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EVENT

GO4Europe

Monday March 15th 2010
Hilton Tel Aviv

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innovative business
investors and entrepreneurs
from Israel and Europe

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Breaking News

BIOFINANCING: SHOULD BIOTECH MODELS COME DOWN TO EARTH?



Dr. Laurent Choppe, Managing Partner –
Cukierman & Co. Life Sciences

Is biotech sufficiently in touch with the needs of pharma and the markets? Clearly not, and we urgently need to reassess the situation, given the hit the industry has taken from the crisis and the weakening of the pipelines of their biggest players. This situation is probably more common in Europe than in the United States. Essentially, the problem is centred on the realistic assessment of the commercial or clinical need of future partners. "How can you find financing or attract a big pharma or an investor under these conditions?" asks Laurent Choppe, from the Israeli investment fund Cukierman & Co., who will lead a panel on the theme "Innovation for pharma and access to finance for biotech" at the upcoming Go4Europe conference in Tel Aviv (1). "Technological platforms with X years' worth of projects on blockbusters and break-through innovations, however interesting they may be, don't have much value if they don't deliver products that the markets needs. Biotech companies should have a good look at the medtech model, which is much more realistic." However, should we wipe the table completely clean, especially in France, where the situation appears to be most worrying? "We would need urgent adaptation", as various experts have confided to us. "US entrepreneurs are more in tune with the market. Their thinking is product oriented and they've been having sustained discussions with the FDA for a long time. In France these types of discussions with the French Health Products Safety Agency Afssaps have only recently started to take place." Consequently, "misunderstandings" haven't all been cleared up yet, and this

has obviously slowed down the sector. "Why are French biotechs so reluctant to reveal their strategies? Because they develop a platform in the rarefied atmosphere of the science business, and not products for a market. Simply because they don't want to get their

To consider NEEDS, PRODUCTS AND MARKETS is a NECESSITY

hands dirty", retorts a French consultant in the sector. "And in the same vein, we also observe that the approach of our investors – apart from a few exceptions – isn't changing according to the final product or the need. This originates from the same logic. While the vision of Anglo-Saxon financiers is decidedly industrial, we are looking for leverage affects in an irrational way. With the crisis, this has inevitably led to blockages." So what to do? "Change will have to take place, because awareness is spreading", comments Laurent Choppe. "In the US and in Canada we're already observing biotech companies who don't hesitate to change their approach mid-process, or even use their platforms to directly and quickly address a complementary market, sometimes in an area very different from those of their initial strategy, using profitable solutions." The road ahead is clear for rarefied models in search of refinancing. ■

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H. ELLA

THE POOR FOLKS KICK UP A FUSS

Sometimes we feel the need to release a primal and wonderfully liberating cry, especially if it's about people we appreciate and ideas we defend. Here is the issue that's preoccupying us. A couple of weeks ago, we were happily following the 11th Tremplin Entreprise conference (1). At the time, Senator Adnot, who we regard as one of the eminent personalities of the inner circle, explained to us in record time the true reasons for the multiple modifications in the TEPA law. His embarrassment was

palpable, but he made it perfectly clear to us that the modifications were definitely due to the appalling actions of certain mercenaries from the financial world; crooks who were using the gap in the TEPA law to obtain investments outside the spirit of the text. The consequences of these white collar crimes? The number of participants to the French wealth tax (ISF) has come down, which has caused a fragmentation of investments that is detrimental notably to life sciences.

Investment periods have also been reviewed, under the pretext that management fees were too high, and forgetting in the process that investment in young enterprises is a real obstacle course, because very often the markets don't exist or are being created. There once was a time when, if you did something stupid, you first got a rap on the knuckles, then you got severely reprimanded to make sure you wouldn't reoffend. And many of us would like to think that this practice takes place in assemblies as well. Maybe the government, in its infinite wisdom, leaves the fiscal administration, which never forgets anything or anyone, to give a good old scolding to the financial lawbreakers? That's the question that needs to be asked concerning the form. As to the substance, to see the work of our deputies and senators treated so lightly, especially when the effort to improve businesses is so obvious, is simply scandalous. And that's why we felt the need to release this desperate cry for poor folks. ■



1 – See “After 11 years, the “Tremplins” springboards still have their spring”, in BF No. 451 from February 22nd 2010.

