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<sup>1</sup> For the "Technological resources  
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<sup>2</sup> For the "Business life" seminar

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**O4CP :  
A PHARMACEUTICAL COMPANY  
SPECIALISED IN THE PAEDIATRIC MARKET**

by

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**Overview**

A large number of medicines are prescribed for children despite the fact that their formulations are not adapted for children and they have never been tested on patients in this age group. Furthermore, they do not taste very nice and therefore it is difficult to administer them to very young children. These facts prompted Vincent Grek, who had worked for ten years in well-known pharmaceutical R&D research laboratories, to add an Executive MBA to his medical training and launch Only for Children Pharmaceuticals (O4CP), the first pharmaceutical company dedicated exclusively to children. The company's launch was encouraged by new paediatric legislation adopted in 2007 by the European Medicine Agency, and the fact that the global market for paediatric medicine was estimated to be worth 5 billion Euros. Seven years later, O4CP has already eleven medicines in the pipeline and the company is considering a stock exchange flotation.

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## **TALK : Vincent Grek**

I am a doctor specialising in internal medicine with a degree from the University of Liège. I worked for a number of years in intensive care, oncology and hematology/oncology, but I was very quickly attracted by the pharmaceutical industry. I worked for GlaxoSmithKline in the development of vaccines, then for Genzyme, Yamanouchi (where I managed a clinical pharmacology unit), and finally at Sanofi-Aventis where I worked in gene therapy development. After my experience at Sanofi-Aventis, I felt that I had exhausted what I was able to do in a company of this nature, and I wanted to create my own company.

In 2007, I started studying for an MBA at the ESSEC (École supérieure des sciences économiques et commerciales) business school. There were 40 students in my class and we had to create a business project. I had heard that the European health authorities had just adopted new paediatric legislation. This prompted me to draw up a business plan for a pharmaceutical company specialised in medicines for children, which I called O4CP (Only For Children Pharmaceuticals).

### **The need for paediatric medicines**

Paediatric medicines cover a relatively broad spectrum because there are important differences between a baby, a four-year-old child and a teenager. Each age has its own particularities and therefore one cannot administer the same medicines as one would for an adult population.

For example, a premature baby weighing 800 grams cannot be given more than 20 millilitres of intravenous medicine a day. If its state of health requires several medicines, then this limit will be reached quickly. Likewise, in children, the brain and other organs are not yet fully developed and so this may make it impossible to use certain medicines. It is not always easy to make teenagers take medicines. One solution might be to present the medicine in the form of chewing gum and set an alarm on the teenagers' iPhones to remind them of when to take the medicine 'chewing gum'.

Approximately 50 % of medicines which are currently used in paediatrics have never been tested on children. Sometimes parents read the instructions of a medicine prescribed for their eight-year-old son's asthma, and discover that it is forbidden for children less than twelve years of age.

90 % of medicines administered for newborns have never been tested on infants this young. This is understandable since carrying out trials on newborns, and especially premature babies who are particularly vulnerable, would raise ethical concerns.

Finally, for rare diseases (also referred to as orphan diseases), most paediatric medicines are administrated without an authorisation for placement on the market.

This situation puts children seriously at risk from overdoses (which can cause toxicity or side-effects), and under-dosages (which is demonstrated by a lack of the efficiency of the medicine).

### **New European legislation**

In January 2007, the European Community adopted new paediatric regulations which encourage the development and availability of paediatric medicines.

## *PIPs*

Pharmaceutical companies now have to devise paediatric investigation plans (PIPs) for each new medicine, and they are penalised if they do not do so. Guides have been written to help them with regard to formulation, bioequivalence and even ethics.

## *The paediatric committee*

A paediatric committee composed of representatives from the 27 EU member states was created by the European Medicines Agency. Its mission is to assess the content of PIPs of new medicines. These PIPs have to be submitted for evaluation very early on in the development process. For example, if Sanofi-Aventis develops a new treatment for high blood pressure in adults, it has to present its PIP at the very first stage of development if it wants to register this medicine for adults. Generic medicines and biosimilars are not subject to this process. Vaccines, however, must submit a PIP. Since 2007, approximately one thousand PIPs have been filed.

