

# BIO/PHARMACEUTICAL Outsourcing Report

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## BUSINESS CONDITIONS

### 2009 ENDS WITH SOME POSITIVE SIGNS FOR 2010

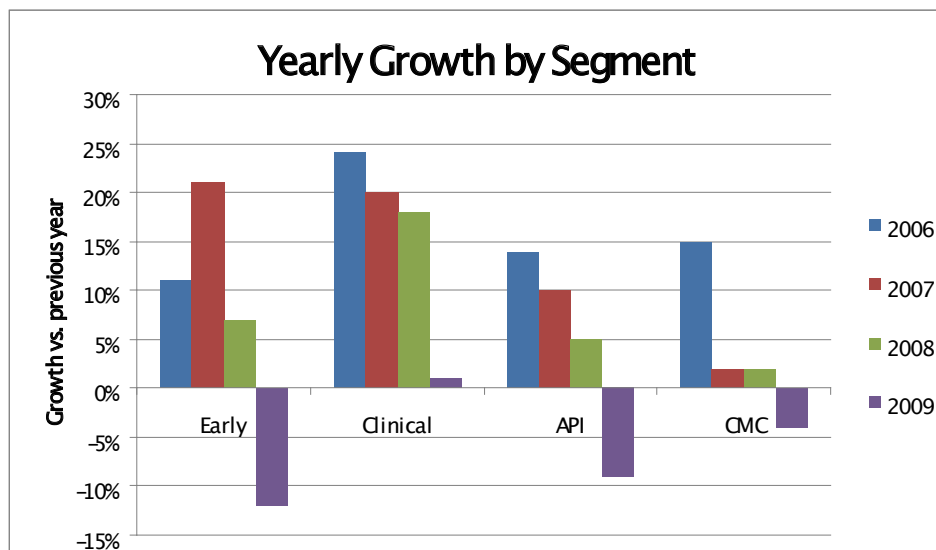
January marked the end of 2009, a bad year for all but the top contract service providers. Revenues at publicly traded CROs and CDMOs in the preclinical, API and CMC sectors declined significantly during the year due to reduced funding for startup companies and R&D cutbacks and inventory management at large bio/pharmaceutical companies. Revenues at publicly traded clinical CROs grew slightly during 2009, although that can be attributed to market share gains at a few of the top players.

The fourth quarter of 2009 turned out to be the best quarter of the year even though many companies and the entire preclinical sector still experienced a down quarter. Many of the largest contractors, however, performed well.

Revenues for CMC services grew by 7% during Q4 2009, mainly bolstered by strong results in Patheon, Catalent and Hollister-Stier's commercial manufacturing divisions. Multiple providers of injectables manufacturing and packaging services reported a boost during H2 2009 due to H1N1 influenza orders.

Demand for clinical CROs with global capabilities helped Covance's late-stage division, Parexel and Icon (the second- through fourth-largest public CROs) lead the clinical sector to positive growth in Q4 2009, even though the largest public CRO (PPD) posted a decline in revenues.

Demand for development services was still down significantly during Q4 2009 as evidenced by lower revenues almost across the board for preclinical CROs and process development and formulation CDMOs.



**What it means** →

The early indicators for 2010 provide some reason for optimism. New business signings at clinical CROs picked up in Q4 2009 after hitting a low in the third quarter. Book-to-bill ratios – the value of new contracts signed less cancellations – at the five biggest public clinical CROs grew 8% over Q3 2009 to 1.1, a figure that is still well below the boom years of 2007 and 2008, when book-to-bill ratios of 1.4 to 1.5 were common. While some of the pickup is certainly due to vendor consolidation, it is also a sign that large bio/pharmaceutical companies are returning their focus to R&D efforts after completing megamergers and pipeline reorganizations last year.

Project pipelines at many CDMOs are also growing. Sigma-Aldrich reported that the pipeline of projects at its SAFC unit grew significantly in 2009 and has approximately doubled since 2006 to almost 450 projects. Most of the growth in recent years has come from early development candidates (preclinical and Phase I), although late development projects (Phase II/III) swelled to almost 140 at the end of 2009. Hollister-Stier and Draxis Pharma's combined pipeline grew 20% in Q4 2009 vs. the previous quarter, with the addition of three new projects in both Phase I and Phase II and two new Phase III projects.

