

# BIO/PHARMACEUTICAL Outsourcing *Report*

PHARMSOURCE™

## Inside this issue

<b>Business Indicators</b> .....	2
<b>Outsourcing Strategies</b>	
Outsourcing IRB Review	
Growing as Viable Option	
For Busy Sites .....	3
<b>Best Practices</b>	
Simplifying LIMS	
Implementation .....	4
<b>Company Update</b>	
DPT Denies Bradley	
Charges .....	6
<b>Industry News</b> .....	6
<b>Outsourcing Events</b> .....	8



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## Business Conditions

### More Signs of Market Softness

The stock prices of two publicly traded contractors took a big hit this month when the companies reported signs of the softening market for contract services. Both Inveresk and Patheon saw declines in the price of their stock.

Inveresk Research Group Inc. (Research Triangle Park, N.C.), a provider of preclinical and clinical research services, warned its Montreal preclinical testing operations have been experiencing “volatility” in the flow of short-term toxicology work. The company said the work slowdown, coupled with the impact of the weakening U.S. dollar on reported financial results, would reduce first-quarter earnings by between one cent and three cents per share.

Inveresk stressed that it traditionally experiences fluctuations in first-quarter activity as pharmaceutical companies formulate programs for the new year and that new business signings remain strong. Nevertheless the company’s stock price dropped 25% after the release of the warning, and Inveresk was forced to withdraw a previously announced secondary offering of 10.2 million shares of its common stock.

Contract dose manufacturer Patheon Inc. (Toronto, Canada) reported growth in revenues and profits for its first quarter (ending January 31, 2003), but its stock price still took a 20% hit. Total revenues were up 31% to

CAD 123.1 million, but 42% of that growth was due to the impact of acquiring the Aventis site in Cincinnati, Ohio, last year, and 20% was due to favorable exchange rate movements. Organic growth was just 12%, most of that in Europe, where the commissioning of Patheon’s new lyophilization units has been a strong revenue driver. Organic growth in North America was just 2%.

The market softness was reflected in Patheon’s Pharmaceutical Development Services unit. European development revenues grew 192% from a tiny base of CAD .5 million in 2002 to CAD 1.5 million in 2003, but North American revenues, which account for 85% of total development revenues, grew just 1% to CAD 9.5 million. Like at Inveresk, executives blamed traditional first-quarter weakness and projected strong results for the rest of the year.

The Inveresk and Patheon reports confirmed what *B/POR* heard at the recent Informex trade show in New Orleans—business is soft, not just for API manufacturers, but for most companies offering preclinical and CMC development services. Contractors seem somewhat perplexed by the downturn, but it’s hard to understand why. Big pharma pipeline problems and the lack of financing for early-stage companies have been widely publicized and discussed, so why are contractors surprised they are feeling the impact of those developments?

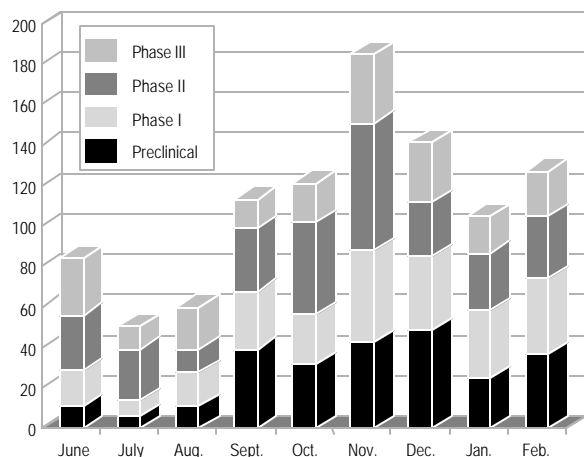
Undoubtedly, translating macro trends into annual budget projections is tricky business. Yet making projections based on previous years' results can be dangerous, especially when previous years have been very robust and the potential for major shifts is so apparent. Contractors have failed to recognize the all-out efforts that small companies are making to

conserve cash, principally by slowing the development programs for many of their candidates. It is not uncommon, for instance, for a company with five development candidates to halt three of them to conserve cash until financial market conditions improve. Multiply that times hundreds of companies, and it's not hard to understand why CROs are feeling the pinch. ♦

## Business Indicators

As part of PharmSource's efforts to monitor business conditions for the contract service industry, we have developed key indicators of market elements that underlie demand for contract services. The data is extracted from our **Contractor's Lead Sheet** service, a business development tool for contract service providers.

