

# From bench to bedside: a new preclinical development strategy

**Leads To Development is a new company that manages the development of lead compounds for its clients from *in-vivo* proof of concept to clinical trials. The company capitalises on the non-clinical development expertise of its founders to allow biotech and pharmaceutical companies to confidently outsource this highly specialised phase of drug development.**

To remain successful, pharmaceutical companies are changing their business strategies in order to adapt to the changes in their environment caused by the increasing pressure of generics, patent expirations, the poor state of product portfolios, price restrictions and a fragmenting market. Many are adapting by increasing their use of outsourcing, which allows them to reduce costs and at the same time accelerate their programmes. Since 2001, outsourcing by pharmaceutical companies has been shown to be increasing at a steady rate of 16 per cent per year.

For biotech companies, financing is much more difficult today than ever before as investors are more selective and try to de-risk their investments as much as possible. As a result, many European biotechs can only afford to develop one or two lead molecules at the same time. For these companies, the strategy of outsourcing is clearly advantageous, as it allows them to reach their milestones rapidly without the burden and cost of building large internal teams. For the same reasons, many companies are simply choosing to take a virtual path by outsourcing all of their non-clinical and clinical tasks.

Leads To Development is a new company that provides an outsourcing solution for the management of the non-clinical development of lead compounds. The company has particular expertise in the areas of oncology, neurology and diabetes, and in addition works with a number of therapeutic agent types, including small molecules, cell/gene therapies and biologics. Its non-clinical development work encompasses all the activities that need to be undertaken in order to submit a clinical trial application, whatever the phase.

"We established Leads To Development in July 2009, because we saw an opportunity to support biotech companies in developing their non-clinical therapeutic programmes in a more rapid and cost-effective manner," says Jonathan Kearsley, Leads To Development's director of business development. "Investors are becoming increasingly risk-averse, which

means that many biotech companies have only sufficient resources to develop one or two therapeutic leads in parallel. The most cost-effective manner to develop these leads is through outsourcing. We have positioned ourselves as an operational management team in order to help these companies reach their development objectives.

"We can manage the whole of the preclinical development for our clients or undertake actions 'à la carte' on their behalf. In general, the first step is to define and validate a preclinical development plan, which incorporates the experimental design of safety pharmacology, together with GLP toxicology, GMP manufacture and stability studies, as well as the clinical trial logistics. Timelines and budgets can then be set based on this plan.

"Since the majority of preclinical tasks have to be performed under GLP or GMP conditions, they must be outsourced to CROs and CMOs with these capabilities. We identify the CROs and CMOs best placed to undertake the programme and negotiate with them to obtain the optimal price, quality and time frame. Once these contracts have been signed, we proactively manage the selected service providers to ensure that all tasks are completed on time and to budget," he says.

Leads To Development then builds the Clinical Trial Application (CTA) dossier in accordance with the regulatory authorities' requirements. The CTA comprises the Investigator's Brochure (IB), Investigational Medicinal Product Dossier (IMPD), and a large range of other documents that the company writes and submits in preparation for the initiation of clinical studies. There are also many aspects of toxicology, pharmacology and manufacturing that need to be addressed during all clinical phases, and Leads To Development can manage all these non-clinical tasks, which clinical CROs do not perform.

## Highly experienced scientific and business management team

All three of the founding partners of L2D have

held senior management positions within the biotech sector and are highly experienced in both the scientific and business aspects of therapeutic drug development. Prior to forming Leads To Development, they worked together for more than six years and had established a track record of successfully taking therapeutic drugs through preclinical development into Phase 1 and 2 clinical trials.

"Biotech companies have more limited resources than their pharmaceutical counterparts, both financial and human," says Kearsley. "The financial runway for a biotech company is often less than 18 months, making it difficult to attract highly experienced developers to manage the development of only one or two products. Nevertheless, their development programmes need to generate sufficient value within that short time period, including progress to Phase 1 clinical milestones. Outsourcing the management of non-clinical development therefore provides an attractive novel solution for these companies.

"We provide a ready-formed team of non-clinical development experts who can immediately start to advance clients' projects, thereby reducing the development timeline by up to the 7-9 months that it would take them to establish an internal development team," he adds. "We are independent, but have a large established network of validated CROs and CMOs, allowing us to rapidly select the best service providers and to finalise their contracts. Furthermore, our extensive experience in preclinical development enables us to use meticulous parallel planning, which, together with the synchronisation of all tasks, allows further timeline optimisation. Our problem-anticipation and problem-solving skills allow a smooth progression through development milestones. The overall outcome is that outsourcing to Leads To Development enables project timelines to be significantly reduced."