## *The priority list of paediatric medicines*

The paediatric committee is also in charge of updating every year a list of paediatric medicines which are to be developed as a priority from molecules which already exist. The companies in this sector of adapting these 'off-patent' medicines can receive grants of up to 6 million Euros per medicine. They can also benefit from free scientific advice from professionals at the European Medicines Agency, for example to check if the formulation is adequate, to help choose the company to carry out the tests on animals, or to ensure that the tests will be predictive. This sort of advice would ordinarily cost between 80,000 and 100,000 Euros.

## *Designation of an orphan medicine*

Once a paediatric medicine has been registered, it can either qualify for orphan designation, or receive the authorisation for placement on the market for paediatric use (PUMA : Paediatric-use marketing authorisation).

When a medicine is intended for treatment in less than 200,000 patients per year throughout Europe, it is considered 'orphan' and the manufacturer can obtain exclusivity for ten years with a high unit price. Some medicines are qualified as 'ultra orphan' because they only concern diseases which affect twenty patients per year. They may cost as much as one million Euros per treatment per year. Genzyme (for whom I worked) developed its business on this model.

In the case of paediatric medicine, the European health authorities have difficulty in applying this reasoning. The general public cannot understand why 500g of a 'generic' medicine may cost 3 Euros and yet 25mg of the same medicine – which has been adapted for children – can cost as much as 1,000 Euros. Development costs can sometimes be huge and if the product in question is only intended for 2,000 patients and is sold for just 3 Euros per treatment, the manufacturer is not able to cover his costs.

## *PUMAs*

Another possibility consists of obtaining a PUMA which grants the company exclusivity for ten years for the medicine in question. The data is protected and cannot be copied by a generic manufacturer. The medicine can benefit from two years' additional market exclusivity in the case of an orphan disease.

However, since 2007, only one paediatric medicine has obtained a PUMA. When it is possible, it is in fact more advantageous to obtain the 'orphan medicine' designation.

## **The idea behind O4CP**

When I started my MBA at the ESSEC business school, I did not know all the details of paediatric legislation. During a lecture about Dell computers, I wondered if it would be possible to transpose the Dell model of product on demand (which already exists not only for computers but also for shoes and cars) into medicine for children.

I asked some of my fellow students if they wanted to work with me on this project, and one of them answered 'I really like your project but I cannot be part of your team because I would be too emotionally involved. My son died from acute lymphoblastic leukemia. I was unable to make him take some of his medicine because the pills tasted too awful and it was a real struggle to make him swallow them.' This person helped me a great deal subsequently, introducing me to paediatricians who were able to help me understand young patients' needs.

Acute lymphoblastic leukemia is a disease which affects 8,000 children a year in Europe, including approximately 500 in France. The survival rate is 80 %, but 20 % of the children relapse and die during the 'maintenance' phase which lasts two years and during which they still receive medical care.

One of the drugs they have to take is mercaptopurine. It was created in 1945 and comes in a large 50mg tablet form. The peak age of incidence of this form of leukemia in children is 7 years old, and tablets this size are badly adapted for such young children. They also do not taste nice. Parents often crush the tablet into a powder and then mix it with milk or jam but this makes it difficult to know the actual intake of the drug. Furthermore, handling it is dangerous because the molecule is cytotoxic and may even be carcinogenic. In the laboratory, it is manufactured by people wearing protective suits, and yet mothers, even when they are pregnant, can crush the tablets, and traces of the molecule have been found in their blood. This situation is clearly outrageous.

Mercaptopurine is one of the priority medicines on the list drawn up by the European Medicine Agency's paediatric committee. The five of us on my ESSEC team decided to tackle this problem with two specific aims : to make this drug available in an oral liquid formulation to make dosage easier and more precise ; and to give it a taste 'on demand', determined by the child patient.

## **Filing the first dossier**

During our coursework at the ESSEC business school, we submitted a grant application to the European Medicines Agency to develop a paediatric medicine from mercaptopurine. We named our future product 'Loulla-Philla' and added the slogan 'The medicine I need with a taste I like'.

Some time later, I got a telephone call from the Ministry of Industry notifying me that we had got top marks, 15 out of 15, and that we were going to receive a grant : we had got 5 points for innovation, 5 points for the consortium, and 5 points for the expected impact. Having started from nothing, we had won a grant for 6 million Euros. Our notoriety spread instantly and widely, and very soon afterwards we were contacted to launch new projects and were treated as if we were already specialists in the field !