### Number of Product Announcements

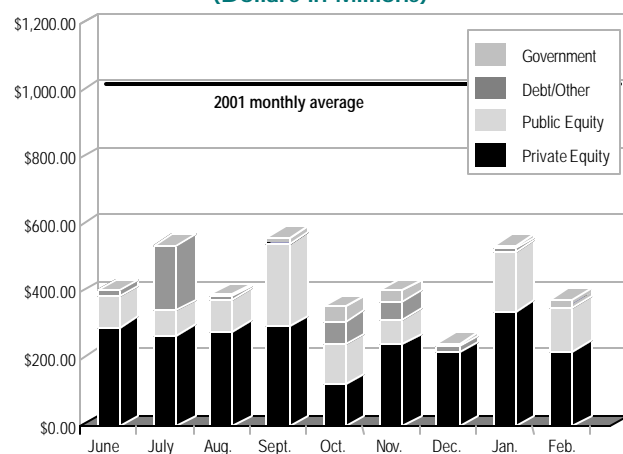


"Product Announcements" is an indicator of preclinical and clinical research activity. It tracks announcements of therapies in the development pipeline by stage, including products advancing into later development stages, new clinical trial starts, and new regulatory designations (e.g., orphan drug and fast-track status).

As might be expected, product announcements peaked toward year-end, after being slow during the summer.

This is consistent with industry experience, because sponsors often push to show development progress as part of their year-end reporting. Phase II announcements dropped off sharply after the late-year push, but early-stage activity seems fairly constant.

### Bio/Pharma Fundraising (Dollars in Millions)



"Bio/Pharma Fundraising" tracks the ability of small and mid-size pharmaceutical and biopharmaceutical companies to raise capital. As has been widely reported, investment in the sector has been trending downward, and it has been only 40% of what it was in 2001. Public equity has been scarce, and debt financing has all but dried up. Private placements, which include venture capital investments and private placements of public equities, have been the most consistent cash source, though month-to-month amounts have varied considerably since October. ♦

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### Outsourcing IRB Review Growing as Viable Option for Busy Sites

Outsourcing for clinical trial management is commonplace. But historically most have viewed the review and approval of protocols as tasks best left in the hands of local institutional reviewers. Now a growing number of sites are choosing to outsource at least some of their human subject protection program responsibilities. The chief reason is increased scrutiny from the feds.

“It was just the right decision at the right time for us,” explains David Stanley, executive director, integrated specialist, at St. Agnes Health Care, in Baltimore, Maryland. “The chairman of our IRB was retiring, we were feeling the increased burden of federal regulations, and we could not respond quickly to investigator submissions,” he says.

St. Agnes is a health system that includes an urban hospital. Most of the more than four dozen research protocols it approves each year are for drug studies in common disease areas, such as asthma, diabetes, and cardiovascular disease. According to Stanley, research is important to the medical community at St. Agnes. “We have medical and surgical residency programs, and these physicians want to be able to do research,” he notes.

But the all-volunteer IRB at St. Agnes was feeling the crunch of increasing regulation and burgeoning protocols. Because it often took two months for IRB approval, St. Agnes decided to outsource IRB review for all of its industry-sponsored trials to Chesapeake Research Review Inc. (CRRI) in nearby Columbia, Maryland.

“There are several factors that make outsourcing appealing,” says Matthew Whelan, Ph.D., president of CRRI. He sums up those factors in two words—efficiency and effectiveness. “We have a large support staff who can offer personal attention to the institutional needs,” he reports. “We also are within commuting distance of five medical schools and the federal government, and we can pool expertise and talent to our IRB review from these leaders in the community.”

But perhaps the most important reason sites are outsourcing is the need to stay current with government regulation. “Our inside expertise clearly doesn’t match what Chesapeake can offer us,” notes Stanley. The larger and better-known central IRBs such as Chesapeake can also offer additional services to meet

the needs of individual sites, Whelan asserts. For example, CRRI can translate consent documents into different languages.