In addition, funding has picked up for small bio/pharmaceutical companies. According to the *PharmSource Lead Sheet*, venture capital investments in US-based startups climbed back over USD 1 billion in Q4 2009, the first quarter above that mark in at least two years. And the public market spout has opened again; the *PharmSource Lead Sheet* counted more than USD 3 billion raised via IPOs, secondary offerings and PIPEs last quarter.

Order volatility due to inventory management by bio/pharmaceutical companies is one issue that could continue to plague commercial suppliers in 2010. Many CMOs, most notably Lonza, were hit hard by delayed and canceled orders last year. Although analysis of inventory turns (a measure of inventory efficiency) reveals that both large and mid-size bio/pharmaceutical companies made some progress in 2009, there is still much room for improvement.

**User Tip**

The **PharmSource ADVANTAGE** contractor database allows subscribers to identify contract service providers based on capabilities and location. This portion of the database is organized according to several main categories of contract services including Analytical Services, API – Biomanufacturing, API – Small Molecule, Clinical Dose Manufacturing and Packaging, Commercial Dose Manufacturing, Commercial Packaging, Consulting Services, and Phase II-IV Clinical Services.

**To search by capability:**

- ◆ Log in to the **PharmSource ADVANTAGE** home page.
- ◆ In the “Contract Service Providers” box, select one of the main categories of contract services listed by clicking on the gray arrow at the right-hand side of each category.
- ◆ Choose one of the types of services listed under the main contract services category.
- ◆ The number of contractors in the database that provide this service will be displayed at the top left-hand side of the screen. In addition, criteria to refine the search will also be displayed. Subscribers have the option to search by country, region, contract revenue range, regulatory approvals and certifications, as well as specific capabilities. Once the criteria have been chosen, select “Search With Added Criteria” at the upper right-hand side of the screen.
- ◆ A chart displaying all the contract service providers in the database that meet the selected criteria will be displayed on the screen. The chart will also include information on the location of the provider, the facility that offers the specific type of service requested and the provider's contract revenue range.

**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</b>				
Anderson Packaging	Somaxon Pharmaceuticals	FDA approval	Silenor	Commercial packaging
Catalent Pharma Solutions	Intermune	MAA filed	pirfenidone	Solid dose manufacturing
Contract Pharmaceuticals Ltd. (CPL)	Medivir	US marketing agreement signed with Meda	Xerese	Semisolid manufacturing
Patheon	Somaxon Pharmaceuticals	FDA approval	Silenor	Solid dose manufacturing
Solvay (Abbott) Injectables	Watson Pharma	FDA approval	diluent for Trelstar	Injectables manufacturing
<b>Potentially Negative</b>				
3M Drug Delivery Systems	Graceway Pharmaceuticals	Generic competition (ANDA approval)	Aldara Cream	Semisolid manufacturing
Ash Stevens	Celgene	Negative recommendation for reimbursement by NICE	Vidaza	Small molecule API manufacturing
Baxter BioPharma Solutions	Cadence Pharmaceuticals	Complete response letter from FDA	Acetavance	Injectables manufacturing
Baxter BioPharma Solutions	Celgene	Negative recommendation for reimbursement by NICE	Vidaza	Injectables manufacturing
Ben Venue Labs	Celgene	Negative recommendation for reimbursement by NICE	Vidaza	Injectables manufacturing
Ben Venue Labs	TopoTarget	product to be acquired by SpePharm	Savene	Injectables manufacturing
Catalent Pharma Solutions	Celgene	Negative recommendation for reimbursement by NICE	Vidaza	Commercial packaging
Hyaluron Contract Manufacturing	Novelos Therapeutics	Development discontinued	NOV-205	Injectables manufacturing
Oregon Freeze Dry	Novelos Therapeutics	Development discontinued	NOV-205	Lyophilization services
Synthetech	Novelos Therapeutics	Development discontinued	NOV-205	Small molecule API manufacturing

Source: PharmSource Lead Sheet

**COMMERCIAL DOSE MANUFACTURING**

**BioVectra** (Charlottetown, Prince Edward Island, Canada) entered an agreement with **Sandoz** (Princeton, N.J., USA). According to the terms of the agreement, Sandoz will commercialize and market the ANDA for docetaxel injection, which was filed in June 2009. In addition, BioVectra agreed to extend the marketing rights of Sandoz within the United States.

**Capsugel** (Morris Plains, N.J., USA) plans to undergo a USD 15 million expansion project, according to local publications in Greenwood, S.C., USA. The expansion will create 50 new jobs at Capsugel's soft gelatin capsule manufacturing facility in Greenwood, as well as add 14,500 square feet of new office, lab and manufacturing space at the site.

