategic alliance with CritiTech, a nanotechnology company focused on the delivery of therapeutic molecules and compounds, to provide additional drug delivery options during early animal toxicology and clinical studies. CritiTech's technology, which improves the delivery of therapeutic molecules with low aqueous solubility, will allow AAIPharma to offer parenteral administration in addition to oral drug delivery.

### **AAIPharma Services Corp.**

**Headquarters:**

- **Wilmington, NC, USA**

**Services:**

- **Analytical Services**
  - ◆ **Analytical Chemistry and Stability**
  - ◆ **Biosafety and Product Characterization**
  - ◆ **Microbiology**
  - ◆ **Particle Characterization**
- **Clinical Dose Manufacturing and Packaging**
  - ◆ **Drug Delivery**
  - ◆ **Clinical Labels**
  - ◆ **Clinical Packaging and Distribution**
  - ◆ **Injectable Phase I/II CTM and Formulation**
  - ◆ **Solid, Semi-solid/Liquid Phase I/II CTM and Formulation**
- **Commercial Dose Manufacturing**
  - ◆ **Injectables Manufacturing**
  - ◆ **Solid Dose Manufacturing**
- **Consulting Services**
  - ◆ **Regulatory, Validation and QA Services**

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.

*Continued on next page*

## AAIPharma Services Corp.

Mergers/Acquisitions

News & Analysis

Known Clients

### Corporate Profile:

**Address:** 1817 Hall Drive  
 Wilmington, NC 28405 USA

**Voice:** 800-575-4224 , 910-254-7000

**Fax:** 910-815-2345

**Website:** [www.aaipharma.com](http://www.aaipharma.com)

**E-mail:** [services@aaipharma.com](mailto:services@aaipharma.com)

**Ownership:** Private: private equity or venture capital

**Parent Company:** Water Street Healthcare Partners

**Primary Business:** Contract Services

### Contract Business:

**Contract revenues:** \$50-99 million

**Number of employees:** 251-500

**Corporate Head contact:** Lee Karras  
 E-mail: [lee.karras@aaipharma.com](mailto:lee.karras@aaipharma.com)

**North American contact:** Jon Anstett  
 Voice: 910-254-7650  
 Fax: 910-815-2300  
 E-mail: [jonathan.anstett@aaipharma.com](mailto:jonathan.anstett@aaipharma.com)

Lonnie Barish  
 Voice: 925-803-1080  
 E-mail: [lonnie.barish@aaipharma.com](mailto:lonnie.barish@aaipharma.com)

**Trade shows:** AAPS Annual Meeting, AAPS Biotechnology, Interphex, PDA

### Contract Services:

#### Analytical Services

Analytical chemistry and stability  
 Biosafety and product characterization  
 Microbiology  
 Particle characterization

Wilmington, NC Facility  
 Wilmington, NC Facility  
 Wilmington, NC Facility  
 Wilmington, NC Facility

#### Clinical Dose Manufacturing and Packaging

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

Wilmington, NC Facility  
 Wilmington, NC Facility  
 Charleston, SC Facility  
 Wilmington, NC Facility

#### Commercial Dose Manufacturing

Injectables manufacturing  
 Solid dose manufacturing

Charleston, SC Facility  
 Wilmington, NC Facility

#### Consulting Services

Regulatory, Validation and QA Services

Wilmington, NC Facility

Continued on next page

**Briefing****AAI Pharma Services Corp.**

Charleston - SC - USA Facility  
 4221 Faber Place Drive  
 Charleston, SC 29405-8510 USA  
 Phone: 843-746-2500 Fax: 843-746-2550

FDA Number: 1055790

Size: 48,000 sq. ft.

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

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

**Project acceptance criteria*****Antibiotics***

Cephalosporin: No  
 Penicillin: No

***Controlled substances***

DEA schedule II: Yes  
 DEA schedule III, IV, V: Yes

***High potency and cytotoxic***

Cytotoxic materials: Yes  
 High potency - not specified: Yes  
 Hormones/steroids: Yes

***Vaccines and viruses***

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

***Other materials***

Proteins & peptides: Yes  
 Radiopharmaceuticals: No

**Development capabilities**

Formulation development (non-GMP): Yes  
 Lyophilization cycle development: Yes  
 Package/closure testing: Yes  
 Preformulation studies: Yes  
 Sterilization process development: Yes

**Vials and Ampules - Standard Potency - GMP*****Production scale***

Clinical (10,000-50,000 unit batch size): Yes

*Continued on next page*

**Briefing**

<b>Clinical batch size-vials:</b>	500 to 25,000 vials
<b>Early clinical (&lt;10,000 units, GMP):</b>	Yes
<b>Hand fills (GMP):</b>	Yes
<b>Number of compounding suites:</b>	4
<b>Number of GMP clinical fill suites:</b>	2
<b><i>Vial and ampule processing</i></b>	
<b>Aseptic fill:</b>	No
<b>Aseptic formulation:</b>	Yes
<b>Inert atmospheres:</b>	Yes
<b>Light sensitive:</b>	Yes
<b>Lipid formulations:</b>	Yes
<b>Oxygen sensitive:</b>	Yes
<b>Terminal sterilization:</b>	Yes
<b>Terminal sterilization technologies:</b>	Autoclave
<b>Vacuum drying:</b>	No
<b><i>Lyophilization</i></b>	
<b>Lyophilization capability:</b>	Yes
<b>Lyophilization capacity:</b>	54 sq. ft.

**Related services**

Clinical packaging and labeling:

Stability testing and storage:

**Regulatory approvals and certifications**

Europe - EMEA or constituent countries:

UK - MHRA:

USA - FDA:

**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.

**For a limited time only, we are offering new subscribers a 15% discount when you subscribe within 10 days of your test-drive.**

To take advantage of this special offer, simply click here:

[www.pharmsource.com/productsservices/pharmsource-advantage/request-pharmsource-advantage-test-drive](http://www.pharmsource.com/productsservices/pharmsource-advantage/request-pharmsource-advantage-test-drive) or contact Kasaundra Coleman at 703-383-4903 or [kasaundra@pharmsource.com](mailto:kasaundra@pharmsource.com).

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