#### Rochester Leads Pack

One of the first sites to outsource IRB review was the University of Rochester Medical Center, following its well-documented troubles with OPRR in the mid-1990s. Now viewed as one of the leaders in human subject protection, Rochester continues to outsource all of its industry-sponsored trials to Western IRB in Olympia, Washington.

“There are a variety of reasons that sites come to us,” says David Forster, J.D., director of regulatory affairs for Western. “The primary reason is probably our regulatory expertise.”

Forster and Whelan say sites generally outsource IRB review for industry-sponsored trials. “Usually sponsors agree to pay for the IRB review so these costs are covered,” explains Forster. “If a site is thinking of outsourcing federally funded trials and/or investigator-initiated trials, it should carefully consider whether this will be cost-effective,” he adds.

#### Local Differences

“Before an institution considers outsourcing IRB review, it should determine how the independent IRB will fit into its review process,” Forster asserts. The IRB will also want its own assurances. “Our IRB wants to be sure that there is good clinical practice and that informed consent is being conducted under proper conditions,” says Felix Gyi, M.B.A, Pharm.D., C.I.P., chief executive officer of CRRI. “Just because you outsource IRB review does not relieve you of the responsibility for human subject protection,” he cautions.

“One of the issues we look at in determining whether to contract with a site is the institutional commitment to doing clinical research,” adds Gyi. “If the will of the institution is that research is a high priority, then we look at what resources are available to do it right.” One of the criticisms found in recent government oversight reports on human subject protection is that sites say they want to do research but do not set aside the resources for the necessary oversight. “This is a question the site has

to answer for itself before deciding to outsource,” according to Gyi.

The relationship between the institutional officials and the central IRB must be collaborative. Stanley stresses it is important for a site to iron out any institutional policies that might conflict with those of an independent IRB. For example, as a Catholic health care system, St. Agnes does not want to approve studies involving stem cells or any other types of trials that might conflict with the religious tenets of the institution. These concerns were written into its contract with CRRI, reports Stanley.

Another essential element is a point person at the site for IRB outsourcing. St. Agnes appointed its director of risk management to be the main contact with Chesapeake. “For us this makes the most sense because he is the individual responsible for a high level of legal and regulatory issues,” Stanley says.

St. Agnes is using Chesapeake only for the review of its industry-sponsored trials. But the site may outsource some of its other human subject protection needs in the future. “We are diligently reviewing all clinical trial efforts and hope to place them under one umbrella,” explains Stanley. Options include

outsourcing clinical trial education and oversight of institutional conflict of interest.

Many academic medical centers, small community hospitals, and physician practice sites are now outsourcing IRB review or thinking about it, according to Whelan. They also are contemplating the pros and cons of seeking outside help in ensuring compliance with other federal regulations, such as HIPAA, he adds. Last month the New England Institutional Review Board announced it had established an independent privacy board to help sites meet the requirements of this new law. The board was set up initially to meet the requirements for a waiver of authorization outlined in the new privacy regulations. ♦



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## Best Practices

### Simplifying LIMS Implementation

Pharmaceutical companies expect their contract labs to have sophisticated capabilities such as a laboratory information management system (LIMS) to support their sample management, data collection, and reporting activities. At most labs LIMS is a work in progress as contractors start with basic needs (e.g., sample tracking and loading SOPs) and move to increasingly sophisticated data collection capabilities.

Most sponsors are seeking to establish long-term relationships with their contract labs, so they have a vested interest in assuring themselves that LIMS development and operation are well managed. LIMS implementations frequently go over schedule and over budget, however, which can undermine the contractor’s performance.

Good planning is the key to successful implementation, explains Lynn Hilt, president and CEO of The Ashvins Group, a Miami-based consulting firm that specializes in LIMS implementations for CROs. But, she cautions, CROs must be willing to take the time

upfront to determine exactly what they want from a LIMS solution, define and consolidate their requirements, identify and streamline redundant processes, and assemble the best-possible implementation team.

### An Uphill Battle

LIMS solutions have evolved over the past 20 years to become more standardized and intuitive. Yet adapting them to specific organizational situations raises the level of complexity and the odds of failure. Hilt and her colleagues see five typical problems that CROs grapple with during LIMS implementation.