NEWS BITE

BMS takes sublicense on Exonhit's EHT/AGN 0001

This signals a double recognition for ExonHit. After signing a co-development deal with Allergan for its EHT/AGN 0001 compound, now Bristol-Myers Squibb Company gives the product its recognition by joining the R&D consortium. BMS has signed an exclusive global license agreement for the

development and commercialization of this candidate drug, which is ready to start phase II for neuropathic pain. The agreement between Allergan and Bristol-Myers Squibb also includes EHT/AGN 0002 and associated compounds. According to the sublicense terms, ExonHit will receive nearly 3 M€ as well as potential milestones worth over 23.4 M€. ExonHit will also receive royalties on future worldwide sales. Meanwhile, the

collaboration between ExonHit and Allergan (1), which started in 2002, will continue, with the objective of developing and synthesizing new molecules in the areas of neurodegenerative diseases, pain and ophthalmology. ■

1 – See – “ExonHit Therapeutics expands its strategic collaboration with Allergan”, in BF No. 246 from May 30th 2005 (in French).

FRANCE



IMPROVING CTC/DTC DETECTION TESTS CRUCIAL FOR RESEARCHERS, CLINICIANS AND BUSINESSES



Analysis by Professor Marc Colombel, urology surgeon at the Hospices Civils de Lyon and Director of the Urezus Group at the Lyon 1 University

Prostate cancer is the most frequent cancer in men and the third biggest cause of death in the West. The epidemiology of prostate cancer is evolving constantly. As it stands, early diagnosis using the PSA test, measuring the serum PSA level, improves survival rates due to treatments such as surgery, radiotherapy and hormone therapy, which are particularly efficient if the disease is caught early. However, the return of cancer remains hard to predict.

There is an INCREASED INTEREST from the scientific and the business community to DEVELOP CLINICAL EVALUATION PLATFORMS

Recurrence is linked to the migration of cancerous cells in the body and their detection is proving a challenge for the cancer marker industry. Existing tests are not satisfactory because they analyze the characteristics of tumor cells in the original tumor, and not metastatic cells that are already present elsewhere in the body, in the case of prostate cancer usually in bone tissue. It is clearly established that cancer metastases originate from cells that migrate from the original tumor. For metastases in the bones the following sequence of events take place: dispersal in the blood stream, receipt in the medullar tissue, invasion of the bone tissue, and

eventually the proliferation of cancer cells leads to bone destruction.

THE PERTINENCE OF CTC/DTC TESTS IS PROVEN IN EARLY-STAGE METASTASIS DIAGNOSIS

The greatest source of controversy is the time and the stage at which metastatic cells are dispersed and the time they need to develop. Existing tests don't give us any insight into these variables, which determine the prognosis and therapeutic strategies. Circulating cancer cells can be identified using techniques such as RT-PCR, flow cytometry and others, but the researchers (Weckerman et al.) have only recently established the direct connection between identifying prostatic cancer cells in bone tissue and the prognosis of the disease. The inventors rightly suggest that the detection of circulating tumor cells (CTC) or bone marrow disseminated tumor cells (DTC) is the most pertinent way to establish an early diagnosis of metastases. Another reason why CTC/DTC requires more attention is that comparative analysis between the original tumor and the circulating cells shows that disseminated cells have a different phenotype, and therefore it will always be difficult to extrapolate information from the original tumor, regardless of how advanced the biotechnology applications are. The requirements from government agencies for the ratification of this type of marker are the test reproducibility and proof of its pertinence in the early diagnosis of metastatic cancer, whether it's for

prostate, breast, colon or other cancers that may be added in the near future. Consequently, there is an increased interest from the scientific and the business community to develop clinical evaluation platforms. These evaluation platforms will also be used to establish a consensual method for the genomic analysis of the disseminated cells and their response to pharmacological agents. We anticipate that personalized treatment for metastatic cancer will be developed in the future.