**DPT Laboratories** (San Antonio, Texas, USA) restructured its operations, creating three Centers for Excellence – one dedicated to sterile and specialty products in Lakewood, N.J., USA; one dedicated to semisolids and liquids in San Antonio, Texas, USA; and another dedicated to research and development in San Antonio, Texas, USA. Both the sterile and specialty products center and the semisolids and liquids center will provide manufacturing for clinical trial material and commercial scale products. The research and development center will provide preformulation and formulation development as well as analytical development services.

**Excella Pharma Source** (Feucht, Germany), a subsidiary of **Fareva** (Quetigny, France), entered a partnership with **Atacama Labs** (Helsinki, Finland) to jointly market and sell Atacama's pneumatic dry granulation technology for granule and tablet manufacturing services.

**Haupt Pharma** (Berlin, Germany) successfully underwent an FDA inspection at its Latina site in Italy. The company is now approved to manufacture two sterile penicillin antibiotics for the U.S. market.

**Hollister-Stier Laboratories** (Spokane, Wash., USA) and **Draxis Specialty Pharmaceuticals** (Kirkland, Quebec, Canada), two North American manufacturing operations of **Jubilant Organosys** (Noida, India), successfully underwent inspections. Hollister-Stier Laboratories completed an audit by the Japanese Pharmaceutical and Medical Devices Agency (PMDA) for a client's sterile injectable product. Draxis Specialty Pharmaceuticals completed an audit by the FDA and Health Canada.

**Patheon** (Durham, N.C., USA) entered an agreement with Orexigen Therapeutics to provide commercial manufacturing services for Contrave, Orexigen Therapeutics' obesity drug candidate. The agreement also includes development services for future formulations of products produced by Orexigen Therapeutics.

**Stirling Products Limited** (Sydney, Australia) acquired a manufacturing facility in Cape Breton, Nova Scotia, Canada, for USD 3.85 million. Stirling Products provides contract manufacturing services for pharmaceutical and natural health products, including generic drugs. The company also produces its own proprietary products.

The newly acquired 46,400-square-foot cGMP facility contains a laboratory; auto mixing units with a 3,000 kg maximum capacity; and two fully automated filling, labeling and packaging lines. It contains a 10,600-square-foot drug manufacturing plant that has an annual capacity to manufacture and package 550 million tablets and 5 million bottles and blend 1.5 million kg of product. It also has granulating and grinding capabilities.

The facility previously belonged to Keata Pharma, the wholly owned manufacturing subsidiary of PharmEng, which filed for bankruptcy in 2009.

CLINICAL DOSE MANUFACTURING AND PACKAGING

**Almac** (Craigavon, UK) is currently building two new laboratories as a part of its USD 120 million North American headquarters in Souderton, Pa., USA. The laboratories will provide analytical and solid-state chemistry services. Almac is also expanding its radiolabeling facilities to include carbon-14 API and IMP services. In addition, Almac's facility in Durham, N.C., USA, successfully underwent an FDA inspection.

**Bilcare Global Clinical Supplies** (Pune, India) opened a second unit at its Crickhowell, UK site. The 30,000-square-foot unit doubled Bilcare's capacity to package, store and distribute clinical supplies in Europe.

**Biovian** (Turku, Finland) expanded its aseptic filling capacity with the addition of two stand-alone automated filling lines. The first line is designed for aseptic filling of small batches of cytotoxic and other hazardous compounds in vials. The second accommodates a higher capacity and will be used for the aseptic filling of recombinant proteins or antibody products in vials. Vial sizes range from 2 ml to 15 ml. Lyophilization and sterile manufacturing services are both offered in addition to dilution, formulation, QC testing, labeling, color coding, packaging and warehousing, as well as QP release and delivery.

**Nerviano Medical Sciences'** (Nerviano, Italy) facility successfully underwent an FDA inspection for the manufacture of Cell Therapeutics' drug pixantrone. Cell Therapeutics has an NDA currently under review for pixantrone as a treatment for relapsed/refractory aggressive non-Hodgkin's lymphoma.

**NextPharma Technologies** (Send, UK) announced a EUR 2.4 million (USD 3.2 million) investment to upgrade its sterile vial area at its facility in Braine-l'Alleud, Belgium. The new area, which is expected to be operational by the end of the year, will provide services for both solution and lyophilized vials of noncytotoxic products. The facility's portfolio currently includes services for ampoules, eyedrops and cytostatics in vials.