- ♦ **Manual processes and a lack of process standardization among different laboratories and departments.** Often the various groups are not consistent in what they want out of a LIMS application, leading to conflicting requirements, unaligned priorities, and ill-defined goals.
- ♦ **A need for integration.** The LIMS solution must be integrated with the various instruments, applications, and existing databases.

- ◆ **Unrealistic expectations.** Many CROs have an unspoken sense that LIMS will automatically “think” for them and streamline organizational workflow. But this goal requires “rules-based” programming, a task not often included in the scope or budget of the LIMS implementation.
- ◆ **A desire to migrate historical data into the LIMS.** Depending on the various sources, types, and amounts of data, this can be a risky and complex procedure. Sometimes data that’s migrated into the system turns out to be incorrect and then a whole validation and clean-up effort must occur.
- ◆ **A lack of resources.** Internal information technology resources are often inadequate.

“The real result of all this is that the project the CRO originally estimated would take six months to implement will take 12 months and cost it twice as much,” says Hilt. “And, even then, the contractor may not be getting the benefits it expected.”

### A Perfect Plan

However CROs choose to implement a LIMS, Hilt advises that this kind of management plan be developed and followed.

- ◆ **Assemble a multifunctional project team.** The team should have internal personnel to help maintain a sense of control and direction, but it can also include the LIMS vendor and outside consultants. Consultants with experience in LIMS and the pharmaceutical environment can provide valuable project management and risk mitigation skills.
- ◆ **Assign an experienced internal project leader to manage the LIMS implementation on a full-time basis.** The project leader should be intimately versed in the needs, goals, and unique business processes of the organization and the particulars of networking, relational databases, enterprise applications, and project management. “Don’t compromise by selecting the closest fit among existing internal candidates,” Hilt warns. “Hiring someone new who has the skills necessary to cover all areas of the implementation is frequently the best choice.”
- ◆ **Establish a standardized project review process.** Link the process to senior sponsors within the organization to maximize the project’s visibility.

The project team should then be tasked with the following key responsibilities.

- ◆ **Develop comprehensive system requirements specifications.** This is the single most critical step in the project, according to Hilt. “It’s very important for the organization to define exactly what it expects out of the LIMS system—not just for now but in the foreseeable future.” Among the questions this document should answer are these: What type of data will be collected and from where will it be collected? What kind of output do we want from the database and at what frequency?
- ◆ **Develop the budget.** Be sure the budget takes into account all human resources (internal and external) and any software or equipment needed to get the job done.
- ◆ **Develop a project schedule.** Plan some type of milestone at a minimum of every 30 days. And break down the discrete milestones into enough detail that they effectively reflect the implementation’s progress.
- ◆ **Develop a risk management plan.** Among the risks that need to be addressed and mitigated are selecting the wrong types of drivers when interfacing with instrumentation, not defining what data is going to be collected, and not planning adequately for the migration of historical information.
- ◆ **Select the appropriate LIMS package.** Gauge a product according to your requirements for data sharing, automation, customization, scalability, and price. Also investigate the vendor’s financial stability. You don’t want a vendor that’s not going to be solvent in five years.
- ◆ **Work with outside vendors and consultants throughout the implementation.** Perhaps the best advice, says Hilt, is to make sure you have a clear contract that outlines roles, responsibilities, key performance measures, quality standards, and schedule milestones.

Hilt notes that CROs already in the throes of a difficult implementation can also incorporate this approach into an LIMS project. “The key is to know what you want out of the system and to do the upfront work,” she says. ◆




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## Company Update

### DPT Denies Bradley Charges

 DPT Laboratories Inc. (San Antonio, Texas) has denied charges made in a lawsuit filed by Bradley Pharmaceuticals, Inc. (Fairfield, N.J.) against DPT subsidiary DPT Lakewood, Inc. In its lawsuit Bradley charges DPT Lakewood with patent infringement, breach of confidentiality agreement, and misappropriation of trade secrets relating to its Carmol 40 Cream. In 1999, when it was owned by West Pharmaceutical Services, DPT's Lakewood operation had discussions with Bradley about contract manufacturing the product and had received proprietary information from Bradley under a confidentiality agreement. DPT Lakewood currently

manufactures a competing product for Dermik Laboratories and Aventis Pharmaceuticals, both of which have been sued by Bradley for patent infringement in relation to the product.