The situation became a little complicated when we were due to receive our first instalment of 1.8 million Euros. It was 2008 and the Madoff fraudulent investment scandal had just erupted. As they were writing the first cheque, the European authorities noticed that our company's capital was only 10,000 Euros, and they became nervous about our legitimacy. To be eligible to receive a grant, we had to submit a transfer guarantee, in other words, we had to prove that the money would be directly transferred to our partners so that the banks would avoid taking any risks.

## **A vial with two bottlenecks**

After some trial and error, we perfected a vial which had two bottlenecks. One of the bottle-tops contains the tablet with the active ingredient. When one presses on the bottle-top, the tablet is released and drops into a flavoured liquid (there is a choice of flavours including caramel, orange, peach and lemon). One then shakes the bottle, inserts a graduated pipette into the other bottle-top and draws off the measured dose of the liquid and gives it to the child.

Separating the tablet from the flavoured liquid and not mixing the two until the last minute guarantees the stability of the medicinal product. This form of vial could be used to sell other kinds of medicines. To present a medicine in a liquid form, one needs to show that the mixture can remain stable for two years, which clearly is not easy to do. Furthermore, even though it is easy to hide the bad taste when one mixes the tablet with the liquid, it is virtually impossible to do so for two years. The last particularity of our invention is that we decided to choose a single-use vial because if we had wanted to make multiple dose vials, we would have had to use parabens (preservatives used to prevent the growth of bacteria) and we wanted to avoid using them.

We asked a number of scientists for their opinions and followed the recommendations of the paediatric committee to avoid using paraben. The European Medicines Agency asked us to carry out tests on hamsters in order to show that our oral solution was not toxic on mucous membranes. We also had to carry out a bio-equivalent study on humans.

Since 2009, we have registered a patent which ensures us exclusivity of the vial in the United States, Canada and Japan. We did not have enough money to extend this patent to Brazil and China. We have already obtained the European patent and we are in the process of obtaining the American and Canadian patents.

However, when we filed our registration dossier in Europe, we were 'pipped at the post' by an English competitor who had designed a vial made with paraben, and had tested it in Africa on healthy volunteers. We discovered that the paediatric committee and the registration committee were two distinct entities and that the second ignored the fact that the medicine contained paraben. The conclusion is disappointing : this product, whose development was financed by the European Union, will be sold in the United States and Canada, but not in Europe. European patients will not be able to obtain our higher quality product.

## **The use of ibuprofen in infants**

Some medicines may appear to be purely for adult use, but they can have specific applications to children. Ibuprofen, for example, is a medicine used to treat headaches in adults, but it can also be administered to correct anomalies found in some premature newborn babies, such as the non-closure of the patent ductus arteriosus (PDA) which causes cardiovascular problems. In the past, this malformation required surgery. Now, doctors can prescribe ibuprofen which activates a hormonal mechanism and closes the PDA in a few days.

In its formulation for adults, ibuprofen costs \$0.15 for a 200 mg capsule. For newborns, a 20 mg intravenous ibuprofen vial costs \$640. Each newborn has to be treated with two vials and there is a market for 60,000 doses per year.

## **A new formulation for bumetanide**

The application of the same drug for different populations inspired us to develop a model for a formulation which is adapted to a paediatric application of bumetanide. This molecule was perfected in the 1970s as a diuretic but it can also treat some forms of epilepsy in newborns. During the first weeks of life, babies have a neuronal receptor called the NKCC1. Bumetanide fixes itself to this receptor and prevents seizures. One must intervene very early because with time, this receptor disappears. In the United States, there is a formulation of bumetanide used for newborns but this formulation includes benzyle alcohol which is toxic for infants.

We decided to develop a formulation without benzyle alcohol and we received European grants for this project. We demonstrated the non-toxicity of our formulation on rabbits, and so we were then able to launch clinical trials on newborns across Europe (in Ireland, Finland, the United Kingdom, France, Sweden, and the Netherlands). Our co-sponsor was the Great Ormond Street Hospital for Children, the largest paediatric hospital in London which is financed by private funds and notably by royalties whenever a performance of 'Peter Pan' is staged or a Peter Pan book is published (in accordance with the wishes of the Peter Pan author, JM Barrie). For a small start-up created two years earlier at the ESSEC business school with a capital of 10,000 Euros, this is very encouraging !