**Pharmatek Laboratories** (San Diego, Calif., USA) received DEA registration for the development and manufacture of Schedule IV and V controlled substances.

**Spotlight on AMRI**

AMRI recently presented at the Informex Exhibitor Showcase held last February in San Francisco, Calif., USA. The presentation focused on AMRI's solid dose formulation development and clinical manufacturing capabilities. The message was that AMRI is a "one-stop shop" for early clinical requirements, given its extensive API development and manufacturing capabilities and dose capabilities. The presentation also emphasized AMRI's preformulation, materials science and analytical capabilities.

AMRI's equipment for solid dose formulation and clinical manufacturing includes:

- ◆ Xcelodose
- ◆ V-blending
  - ◆ 0.5 quart to 16 quart scale
- ◆ Roller compaction/dry granulation
- ◆ Glatt TMG high-shear wet granulation
  - ◆ Jacketed
  - ◆ Spray agglomeration binder capability
- ◆ Glatt mini-fluid unit
  - ◆ Dry, granulator, coater
  - ◆ 5 gram to 350 gram
- ◆ Tableting
  - ◆ SMI Mini 6,000 tablets/hour
  - ◆ As little as 1-2 grams of material

*For more information on the business and capabilities of Albany Molecular Research Inc. (AMRI), click on this box or go to [www.pharmsource.com](http://www.pharmsource.com) and search by company name. If you need your access codes, just call 1-703-383-4903 (ET).*

**SCM Pharma** (Northumberland, UK) was selected by Auralis to provide manufacturing services for Buccolam, an oromucosal solution of midazolam hydrochloride that is designed to treat pediatric epilepsy. SCM Pharma will provide filling, packaging, labeling and delivery to clinical trial sites throughout Europe. The liquid product will be produced in prefilled syringes at varying dosages.

**SurModics Pharmaceuticals** (Birmingham, Ala., USA) submitted a Notice of Termination of a Product License Agreement to Ambrilia Biopharma. The agreement, originally dated November 20, 2001, was for the development, manufacture and sale of a sustained-release formulation of octreotide.

SurModics Pharmaceuticals provides development and manufacturing services. Parent company, SurModics Inc., provides drug delivery and surface modification technologies to the medical device and bio/pharmaceutical industry.

#### API – BIOMANUFACTURING

**Advanced BioScience Laboratories** (Kensington, Md., USA) entered into a contract with NovaDigm Therapeutics to develop and optimize cellular immunological assays for fresh and frozen murine splenocytes in support of NovaDigm's NDV-3 vaccine development program for *Candida* and *Staph aureus*.

**Angel Biotechnology** (Northumberland, UK) signed two additional clinical-scale stem cell manufacturing contracts with ReNeuron to produce ReN001, a stem cell therapy for stroke patients, for the clinical trial Pilot Investigation of Stem Cells in Stroke (PISCES) and to provide manufacturing process validation services.

**VGXI** (The Woodlands, Texas, USA) announced the expansion of its cGMP plasmid manufacturing facility. VGXI provides DNA plasmid manufacturing and development services for DNA vaccine and gene therapy research.

**Vivalis** (Nantes, France) granted Kyoto Biken Laboratories, a Japanese-based manufacturer of veterinary vaccines, the rights to its duck embryonic stem cell-derived line EB66. Kyoto Biken plans to evaluate the cell line for the manufacture of viral vaccines.

Vivalis offers manufacturing services for vaccines and proteins using its proprietary cell-based products and platforms. The company also develops drugs for the prevention and treatment of viral diseases.

**Wacker Fine Chemicals** (Munich, Germany) completed a USD 24.5 million expansion of its biologics production facility in Jena, Germany. Wacker doubled its GMP manufacturing capacity and added a new facility for product purification as well as a laboratory for process development and quality control. Prior to the expansion, the facility had reactor sizes from 20L to 300L. Future expansions to 1500 L are planned. The facility will utilize Wacker's proprietary technology for biologics production, Esetec and Densetec.

Wacker Chemie also announced that the Wacker Fine Chemicals division has been renamed **Wacker Biosolutions**.

**Xcellerex** (Marlborough, Mass., USA) signed an agreement with Humacyte to provide development and manufacturing services for Humacyte's vascular grafts, using Xcellerex's XDR single-use bioreactor system. The initial grafts will be used for preclinical testing.