CLINICAL PRACTICE IS CALLING FOR THE DETECTION OF CIRCULATING CELLS

In clinical practice, and particularly that concerning prostate cancer, in what ways could we provide incontrovertible evidence of circulating cancer cells?

1. The first way would be to use the DTC/CTC test as a biomarker for the prognosis of returning cancer after surgery. There are numerous publications about prostate cancer, elaborating on prediction models for recurring cancer (Shariat, 2008). Most of these models have been developed to make a biological (PSA) prediction of relapse using biological clinical parameters and more recently also molecular markers. Typically, the parameters are combined in nomograms that give a probability value to each parameter, based on patient cohorts suffering from prostate cancer. For the validation of the DTC/CDC tests, conformity to clinical research standards are foremost:

(continued on p. 4)

- a. Long-term studies on homogenous patient groups, which requires strictly defined inclusion criteria as well as stratification criteria (phase, tumor grade, PSA level, treatment regime) to obtain relevant and realistic information.
- b. Prognosis evaluation usually has a long follow-up: the use of biological markers as intermediary evaluation criteria is not satisfactory. The evaluation of a detection test for micrometastatic cancer requires the occurrence of metastasis as a primary criterion. Initially, the analysis can be limited to the risk group and the results from this first study can then be used as a basis for an extended confirmation study, with sufficient weight to prove the pertinence of the test.
- c. As the detection tests have to be repeated, they have to be as non-invasive as possible. Medullar puncture is well tolerated, but patients have difficulty accepting repeated tests. Therefore the results obtained from the blood stream (blood sample) and from bone marrow (bone marrow puncture) have to be systematically compared. Studies are already in progress for breast and colon cancer.

rather in an inactive phase. Studies on proliferation markers, for example by Ki67 expression, shows that the cells are actually in phase G0-G1. Therefore it seems that standard chemotherapy is not best suited at that stage.

b. Generally speaking, peri-operative chemotherapy protocols have always been at the lower threshold of statistical significance.

c. In other words, a strategy to eradicate circulating cells requires the development of specific pharmacological molecules for circulating cell markers, adapted and with a low level of toxicity to maintain a good benefit-to-risk ratio.

THE DORMANT STAGE OF CANCER CELLS IS ALSO IMPORTANT IN BREAST AND COLON CANCER

3. The CTC/DTC detection test, whether it is post-operative or during radiotherapy, in prostate cancer has no connection to the patient survival rate, probably due to the markers used, as opposed to for example in breast cancer. Therefore it is likely that, in the case of prostate cancer, the metastatic cells have a strong capacity to stay inactive. The inactive phase of cancer cells is also a very important aspect in breast and colon cancer (Pantel, 2008). The dormant stage of metastatic cells explains why metastases often appear several years after treatment of the original tumor. The challenge today is to identify the factors that “wake up” these cells, and to define new therapeutic targets. It would be particularly important to find out why, in the case of prostate cancer, the dormant stage of disseminated cells is so long compared to breast cancer for example. It’s also possible that other methods should be used. The methods that are currently in development are problematic in terms of taking samples: epithelial markers can present a problem in vein puncture, and blood and bone tissue contamination can be a problem for medullar puncture. There are also puncture timing issues, and above all marker selection issues. Most of the existing methods use cytokeratins, which are expressed by

epithelial cells and don’t reflect the potential evolution of the condition. Therefore it’s crucial to continue the search for pertinent markers that could eventually be used for CTC/CDC tests.

4. Another aspect that needs to be developed for the tests is the capacity to identify for each individual patient a phenotype of the lethal risk of the cancer. In terms of epidemiology, prostate cancer is responsible for a significant portion of cancer deaths. However, given its frequency it seems that the lifetime reduction in years due to the cancer diagnosis is one of the lowest. Therefore it’s important to get an insight into the risk of metastases for each patient. This is the very reason why simple cancer surveillance is one of the top recommendations in Europe. But how do we make this choice and how do convince the patients to adopt a new attitude? One possibility would be to include a gene test in the CTC/DTC test and make a type of genetic map of each tumor by using a simple blood test.