### **The O4CP business model**

O4CP's core activity involves making paediatric medicines from existing molecules. We target orphan childhood diseases such as leukemia, juvenile arthritis and diseases in the newborn which affect less than 200,000 patients per year in Europe. In terms of price for a year's treatment, our medicines cost between 10,000 and 20,000 Euros.

#### *The industry rather than the services*

In the beginning, we hesitated between the industry itself and the services, for example pre-clinical development. We chose medicines mainly because of the size of the market. The size of the global market for paediatric medicines represents one-tenth of that of the market for adult medicines, in other words, 50 billion Euros for the industry and only 10 billion for services. Furthermore, positioning ourselves as manufacturers meant that we had no rivals and we were able to be present in a field where we are both very visible and greatly appreciated, notably by paediatric specialists.

#### *Obtaining grants*

Operating in a market worth 50 billion Euros might seem a little daring for such a small company. However, in making our choices among the priorities outlined by the European Medicines Agency, we managed to raise 25 % of all the European grants intended for the development of paediatric medicines by ourselves. This is how we have managed to create a current pipeline of eleven medicines. We have perfected the formulation for ten of them, four of which are in the stage of pre-clinical trials and three, in clinical trials. Finally, one medicine (mercaptopurine) is in the registration stage.

#### *Accelerated processes*

Our positioning allows us to advance in certain stages of development more quickly than using mainstream processes. There is a great deal of literature about medicines which have been present on the market since the 1970s, especially regarding the various side effects in adults and children. Furthermore, as I mentioned, we can ask the European Medicines Agency for advice for free. Subsequently, we benefit not only from the mass of knowledge accumulated by academic research over a number of years, but also from the creativity which characterises a small company but which is more difficult to find in a large laboratory.

In comparison, the necessity for pharmaceutical companies to draw up PIPs for each new medicine is quite a heavy burden and a complex process : how can one imagine, in the first or second phase of development of a molecule used to make a diuretic, that it will be possible to have a neurological application with newborns ? Our approach is, in a way, much more 'comfortable'.

### *Ease of distribution*

In France, the leukemia treatment which we offer is only of interest in four or five hospitals, and about twenty-five in total in Europe. The neonatal market is a little bigger with approximately 400 units in Europe. The marketing and distribution networks which we have to establish will remain minimal and therefore not very expensive, compared to the distribution for usual medicines.

### *The problem of sourcing*

The principal inconvenience of the model which we chose is the difficulty to obtain the molecules to manufacture our medicines. The company which markets ibuprofen intended for newborns sells 60,000 20 mg doses every year, which represents a total of 10 kg. However, this product is sold in tonnes, and many manufacturers refuse to sell it in such small quantities.

Furthermore, 80 % of the molecules which we target are made in India, China or Japan, and there are sometimes problems with quality. For example, when we have analysed isoniazide in the past, we did not find any trace of this antibiotic in the product which we were delivered.

In view of the problems of falsification of medicinal products, a certain number of laboratories are starting to resynthesise molecules in Europe. We are thinking of asking them for help as this would enable us to solve the problem of low-volume orders. To supply a market worth 20 million Euros, the manufacture of molecules in Europe could cost us as much as 1 million Euros, but the model would still be profitable and we would be sure of the quality of the product.

### **A small team**

Our business model corresponds with our decision to remain a very small company. We look for skills which we need outside the company and we employ a number of subcontractors.

In the beginning, there were just four of us, and we worked very informally. As a doctor with experience in the pharmaceutical industry, I was not particularly keen to become a CEO. We would talk to each other in the corridors, asking each other to telephone various laboratories or send out bills to clients. It was rather stressful.

After a while, it was clear that we had to organise things differently. I created four committees : a development committee, a business development committee, a management committee, and a quality committee. The four committees were made up of the same four people but sharing tasks and responsibilities became clearer. With these committees, we were able to structure our decision-making process better and slow down the rhythm (by suggesting discussion of specific matters at relevant committee meetings) which, paradoxically, was a good thing.

Six years after its creation, O4CP has just ten full-time positions. In the long term, I think that we will have about fourty employees but I do not want the company to become too big.