DPT Laboratories issued a statement through its general counsel Mark Mitchell following Bradley's announcement. Mitchell said he had not yet seen the lawsuit and asserted the claims were "completely without merit and have no factual basis." Mitchell further stated that "the respect of our client's confidentiality is a hallmark of our company and of our affiliates."



## Industry News


### Mergers, Acquisitions, and Alliances

TherImmune Research Corporation (Gaithersburg, Md.) has signed an agreement to be acquired by Gene Logic Inc. (Gaithersburg, Md.). TherImmune is a CRO providing preclinical and bioanalytical testing and Phase I-Phase II clinical trial management. Gene Logic is a provider of genomic information and testing services, including tissue sample collection, genomic data management, and software development. The deal has a total value of \$52 million, including \$31 million in cash and \$21 million in Gene Logic stock. (Gene Logic trades on NASDAQ.) The deal is expected to close in the second quarter of 2003. The combined companies plan to integrate their offerings so they can provide services such as predictive *in vitro* toxicology linked to preclinical toxicology testing and genomic-based patient stratification in early clinical development.

Cato Research Ltd. (Research Triangle Park, N.C.) has acquired a "substantial interest" in German CRO Studika Monitoring + Audit GmbH (Cologne, Germany). Privately held Studika, with a staff of 10 professionals, provides clinical trial monitoring, management, and audit services in the European Union countries. The terms of the cash transaction were not disclosed; both Cato and Studika are privately held. Under their agreement, the companies will cooperate in marketing their services to pharmaceutical and biotechnology companies. Cato and Studika have worked together on clinical programs in Europe. Cato has a staff of approximately 300 and offices in Canada, Europe, Israel, South Africa, and the United States.

 Chemical Synthesis Services (CSS—Craigavon, Northern Ireland) has acquired ABC Laboratories (Europe), a provider of analytical services located in Coleraine, Northern Ireland, from  ABC Laboratories (Columbia, Missouri). The unit has been renamed CSS Analytical, and it will remain at Coleraine with the same management and staff. CSS Analytical's services include bioanalytical, structural, and drug product chemistry.

 PPD, Inc. (Wilmington, N.C.) is reported to be part of a group bidding for  Quintiles Transnational Corp. (Research Triangle Park, N.C.). According to the TheDeal.com, PPD is part of a bidding group that includes Apax, J.P. Morgan Partners, and Warburg Pincus. Binding bids were due March 10.

 Parexel International (Waltham, Mass.) has terminated its alliance with the clinical research unit of Suven Pharmaceuticals (Hyderabad, India). The company is reported to be seeking another alliance partner in India.


### Corporate Finance


Hauser Inc. (El Segundo, Calif.), whose Hauser Technical Services (HTS) unit provides contract research and process development services, has received a nonbinding offer from Zuellig Botanicals, Inc. (Long Beach, Calif.) to acquire its extracts, nutritional, nutraceuticals, and vitamins business. Hauser is in default of its loan agreements, and the company ended its third quarter with no cash on


hand. Hauser's board of directors has established a special committee of independent directors to evaluate the offer from Zuellig. Hauser sold its contract laboratory businesses, Hauser Laboratories and Shuster Laboratories, in 2002. HTS had revenues of \$5.4 million for the first nine months of fiscal 2003.

Commonwealth Biotechnologies, Inc. (Richmond, Va.) has avoided delisting from NASDAQ. The company had been warned in September 2002 that it risked delisting under NASDAQ's minimum price rule, but its share price has bounced back in recent months.


## New Services and Expansions


 MDS Pharma Services (Montreal, Canada) will open a new 12,000-square-foot bioanalytical testing facility at the Sittingbourne Research Centre in Kent, United Kingdom. The new facility will be equipped with Sciex 4000 instruments; Sciex is a sister company of MDS Pharma Services in the MDS International group. MDS Pharma Services recently expanded its bioanalytical facility in Zurich, Switzerland, to 30,000 square feet.