All these objectives require the continuation of transfer studies and analysis on patient cohorts that are sufficient in size. Today, we have the necessary procedures to achieve our goals: the CTC/DTC test methods are being investigated by the FDA. They each have their own limitations, whether it’s the limited evaluation of markers, or simply of the test’s pertinence in view of the cancer progression. Today, the CTC/DTC tests are available, but their performance definitely needs to be improved to be in line with clinicians’ needs. Now it’s up to transfer research, in partnership with the industry, to evaluate and develop the technique. Our university is ready and waiting for such a project. In France, universities are ready to welcome strong projects in which researchers and clinicians work together with business, all the way through to creating mixed teams for a true industrial project. ■

Marc Colombel

Most of the EXISTING METHODS don’t reflect the POTENTIAL EVOLUTION of the condition. Therefore it’s crucial to CONTINUE THE SEARCH for PERTINENT MARKERS

2. The second reason to use DTC/CDC tests would be for identifying patients who would benefit from treatments such as chemotherapy or hormone therapy as an additional treatment for their first tumor. There are several obstacles to overcome:

a. The circulating cells are not necessarily in a proliferation phase but



FRANCE



AXS MEDICAL IN SEARCH OF 2.5 M€ TO TAKE OFF

While the market is estimated at 500 to 800 M€ for Europe and 1 B€ for the US, with medical devices carrying the CE mark already on the market, and with annual sales figures of 7 to 10 M€, AXS Medical is still finding it difficult to raise 2.5 M€. And yet, this young medtech in Le Havre, France, which possesses expertise in the medical algorithm engineering of simulation, has developed the BIOMOD platform, an innovative non-invasive optical procedure for bone analysis for specialists in spinal diseases. "So far, our platform is already installed and operational in six centers in France and

Our BUSINESS ORGANIZATION is SOLID

Belgium, for example at the CHU in Bordeaux, the AP-HP Raymond Poincaré at Garches, and soon also at the Foch hospital in Suresnes and the university hospital Mont-Godinne in Leuven, Belgium", comments Fouad Elbaroudi, CEO of AXS Medical. "We're not in a replacement market, but in a market of true innovation. We even have the good fortune to be challenged by a German competitor whose concept is in our opinion not as successful as our own and is also much more costly. So our next step is to find financiers to support our commercial expansion. This would

be a great step forwards." The nervous market climate and scepticism of their business model have kept AXS Medical in limbo. "So far, we have progressed our developments using partly our own funds, but also an OSEO grant of about 400,000 € and research tax credit" explains Fouad Elbaroudi. "We have gone through all the phases: prototypes, clinical trials, patents, market authorization for the various platform modules in 2008 and 2009. We now have a solid business organization." All this has reduced the risk considerably, and should make the company an attractive proposition for investors.

NEW MODEL IN THE MAKING

While waiting for a financial partner to step in, AXS remains focused on its research and development to complete its offer. "So far, we are commercializing the Biomod L and the Biomod 35", comments Fouad Elbaroudi. "The former is the only product that is in competition with our German rival. It's a morphometric analysis device of the spine using optical data, mainly targeted at medical practitioners. It offers a more reliable way to collect, store and analyze clinical parameters in real time. As to the Biomod 35, this device offers a unique patented 3D reconstruction system and analysis of the rachis and profile of the spine, which is compatible with existing radiology

equipment without any modifications and adds highly pertinent information and support for the therapeutic strategy." The Biomod 35 should help bring in the required funds, with its increased potential to access new markets. ■

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AXS MEDICAL

ESTIMATED VALUE

Unknown

PARTNERS

Banks

CIC and Crédit Mutuel

Legal advisors, intellectual property

Harle & Felipe (Paris)