## API – SMALL MOLECULE

**SAFC EXPANDING API AND BIOLOGICS CAPABILITIES**

**SAFC** (St. Louis, Mo., USA) is in the midst of a USD 90 million project to expand its API production and biologic capabilities. The company's USD 30 million expansion of its commercial-scale high potency manufacturing capacity in Madison, Wis., USA, is scheduled to be completed by the end of Q1 2010. The 51,000-square-foot facility will contain two 100L cGMP suites, a suite containing two 2,000L reactors, and an additional suite with two 4,000L reactors. SAFC also invested USD 4.5 million to increase cGMP pilot plant and large-scale kilogram laboratory HPAPI capacity at the Madison facility.

As a part of its expansion efforts, SAFC is also investing USD 29 million in its capability to manufacture large-scale quantities of bacterial and fungal fermentation-derived biologic HPAPIs. Scheduled to be completed by H1 2010, the 50,000-square-foot facility will be dedicated to the production of secondary metabolites, cytotoxins and large-molecule proteins.

SAFC recently invested USD 12 million to expand its manufacturing facility for viral products in Carlsbad, Calif., USA, and commissioned a suite for the manufacture of HPAPI conjugates in St. Louis, Mo., USA.

*For more information on the business and capabilities of SAFC, click on this box or go to [www.pharmsource.com](http://www.pharmsource.com) and search by company name.*

**API – Small Molecule in Brief**

**Albemarle** (Baton Rouge, La., USA) entered into a partnership with **PharmaCore** (High Point, N.C., USA) to provide manufacturing services to PharmaCore clients requiring high-volume capacity. PharmaCore's service portfolio includes custom synthesis, chemical process research and development, cGMP API manufacturing, medicinal chemistry, analytical testing, and development of molecular building blocks.

**AMPAC Fine Chemicals** (Rancho Cordova, Calif., USA) entered into a collaboration with Codexis to obtain access to Codexis' biocatalysis technologies. AMPAC also entered into a partnership with the chemical division of the Japanese company Inabata. The deal is structured to provide AMPAC with access to the Japanese pharmaceutical market, while Inabata is afforded access to AMPAC's technologies for its API manufacturing operations.

**Cambridge Major Laboratories** (Germantown, Wis., USA), **Xcelience** (Tampa, Fla., USA), **Beckloff Associates** (Overland Park, Kan., USA) and **Avantium Pharma** (Amsterdam, the Netherlands) have formed a consortium, Chemistry Playbook, to offer CMC services designed to accelerate drug development. Each partnering company provides specific capabilities to the consortium - API production from Cambridge Major, solid-state characterization from Avantium, formulation development from Xcelience and CMC regulatory oversight from Beckloff.

**Carbogen AMCIS** (Bubendorf, Switzerland) announced the appointment of Mojmir Vavrecka as chief operating officer.

**Dottikon Exclusive Synthesis** (Dottikon, Switzerland) announced that it plans to shorten the hours of operation at some sections in its plant in response to fluctuations in capacity utilization.

**Evonik Degussa** (Parsippany, N.J., USA) acquired Membrane Extraction Technology, a company that specializes in chemical separation services for the pharmaceutical and fine chemicals industries.

**Isochem** (Paris, France) was acquired by German private equity group Aurelius for an undisclosed amount. Isochem develops chemical processes and produces fine chemicals for the pharmaceutical, plant protection, and polymer/specialty chemical industries. The company offers cGMP API manufacturing services at a site dedicated to the production of pharmaceuticals in Paris.

## ANALYTICAL SERVICES

## PPD CONTINUES GEOGRAPHIC EXPANSION WITH SITE IN ATHLONE, IRELAND

PPD (Wilmington, N.C., USA) expanded its European presence with the opening of a USD 19 million contract research facility in Athlone, Ireland. The 18,000-square-foot site includes an analytical testing laboratory and clinical supplies business. It will offer analytical services for all phases of drug development, including method development; validation; and stability, release and quality control testing. PPD will also provide secondary packing, labeling and storage services as well as regulatory services and support for product licensing and marketing. In addition, the facility's portfolio, which has been designed to specialize in inhalation and biopharmaceutical products, will include qualified person services for all drug dosage forms.

The Athlone site, now under consideration by the Irish Medicines Board, is currently being staffed by 21 employees. However, PPD announced plans to create 250 more jobs to fully staff the facility.