## Competitive edge

Kearsley says that there are currently very few

companies offering independent non-clinical management services and that those that do are mostly based in the USA. He adds:

"Our service is flexible and personalised, tailored to each customer's needs. Our competitive edge also comes from our long experience of developing therapeutic agents within both the time and financial constraints of the biotech sector, coupled with our understanding that every euro or pound counts, and every delay could be mission-critical.

"We are breaking new ground: 25 years ago, clinical trial management was rarely outsourced, yet today, no one would envisage launching a clinical study without using a clinical research organisation. We provide a similar service to the clinical research organisations, but covering all non-clinical aspects of development. We are opening a new avenue towards more efficient and flexible drug development, and we believe that this will become the norm within the coming years.

"Our move into new offices in one of Paris's foremost bio-incubators, Paris Biotech Santé, has given the company a real boost and has

allowed us to expand our work force to meet our growing business activities. From our office at Paris Biotech Santé we are ideally positioned to support biotech and pharmaceutical companies with their non-clinical development management.

"We are highly flexible: we can work on a fee-for-service basis with a fixed monthly fee, a set project fee or an hourly rate. We find that many of our current clients prefer a fixed monthly fee as it simplifies their financial forecasting. Our customers include both European and US biotech companies: however, our geographic focus is on Europe.

"We have found that there is a great deal of interest from virtual companies, start-ups and academics that want to advance therapeutic programmes without building internal operational teams. We are also working with a number of investment companies that have realised that their investment risk in their portfolio companies can be minimised by using our services. Using our services also provides an independent project validation that generates added value for any pharmaceutical company wishing to acquire the programme at a later date."

In addition to drug development management services, the company also offers a range of strategic and business services and advice, including strategic planning, drug positioning, strategic advice (target drug profile, competition, intellectual property), in- and out-licensing technical evaluations, and technical due diligence.

"I am convinced that Leads To Development offers the most rapid approach to building company value for both our clients and their investors, whilst providing the peace of mind of knowing that their therapeutic development is in safe hands," concludes Kearsley.

#### Further information

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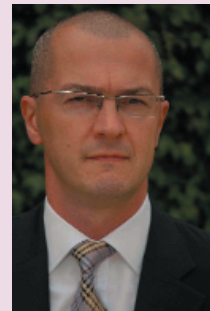
## Meet the founders of Leads To Development



*Jonathan Kearsley PhD, Director of Business Development, Director of Pharmacology, has ten years' experience in the design and execution of translational research within the biopharmaceutical sector, gained in two Paris-based biotechnology companies (ExonHit Therapeutics and Diatos) where he held director of research positions. Within these roles, he was responsible for the preclinical development of small-molecule, oligonucleotide and antibody therapeutics, principally in oncology, and contributed to the development of a number of therapeutic agents, up to clinical Phase 2. He is highly experienced in all aspects of research and preclinical drug development, but also in international intellectual property management, business development and due diligence. He completed a postdoctoral fellowship at Oxford University and holds a PhD from the University of London.*



*Jérôme Quinonéro PhD, Director of Toxicology & Safety Pharmacology, is a research manager with fourteen years' experience in the design and conduct of safety pharmacology, toxicology, pharmacokinetic and tissue distribution studies within the biopharmaceutical industry. He co-founded USA-based Neurotech in 1996, where he developed cellular gene therapeutics involving genetically modified cells expressing growth factors and cytokines. He joined Diatos in 2001 as the director of toxicology and safety pharmacology to coordinate the non-clinical development activities including the in-vivo pharmacology and toxicology programmes, where he helped advance four oncology therapeutic agents into the clinic. He holds a PhD in Neurosciences from the Pierre & Marie Curie University, Paris, and is an inventor of several patents.*



*Vincent Dubois PhD, Director of Product Development, has accumulated twelve years' experience of non-clinical development in the biopharmaceutical industry. In 1997, he joined Coulter Pharmaceutical as a team leader and was responsible for a research programme and the initiation of the preclinical development of anti-cancer prodrugs. He then joined Diatos in 2001, where he held the position of director of preclinical & product development. He contributed to the development of four therapeutic agents, up to clinical Phase 2. He is highly experienced in all aspects of non-clinical development, including manufacturing process development and scale-up, analytical chemistry, formulation development and GMP production of active pharmaceutical ingredients and clinical trial material. He holds a PhD from the University of Louvain and is a co-inventor of 13 patents.*