Academic partners

Laboratoire de Biomécanique et de mécanique des Chocs (Inrets – Lyon I University)

Clinical partners

CHU de Bordeaux, Pole Orthopédique - France

University hospital of Leuven – Belgium
AP-HP Raymond Poincaré, Garches - France
Clinique Saint Grégoire, Rennes – France

BUSINESS OPPORTUNITIES

Recruitment

Commercial engineers

International requirements

Distributors in Northern Europe and Germany

WHAT THE ANALYSTS SAY



Professor Jean Legaye, orthopaedic and trauma surgeon working with the device, University Clinics of Mont-Godinne – Belgium

"Domainex's strength lies in the fact that they have both a leading edge management team and a very promising technology platform all in the same structure. This combination, which is essential for success, is unfortunately not always present in European biotech businesses.

The deal that Domainex has signed with Takeda Research Investment (TRI) is the first public industrial recognition the company has received. It is a big step forward for the company, opening many partnering opportunities, either with Takeda for its services activity or its pipeline, or with other pharmas because of Domainex's increased visibility.

To reach the next stage, Domainex needs to advance its internal pipeline significantly and rapidly, with the objective to increase value as much as possible before selling its first program to a pharma or a biotech."

AUSTRIA



VACCINES: AFFIRIS REDUCES ITS FINANCIAL PRESSURE

Affiris's hypertension vaccine program, which had so far been funded by the company internally, has received a boost from a government agency. The Austrian state, or more precisely the Austrian Research Promotion Agency (FFG), is providing a grant of 1.2 M€ which is 50% of the total funds required for the project. These funds should enable the company to complete clinical development for its candidate drug and the Investigational New Drug (IND) application by 2013 at the latest. At that stage, several options will be considered by the management team. "Our approach is pragmatic and leaves room for partnering", explains Dr Walter Schmidt, CEO of Affiris. "We are making good progress in discussions with pharma businesses. Two or three years ago I used to be told to come back with clinical results, but now the large pharma companies are ready to sign a very early-stage deal, with reviewed contract terms on for example the distribution of upfront and milestone payments."

RECOGNITION FROM GSK

Affiris has been in a similar situation before, when it signed its first contract with GlaxoSmithKline Biologicals for its first two vaccines AD01 and AD02 against Alzheimer's disease, which was still at preclinical stage at the time. The deal was signed for an amount that could go up to 430 M€ at

commercialization stage. After 18 months' collaboration, the two partners reached the start of phase I last fall, which has enabled the release of the first milestone of 10 M€ (1). "The recognition from GSK is crucial for the future of our portfolio and the validation of our AFFITOME® platform", continues Walter Schmidt. "It gives us much more weight in our negotiations and priority access to big pharma business developers." These strategic discussions currently cover six compounds, for three of which Affiris has disclosed the indications: Parkinson's, atherosclerosis

Internal DEVELOPMENT up to PHASE III is a POSSIBILITY

and hypertension. The biotech can also draw on its financial solidity, which makes negotiations all the more relaxed. "If we don't receive satisfactory proposals for one or other of these products, we will continue development internally up to phase III, or even to registration and commercialization", concludes Walter Schmidt. On this prospect Michael Motschmann, senior fund manager at MIG Verwaltungs-AG, one of the company's first shareholders who joined the Board, comments: "In that case we would have to plan for a large scale recapitalization." Amongst

the various options, an IPO seems the most appropriate. All we need now is the market to wake up. ■

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1 – See "Affiris receives 10 M€ from GSK Biologicals", in BF No. 436 from October 23rd 2009.

AFFIRIS

ESTIMATED VALUE

Unknown

PARTNERS

Bank

Erste Bank

Legal advisors, current affairs

Baker Mckenzie

Legal advisors, intellectual property

Sonn & Partner

Communications & Press relations

Public Relations für Forschung & Bildung.

Till C. Jelitto – Vienna

Investors

MIG Verwaltungs-AG

Industrial Partner

GlaxoSmithKline Biologicals

BUSINESS OPPORTUNITIES

Partnering

Affiris is looking for partners to co-develop its vaccines in hypertension, Parkinson's and atherosclerosis.

