AN AUDIENCE WITH…

Carlo Incerti

Head of R&D, Genzyme Europe. Co-chairman of the European Management Committee, Member of the Corporate Portfolio Management Committee and Head of R&D for Genzyme Europe, Carlo Incerti is responsible for the strategic direction of Genzyme R&D. President of the Board of European Biopharmaceutical Enterprises since 2005, he is also a member of the board at the European Federation of Pharmaceutical Industries and Associations. In addition, Incerti serves on the governing board of the Innovative Medicines Initiative.

What does the Innovative Medicines Initiative (IMI) aim to achieve and what are the benefits for companies to be involved?
The IMI represents a milestone because for the first time there is a consortium of private enterprises that, together with the European Commission, will address research bottlenecks. We spent a lot of time putting together a Strategic Research Agenda (http://imi.europa.eu/docs/imi-gb-006v2-15022008-research-agenda_en.pdf) to identify which pre-competitive issues prevent us from developing more efficacious medicines safer and faster. During this process it has been remarkable to see how the member companies of the research director group of the European Federation of Pharmaceutical Industries and Associations (EFPIA) have talked in an unprecedented collaborative way. There is a general agreement that in research the low-hanging fruits have been taken and now to answer the unmet medical needs we must unify efforts to find better tools. What we have planned is that there will be a close collaboration between the creative, innovative parts of research — the small and medium-sized enterprises (SMEs) and academic institutions — and the larger established companies.

There are many advantages for SMEs and academic groups to participate in the IMI. They often have brilliant ideas but their vision towards a product is often lacking. The IMI could help them with their development process because it creates collaboration possibilities with bigger companies. Also, their research could benefit from tapping into databases of bigger companies for toxicology results or clinical data and samples — this is extremely difficult for smaller companies or academic institutions to do alone. Last, but not least, there is the possibility of receiving funding as we will dispense 2 billion euros over the 7 years of the project.

Will only the companies involved in projects benefit from the research?
There is an intrinsic funding benefit for the non-EFPIA members of each consortium involved in a specific research project. It's not expected *per se* that a specific project will result in a new therapy but in better knowledge, which will then foster the development of a specific therapeutic. What we hope is that we will create more tools for research. But, for the sake of an example, let's say that a new biomarker for efficacy is identified for a neurodegenerative disorder. If this biomarker is developed into a commercially available diagnostic kit then the initial benefit will be to the members of the consortium. However, the beauty of the mechanism is that for research purposes the product will be validated and made available at reasonable terms or for free to other companies and academic institutions.

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How will the IMI address challenges that EU companies have faced when responding to EU initiatives in the past?
Many SMEs communicated to us at the European Biopharmaceutical Enterprises that the EU framework programme of funding is inflexible and sometimes too bureaucratic. With the IMI we hope that we have made the infrastructure as simple and as realistic as possible. We have added an industrial project management perspective into the bureaucracy of European Commission funding and we hope that this will make funding available faster and easier for academic groups and SMEs. For larger companies, we hope that this Initiative will foster more collaboration in the pre-competitive area because there has not been a vehicle to enable this in the past.

Another big challenge is the issue of intellectual property (IP). To address this we have revised the IP rules used in the EU framework programme to make them more user-friendly and also to help recognize the foreground and background protection needed for SMEs because they could bring some proprietary information. On the IMI website (http://imi.europa.eu) there is an extensive dissertation on IP issues and we also have a helpdesk for participants. We expect the members of each consortium to agree on how they are going to deal with the generated IP. This is a delicate discussion and will have to take place before the granting of the funds because we do not want obstacles during programme development. The timing is such that in order to use the budget that has been made available in 2008, we need to have the selection process completed by the end of this year.

What are the remaining challenges?
As the first deadline for submitting expressions of interest has only just passed, I would say that we have tried to foresee the foreseeable. We have put a machine in place and will try to oil it, but the engine will only start to work in these months. We hope that the process will advance as we have planned, and that the SMEs, academic institutions and other eligible entities will present really good expressions of interest. There will be minimums required in terms of scientific soundness, composition of the proposed partnerships and ability for the partners to deliver. In the end we have created the IMI to resolve bottlenecks of research so we need to aim for excellence. This is not just a funding mechanism — it is something that is funding innovation to improve the drug development process.