### **The ups and downs of funding**

The company is quite fragile financially because it still depends on grants, and this means that we must manage our cashflow very carefully.

In the beginning, I thought we could attract venture capitalists but, in order to do so, we would have needed a 'miracle molecule' which would have allowed us to target a market worth 80 billion Euros, whereas each of our molecules represents a market of between 20 and 50 million Euros. The entire market is not worth more than 500 million Euros, which is too

small for venture capitalists. Furthermore, the grants which we received (25 million Euros for projects, and between 2 and 3 million Euros for the company itself) have enabled us to develop relatively quickly and, when we started to find investors, they were no longer able to give us sufficient financial support compared to our needs and the extent of our progress : we no longer needed 300,000 Euros but 10 or 20 million Euros. In 2011, after much searching, we managed to find a fund which was ready to invest 16 million Euros. However, when we were ready to sign with them in September 2011, we were 'pipped at the post' on the mercaptopurine project by our English rival. At the last minute, the investor decided to pull out and left us with only enough money to survive a fortnight.

I had to implement legal measures to protect the company from creditors, protecting myself as a director and obtaining terms of payment from our creditors. I refused propositions from outsiders to buy the company for a Euro, and I took the strategic decision to sell the licences of some of our products. The first agreement was signed with SOBI (Swedish Orphan Biovitrum), a Swedish company quoted on the stock exchange. We sold off the licence cheaply but since the transaction was public, it gave us publicity and was intended to make people think that if we could sell off our licences, then there was a market for our products. Following this, I was then able to negotiate a joint development and marketing agreement for Lulla-Philla with a very promising American partner.

### **Next objective : flotation on the stock exchange**

In the end, the three licence agreements which we signed enabled us to increase our credibility, improve our development capacities, show a profit for the first time and rebuild our capital. We can now consider marketing some of our products ourselves, but also float the company on the stock exchange and thereby accelerate our development. When one wants to become an industrial leader, one has to find the means to finance oneself and I think that the stock exchange is the appropriate way to do this. The disadvantage of venture capital is that one has to pay the money back over a short time-frame. Therefore, flotation is important not only for the development of the company but also from an ethical point of view. I prefer not being confronted by venture capitalists asking me to speed up a clinical study concerning newborns.

We have prepared ourselves for this new stage by taking on the status of a limited company and creating an executive board. We have also launched a good Internet site. The feedback we have had makes us optimistic that the company is attractive. We have patents and are free of all investors. I own 70 % of the capital, my associates 25 %, and the ESSEC business school, 5 %. Furthermore, on Alternext (the Euronext market for SMEs), there are not many biotechnology companies which are making a profit. The flotation on the stock exchange should take place in the coming months.



## DISCUSSION

### The driving force behind the new legislation

**Question :** *What is the driving force behind new paediatric legislation : the desire to provide better healthcare for children, or to create a more organised health system in Europe ?*

**Vincent Grek :** I think the primary driving force is the desire to improve the quality of medical care for children. We should be proud of ourselves because Europe is a leader in this field, in particular compared to Japan but also compared to the United States where legislation acts as an incentive. Legislation allows for the prolongation of the length of patents when the medicine is for paediatric purposes but, because of the additional investment which this entails, pharmaceutical companies only develop paediatric medicines which are intended to be sold in large quantities.

The second driving force behind the new legislation is clearly related to economic and industrial factors. When we responded to the first call for tender in 2007, it was possible to just have one industrial partner within the consortium. Since that time, there has been an economic crisis and now, one-third of the budget has to be allocated to one or several SMEs (small and medium-sized enterprises).

**Q. :** *One of the motivations behind the European legislation is also probably to provide legal protection should an accident take place in children regarding a product intended for adults.*

### Hard times

**Q. :** *Apart from the ups and downs of cashflow (which is a common problem for start-ups), at what moment do you think you came closest to a catastrophe ?*

**V. G. :** It was very hard for us when our investor abandoned us at the end of 2011. The employees lost faith and did not want to work any more. Our rival had just received its authorisation, and the European Commission was slow to give us the rubber stamp to file our own registration dossier. We had no more money and everyone was demoralised. I still had to motivate my team to file the registration dossier before the midnight deadline on December 20<sup>th</sup>. On the last night, despite the fact that we still had to work on a large number of things and then save the data to CD-ROMs and post them, everyone went home at 6pm and I was left all alone. I am divorced and two of my children were arriving from Belgium that night to spend the Christmas holidays with me. I had to send them to friends in Normandy. I finished the dossier and ran to the Louvre Post Office (open 24 hours) to send it off before midnight. I felt really alone...