Recruitment

Several researchers will be recruited to join the preclinical and clinical development teams.

WHAT THE ANALYSTS SAY



Michael Motschmann, senior fund manager – MIG Verwaltungs-AG

"Affiris has a first-class technological platform, which is particularly innovative in the area of peptides. It enables the development of vaccines for large indications with a strong medical need, such as Alzheimer's, Parkinson's, atherosclerosis or hypertension. The company has signed an early-stage deal on its first products, AD01 and AD02, with GlaxoSmithKline Biologicals, who offered 430 M€ for its Alzheimer's vaccines, 32.5 M€ of which have already been released. This revenue from partnering has given Affiris a great flexibility to manage its own affairs without having to use private investors. However, this could change in the medium term if the company decides to complete phase III or the registration of the compound internally. In that case, a large-scale recapitalization will be required."



EUROPE



EXTERNALIZE R&D FOR IMPROVED PERFORMANCE

To face up to changes in business practices, notably the increase in duration and cost of product development, pharmaceutical and biotechnology businesses are looking for new strategies to achieve a maximum return on patent exploitation. One of the key elements in these new strategies is the externalization of R&D.

DEVELOPMENT COSTS ARE RISING

It is important for pharmaceutical companies to adapt to changes in their environment due to the increasing pressures of generics, the expiration of numerous patents, the poor state of product portfolios, price restrictions from authorities in countries which are trying to control the debts of their health system, and a fragmenting market. On this last point, the era of blockbusters is about to come to an end in the most profitable therapeutic indications. Or at least, these products are not likely to come along any more, far from it, as the most "accessible" products have come to the market a long time ago. These days there is a real need to tackle chronic diseases, which are much more complex, requiring more and longer studies. Now it is important to develop targeted, personalized therapies, many of which are based on biological products. All of this explains the increasing duration and above all the increasing cost of development.

Profit growth in the pharmaceutical industry, or at least its maintenance at the same level, is more than ever dependent on its capacity of finding ways to rapidly develop very innovative products while at the same time reducing its costs.

THE PHARMA RESPONSE

Strategic changes due to changing rules are not new in this sector of the industry. Now that pharmaceutical businesses, which were originally multidisciplinary, have refocused and specialized, and become concentrated through a process of mergers and

acquisitions, a particular effort in productivity is required to achieve the best possible profits from the exploitation of new products. One of the options used to reach this goal is the externalization of R&D. The evidence is clear when you observe the rise of the contract manufacturers or clinical CROs. In the pharmaceutical area, the annual growth rate in subcontracting has been virtually unchanged since 2001 at about 16%, and there is no change to be expected. These days subcontracting is

MANY COMPANIES can only AFFORD to DEVELOP ONE or TWO PRODUCTS at the same time

no longer just used for non-critical aspects, or as a solution for capacity or internal competencies issues, but it has become a positive strategy choice for cost reduction and speeding up market access (D. Scott, Applied Clinical Trials, August 1st 2008).

THE RETURN ON EXPERIENCE IN BIOTECH

Externalization has always been a compulsory choice for biotech businesses, at least for development aspects that require heavy infrastructures or a very particular know-how, such as production, regulatory studies or clinical development. This is a direct consequence of the funding of most of these businesses through capital risk. Their investors are only present for a

very short time, and so the invested funds have to be used exclusively to build value for the company. But the company value resides mainly in its product portfolio, not in its infrastructures.

THE EVOLUTION OF EXTERNALIZATION STRATEGIES

The changes in the environment and constraints for businesses are also obvious in the biotech industry, which companies are finding it increasingly difficult to find capital. While a very limited number of them are benefiting from partnering with pharma, which has clearly understood that this is the principle source of innovation, the majority has to put up with funds wishing to de-risk their investments as much as possible and therefore being more selective than ever. However, while investors are becoming more and more demanding in terms of targets for an adequate increase in value, the time given to achieve this is not going up. Therefore financial resources are, for many, a much bigger problem than before. Many companies can only afford to develop one or two products at the same time, and it is more crucial than ever to make the money count to build value for those products, which means that they have to reach proof of concept in humans as quickly as possible. Here too, by externalizing R&D, significant savings can be made, projects can be completed more quickly and the risk of failure can be reduced. Next, we'll have a closer look at the true significance of externalization, notably when the strategy is used for the whole development phase.