When commenting on the selection of Ireland as the home of its latest facility, Magdalena Mejillano, vice president of laboratory services at PPD, explained that the country has a highly skilled work force coupled with a business-friendly climate. Mejillano pointed out that Athlone itself has a growing bio/pharma sector. In fact, PPD recently expanded its medical communications safety call center operations in the town.

*For more information on the business and capabilities of PPD Inc., click on this box or go to [www.pharmsource.com](http://www.pharmsource.com) and search by company name.*

## ONE-YEAR POST-ANALYSIS OF COVANCE/LILLY ALLIANCE

Covance (Princeton, N.J., USA) announced a one-year post-analysis of its strategic alliance with Eli Lilly. Last year, Covance acquired Lilly's preclinical research facility in Greenfield for USD 50 million, hiring the majority of Lilly employees at the site and assuming all of Lilly's toxicology testing and discovery support services there. Lilly also agreed to contract USD 1.6 billion of drug development services with Covance over a 10-year period.

The analysis indicated that 95% of Lilly employees accepted positions at Covance. Covance hired 70 other employees and plans to add an additional 300 people to its workforce in the near future to accommodate growing demand. The company plans to upgrade and expand its animal testing facility.

In addition, both companies entered into a three-year biotechnology services agreement in January 2010. Under the terms of this agreement, Lilly plans to transfer analytical testing for biological drugs to a new USD 15 million biotech facility currently under construction at the Greenfield site. Covance plans to hire 20 additional Lilly employees to work at this facility.

*For more information on the business and capabilities of Covance Inc., click on this box or go to [www.pharmsource.com](http://www.pharmsource.com) and search by company name.*

## *Analytical Services in Brief*

**PPD** (Wilmington, N.C., USA) and **Southern Research Institute** (Birmingham, Ala., USA) entered into a collaborative agreement to offer customers influenza vaccine development services. Under the terms of the collaboration, Southern Research Institute will transfer its seasonal assays and reagents to PPD, while PPD will provide client referrals to Southern Research Institute's preclinical influenza and clinical pandemic/highly pathogenic avian influenza testing business.

### EARLY DEVELOPMENT

**Chiltern International** (Berkshire, UK) and **Charles River Laboratories** (Wilmington, Mass., USA) entered a partnership to conduct and support early phase radiolabeled studies. Chiltern's Early Phase division will manage clinical aspects of the studies at its site in Dundee, Scotland.

**NexMed** (San Diego, Calif., USA), the parent company of **Bio-Quant** (San Diego, Calif., USA), raised USD 2.3 million in a private placement of promissory notes from two investors in the US. The company also received approval for the sale of its New Jersey tax losses, which will generate approximately USD 438,000 in net proceeds. NexMed plans to use the funds to expand its NexACT delivery technology into the oral and biologics transdermal delivery market and for general corporate purposes.

**Quintiles Transnational Corporation** (Durham, N.C., USA) expanded its research facility in London, UK. The company added 35 Phase I beds at the site dedicated to translational medicine. Quintiles now has 105 beds in London and 385 globally. In late 2010, the company plans to add an additional 50 beds with the opening of a Phase I unit in Hyderabad, India.

### PHASE II-IV CLINICAL RESEARCH

**Kendle International** (Cincinnati, Ohio, USA) entered a USD 35 million secured revolving credit facility with JPMorgan Chase Bank. The facility can later be increased by up to USD 15 million, dependent on the consent of the lender or additional lenders.

**Quintiles Transnational Corporation** (Durham, N.C., USA) announced the relocation of its central laboratory in Japan from Saitama to Tokyo, allowing for an expansion of testing capabilities at the site. The site also received Level 1 certification for diabetes testing from the National Glycohemoglobin Standardization Program.

### DRUG DISCOVERY

## **RICERCA EXPANDS DISCOVERY CAPABILITIES WITH FINALIZATION OF MDS PHARMA SERVICES ACQUISITION**

This month, **Ricerca Biosciences, LLC** (Concord, Ohio, USA) finalized its deal with **MDS Pharma Services** (MDSPS – Saint-Laurent, Quebec, Canada) to purchase the discovery and preclinical business of MDSPS for USD 35 million. The acquisition allows Ricerca to add molecular profiling, pharmacology/DMPK and drug safety assessment services to its portfolio, which already includes capabilities in discovery and medicinal chemistry, API process chemistry, cGMP manufacturing and scale-up, as well as IND-enabling toxicology.