There are still some scars left from this period. Some people are happy about the prospect of the flotation, others are not so enthusiastic, but I am sure that we can turn this ordeal into something positive.

### The price of medicines

**Q. :** *How will negotiations about the price of your medicines take place ?*

**V. G. :** Discussion with the authorities involved has not started because we are still at the registering stage. However, we have carried out market studies and we think we shall get the right prices.

**Q. :** *The prices you mentioned seem very high...*

**V. G. :** It all depends on the reference point used to calculate the margin. If the product sells for 600 Euros per unit and one only takes into account the cost price of the molecule, the margin appears to be enormous. However, if one takes into account the development costs, depreciation, and also and importantly the health benefits for the patient, it is a very different matter.

**Q. :** *Your prices will probably be submitted to the Transparency Committee.*

**V. G. :** Yes, and a certain number of medicines are invalidated by this Commission. This is why some companies do not commercialise their products on the French market. I think the system lacks consistency. Paediatric legislation is enacted on a European level but the prices are fixed on a national level. In view of the economic crisis and budgetary difficulties in some countries, it is understandable that they are not ready to agree on a random price for paediatric medicines. Having said this, there could be other solutions, such as calls for tender. The European Medicines Agency could, for example, invest 2 million Euros every year to provide a specific medicine for 40,000 children. Personally, I would prefer to take part in a scheme where the margin is smaller but is guaranteed, rather than one which involves taking risks and being vulnerable to setbacks.

### **Why France ?**

**Q. :** *Why did you establish your company in France ?*

**V. G. :** I cannot imagine creating the company anywhere else. The doctors who implemented the paediatric regulation – Gérard Pons and Françoise Brion – work at the Necker Hospital in Paris. They campaigned for a very long time to highlight these issues. When we created O4CP, they opened their doors to us and helped us constantly, giving us all their professional experience.

I also benefitted from the ESSEC training scheme and the City of Paris' business incubator, Agoranov, which provided me with my first premises where I always found people ready to help me.

Today, I am supported by the Medicen Paris Region competitiveness cluster which granted us certification and helped us get grants. I also hope that we can enjoy working with Alternext which is beginning to show interest in biotechnologies and the pharmacy sector.

Finally, I benefitted from the French social security system. When I was unemployed after I left Sanofi-Aventis, I was able to get a grant to create or take over a company (from the ACCRE fund). When the advisor at the Job Centre realised that I was a specialist doctor with a degree from the ESSEC business school and was unemployed, she looked at me as if I was from another planet ! The 40,000 Euro grant from the ACCRE fund was very useful in order to set up my company. In the end, the system which I found in France really helped and protected me.

### **Naive but tenacious**

**Q. :** *Yves Dubreil, former head of innovation at Renault, once said in this very room that when he came across a problem which was very complicated, he talked about it to young people as they are a little naive and since they do not know that the problem is unsolvable, they are likely to find a solution. You too seem to be a little naive, but it is clearly to your advantage. No-one, apparently, told you that an MBA from the ESSEC business school and business incubators are useless, and that legal measures taken to protect one from one's creditors are never satisfactory. You also seem to ignore that it is practically impossible in France to float a hi-tech company on the stock exchange, but it is perhaps this naivety which will help you reach your goals in the end.*

**V. G. :** Sincerely, throughout my career I have really only ever met people who are kind. When one door closes, another one opens. All the same, I have had difficult times. At Innobio, for example, when I explained that we had already won three European calls for tender and carried out two clinical trials, they said to me 'But Mr. Grek, you haven't done anything yet.' I admit that this remark infuriated me. The same thing happened when I

contacted Paris Biotech Santé (an incubator in the health care sector which is associated with the ESSEC business school) which is managed by a paediatrician. I thought that it would be easy to get their funding, but again I was naive.

I think one has to be naive and laid-back but also tenacious and, above all, to never lose sight of one's dreams.

Presentation of the speaker :

Vincent Grek : president and medical director, O4CP.

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