(continued on p. 8)

EXTERNALIZATION OF PRECLINICAL DEVELOPMENT

For the early stages of clinical development, biotech researchers who have identified their first candidate for development will be able to use the expertise of one of the many high-quality clinical CROs that are available on the market. This has already been the sole option in most cases for a long time. The next step is the first studies in humans. To make this transition from the lab bench to the clinic, companies had until now only two options, both requiring a significant investment and/or a relatively long time for project completion.

It is now possible to call in a SPECIALIZED CONTRACTOR to MANAGE all NON-CLINICAL ASPECTS of development

The first option was internal recruitment of the best scientists in the research team and to put them in charge of preclinical development. As they are not experienced in this field, they will learn on the job, usually supported by a panel of consultants. In order to avoid the difficulties of coordinating the various contractors, they systematically use a sequential approach (the projects being carried out one after another rather than at the same time), which is certainly more low-risk, but prolongs development considerably. Their inexperience inevitably leads them to making mistakes, which in turn leads to wasting time and increasing costs. The second option is to recruit an

experienced developer who puts together a small team to take charge of preclinical development. We all know how time consuming and costly recruitment can be. It is notably difficult to recruit qualified and experienced personnel to develop just one or two products, with the added problem of reduced financial visibility. This situation also makes investment hard to justify, because objectively speaking, teams are usually understaffed, and these new fixed charges can present a real problem if the project has to be stopped, whether it's for scientific or strategic reasons.

An alternative option to these two has become available in the US and Europe. This option is a perfect response to the need of experienced professionals, the quick completion of development, and the reduction of fixed costs. It is possible these days to call in a specialized contractor to take charge of all the non-clinical aspects of development, exactly as is done for clinical development. This externalization of the operational management of preclinical development enables an instant start, without any delay due to the formation or recruitment of an internal team, and also enables the reduction of financial risk by transforming fixed costs into variable costs (the costs of the team and its activities). Moreover, the internal resources can remain focused on innovation, which is at the heart of their business, to consolidate the product portfolio by adding new candidates. A further advantage of this externalization is that the experienced team will set out a development program that is optimized according to product characteristics, clinical usage and of course business

objectives. Additionally, the experience of the contractor enables the company to manage a maximum number of tasks at the same time, while controlling the risk which comes with using numerous CROs. The use of the best CROs in terms of price and availability makes this strategy the fastest and most profitable. Compared to the internal option, the time reduction can be up to 12 months, which is crucially important, given the average visibility of most companies. Finally, the involvement of an experienced, independent and objective team gives confidence to investors, as well as to potential partners who are interested in the product. Naturally, this option has its limitations, and the creation of an internal team should be considered if the company's portfolio holds more than three or four products already in development. Biotech companies, like pharmas, have to adapt to the changes in their constraints, and the externalization of the whole development process is the appropriate response for many enterprises. Today, this is a possibility thanks to the emergence of specialized contractors in operational management of preclinical programs, who complement the work of numerous clinical CROs, enabling them to adopt a particularly coherent and profitable strategy for building value for innovation quickly.

*Vincent Dubois,
Product development
manager with Leads
to Development
(L2D) Services*



STARTWEST 2010: SUBMISSIONS ARE OPEN FOR THE 10TH CONFERENCE WHERE CAPITAL AND INNOVATION MEET

STARTWEST takes place on May 19th and 20th 2010 in Nantes, France, at the Cité Internationale des Congrès.

Deadline for candidate dossier submission is April 2nd 2010

Please send you dossier to: <http://www.start-west.com>