“Over the past five years, Ricerca has been making an attempt, quite successfully, to differentiate our capabilities in the marketplace, in contrast to other key providers. We offer a very interesting mix of chemistry and biology services and [we recognize that] it is unique to have a CRO with competencies in both,” commented Ian Lennox, chairman and CEO of Ricerca, to PharmSource. “Our goal has been to offer our clients services very early on from the IP stage all the way through the delivery to IND.” The company has been in the middle of a deliberate attempt to assemble both chemistry and biology capabilities and offer these services to its target clientele, mid-size pharma companies down to smaller biotech firms. Ricerca executives believe that this sector of the market has the strongest growth potential over the next five years.

While it may appear as if Ricerca is backward integrating into discovery services with this acquisition, Lennox asserts that this is not the case. “We are not backward integrating into discovery but rather adding the ability to screen the compounds before making them. It will enable us to be more involved with our clients [as] we will be able to screen compounds *in vitro* to determine which will move forward. This capability fits nicely with the front end of our chemistry business,” Lennox explained.

“Previously, we also couldn’t take our clients to the next step of making [small quantities of] the compound for preliminary safety testing. Clients would have to use another contract service provider for this; [however,] now [they] have the opportunity to outsource with one provider and get drug candidates without having to go to two or three different sources.”

As a part of the acquisition, Ricerca gains facilities in Bothell, Wash., USA; Lyon, France; and Taipei, Taiwan. The Bothell and Taipei sites offer discovery services, while the Lyon site specializes in preclinical toxicology and safety pharmacology testing. “Our clients were looking for these services. [Plus, we] now have drug safety assessment capabilities in Europe. Not only does this provide us with a geographical advantage but it will significantly improve our drug safety and toxicology services in North America as well,” Lennox stated.

### *A Larger Geographic Reach*

The MDSPS acquisition also allows Ricerca to nearly triple its work force to 850 employees worldwide and serves to radically enhance Ricerca’s geographic reach while diversifying its mix of clients. “We have added a European presence and doubled our Asian presence with this deal,” emphasized Lennox.

In fact, prior to the acquisition, Ricerca’s clientele was approximately 85% to 90% North American and 5% to 10% Asian. The company had no European clients. However, with the MDSPS deal, the company’s clientele will be more evenly distributed and better mimic the overall industry, with 50% of its clients coming from North America, 35% from Europe and 15% from Asia.

The MDSPS deal is also a crucial aspect of Ricerca’s strategy for the Asian Pacific region. In fact, 20% of its work force will now be based in Asia. “Taiwan is an important element in Asia, which is continuing to develop and will have a strong pharma basis. We now have capabilities in their time zone and will be well-positioned for the significant growth expected in Asia. The Taipei facility is an important element in our five- to 10-year strategy and [provides us with a] foothold in the region,” explained Lennox.

The Taipei facility currently does a significant amount of *in vitro* profiling with a turnaround time of five to seven days. “With 80% of our business now in North America and Europe, the Taipei facility provides us with fast turnaround, knowledge and information needed to screen compounds quickly,” said Lennox. Over the next 18 months, Ricerca plans to build up its capabilities at the Taipei site, providing it with the ability to synthesize compounds as well. “The Taipei facility will eventually look like the Ricerca facilities in North America. We want to provide both chemistry and biology services to take care of clients in that area as well,” explained Lennox, who is currently planning a trip to the site in April or May 2010 to determine which capabilities need to be added to reach the company’s goals for the facility.

### *Strong and Moving Forward*

Ricerca believes that the MDSPS deal leaves it well positioned for the future and makes it more competitive among other providers that offer services to small and mid-size bio/pharma companies. In fact, not only did the MDSPS acquisition allow Ricerca to expand its service offerings, but the company did not sacrifice its financial health to do so and believes this to be an important part of its overall position in the industry. “We incurred no debt with this transaction; it was completely financed through our equity partners. The Ricerca balance sheet of financial health is very good. While many of our competitors are getting hurt with limited access to capital, Ricerca is fully financed and debt-free. This is a huge competitive advantage for us,” concluded Lennox.

*For more information on the business and capabilities of Ricerca Biosciences LLC, click on this box or go to [www.pharmsource.com](http://www.pharmsource.com) and search by company name.*

## LONZA EXPANDS DRUG DISCOVERY SERVICES WITH ODYSSEY THERA ALLIANCE

**Lonza** (Basel, Switzerland) entered an alliance with Odyssey Thera to make Odyssey Thera’s protein-fragment complementation assay technology a part of Lonza’s compound profiling services. The technology works by evaluating lead compounds against a panel of cellular pathways to produce a unique cellular signature. This signature is compared with a database of other known compounds to pinpoint compound selectivity and potential side effects. The addition of this capability will enable Lonza to offer target identification, screening and predictive ADME.