 Cambrex Corporation (East Rutherford, N.J.) has completed a \$11.5-million facilities expansion for its custom development services business. The expansion includes an addition to laboratory facilities at its Karlskoga, Sweden, location, and new capacity for controlled substances and other API at its site in Charles City, Louisiana.

 Chemical Synthesis Services (CSS—Craigavon, Northern Island) is expanding its chemical process development and manufacturing capabilities at Craigavon. The 86,000-square-foot expansion will house eight reactor suites, including dedicated suites for oligonucleotide, cytotoxic, and high potency materials, as well as additional analytical laboratories. When the expanded facility is completed in August 2003, it will employ another 80 scientists, bringing total CSS employment to 250, including 90 Ph.D. scientists.

## Contracts

 Inveresk Research International (Research Triangle Park, N.C.) is conducting a Phase IIb trial for MediWound Ltd. (Yavne, Israel) on its Debrase gel wound dressing.


 Albany Molecular Research, Inc. (Albany, N.Y.) will provide chemistry-based discovery services to Affinium Pharmaceuticals, Inc. (Toronto, Canada) in support of Affinium's anti-infective drug program.


## Biomanufacturing Capacity Watch


Solvay Pharmaceuticals (Brussels, Belgium) will build an EUR 50 million mammalian cell culture facility in Weesp, the Netherlands, for the manufacture of influenza vaccines. The facility will use a proprietary technology based on its MDCK cell line that will replace the egg culture traditionally used to produce flu vaccine. The new facility is slated for completion in 2005.


Albany will receive development fees plus additional consideration in the event new compounds reach certain milestones.


## Appointments


 MDS Pharma Services (Montreal, Canada) has named Pauline Gee, Ph.D., vice president of predictive biology.

 Quintiles Transnational Corp. (Research Triangle Park, N.C.) has named Richard Levine, M.D., director, medical and scientific services, for the hematology, oncology, cardiovascular and respiratory team.


 DSM Pharmaceuticals Inc. (Greenville, N.C.) has lost its president and CEO, Wesley Wheeler, who has become president, North America, for ICN Pharmaceuticals (Costa Mesa, Calif.).

 Akorn Inc. (Buffalo Grove, Ill.) has appointed Arthur S. Przybyl, president and COO, to the additional position of interim CEO, following the resignation of CEO John Kapoor.

 Cardinal Health, Inc. (Dublin, Ohio) has named Raymond E. Dagger, Ph.D., vice president of synthesis, and Danna Ross, Ph.D., vice president of inhalation services, in its Pharmaceutical Development business.

 Parexel International (Waltham, Mass) has named Richard J. Schwen, Ph.D., vice president, regulatory affairs, the Americas.

PharmaNet (Princeton, N.J.) has appointed Marty Valania to the position of executive director of corporate quality assurance and compliance.

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## Outsourcing Events

**Bio/PharMOS 2003**, Monaco, March 26–28, 2003.  
VB International, +377 607 93 91 39,  
www.bopharmos.net.

**Partnering with Central Labs**, Princeton, N.J.,  
March 26–28, 2003. Institute for International  
Research, 888-670-8200, www.iirusa.com.

**12th Annual Partnerships with CROs**,  
Kissimmee, Fla., March 31–April 2, 2003.  
Institute for International Research, 888-670-8200,  
www.cropartners.com.

**INTERPHEX and Pharmaceutical Contract  
Services & Outsourcing Expo and Conference**,  
New York, N.Y., March 31–April 2, 2003.  
International Pharmaceutical Industry Congress,  
888-334-8704, 203-840-5648,  
www.pharmacongress.net.

**International Outsourcing Law**, New York, N.Y.,  
April 3, 2003. Bierce & Kenerson, P.C., and Tarlo  
Lyons Solicitors, 212-840-0080, att: Beverly Gomez  
or Nick Radulescu, www.outsourcing-law.com/  
registerApr032003.asp.

**Successful Drug Development for the Biotech  
Industry**, San Diego, Calif., April 3–4, 2003.  
Siegfried Ventures, 858-546-4343,  
www.siegfried-usa.com.

**Practical Strategies for Cost-Effective GMP  
Compliance**, London, England, April 29–30, 2003.  
Vision in Business, +44 (0) 207 953 450.

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Vision in Business, +44 (0) 207 953 7450.

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