As a part of the agreement, Lonza obtained exclusive global technology licenses and the two companies will collaborate on technology, product development and marketing. In addition, Odyssey Thera received equity investment and will be eligible to receive technology development funding, milestones and royalties on future sales of the product and services. Additional payments may also be due to Odyssey Thera upon option exercise. As a result of the equity investment, Lonza is now a minority shareholder in Odyssey Thera.

*For more information on the business and capabilities of Lonza Group, click on this box or go to [www.pharmsource.com](http://www.pharmsource.com) and search by company name.*

### OUTSOURCING EVENTS

**Pharma Asia – International Exhibition & Conference 2010**  
 April 2-4, 2010,  
 Karachi, Pakistan  
[www.pharmaasia.com.pk](http://www.pharmaasia.com.pk)

**Pharma Outsourcing Congress 2010**  
 April 8-9, 2010, Munich, Germany  
[www.selectbiosciences.com/conferences/POC2010/](http://www.selectbiosciences.com/conferences/POC2010/)

**Partnerships in Clinical Trials**  
 April 12-14, 2010, Orlando, Fla., USA  
[www.iirusa.com/cropartners/welcome-to-CROs.xml](http://www.iirusa.com/cropartners/welcome-to-CROs.xml)

**INTERPHEX 2010**  
 April 20-22, 2010, New York, N.Y., USA  
[www.interphex.com](http://www.interphex.com)

**ICSE & CPhI JAPAN 2010**  
 April 21-23, 2010, Tokyo, Japan  
[www.icsejapan.com/eng/](http://www.icsejapan.com/eng/)  
[www.cphijapan.com/eng/](http://www.cphijapan.com/eng/)

**LogiPharma Europe 2010**  
 April 27-29, 2010, Geneva, Switzerland  
[www.wbresearch.com/logipharmaeurope/](http://www.wbresearch.com/logipharmaeurope/)

**BIO 2010 Annual Convention**  
 May 3-6, 2010, Chicago, Ill., USA  
<http://bio.org/events>

**Current Challenges in Clinical Trial Materials**  
 May 5-6, 2010, Iselin, N.J., USA  
[http://www.jeiven.com/advanced\\_topics\\_in\\_CTM\\_brochure.htm](http://www.jeiven.com/advanced_topics_in_CTM_brochure.htm)

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#### OUTSOURCING EVENTS

**8th Annual Sales Force Effectiveness USA 2010 Summit** May 17-18, 2010, Princeton, N.J., USA  
[www.eyeforpharma.com/sfeusa/index.shtml](http://www.eyeforpharma.com/sfeusa/index.shtml)

**API China 2010**  
May 18-20, 2010, Harbin, China  
<http://en.apichina.com.cn/>

**INTERPHEX Asia 2010**  
June 7-8, 2010, Suntec City, Singapore  
[www.interphexasia.com](http://www.interphexasia.com)

**46th DIA Annual Meeting**  
June 13-17, 2010, Washington, D.C., USA  
[www.diahome.org](http://www.diahome.org)

**5th Annual Global Pharma Manufacturing Summit**  
June 14-15, 2010, Boston, Mass., USA  
[www.gpmsummit.com](http://www.gpmsummit.com)

**API Global Sourcing Strategies 2010**  
June 29-30, 2010, Berlin, Germany  
[www.api-source.com](http://www.api-source.com)

**PHARMA JAPAN: 4th International Pharmaceutical Ingredients Japan 2010**  
June 30-July 2, 2010, Tokyo, Japan  
[www.pijapan.jp/pijapan/english/index.phtml](http://www.pijapan.jp/pijapan/english/index.phtml)

**5th East Coast Clinical Supply Chain Management Conference**  
July 29-30, 2010, Princeton, N.J., USA  
[www.cbinet.com](http://www.cbinet.com)

**Partnerships in Clinical Trials Latin America**  
August 2-4, 2010, Buenos Aires, Argentina  
[www.iirusa.com/clinicalpartnershipslatinamerica/home-page.xml](http://www.iirusa.com/clinicalpartnershipslatinamerica/home-page.xml)

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