

Newsletter n° 7

January 2017/June 2017

News

BabyLux, the next step is the market!

BabyLux project, started in January 2014, is coming to an end. The clinical validation is entering a decisive phase. Both hospitals, Rigshospitalet Copenhagen and Ospedale Maggiore Policlinico Milan, are engaged in testing the device in a real time setting. However, in order to have the appropriate time to complete the validation phase with clinical tests, the project obtained an extension of 4 months and will be officially finished by the end of April 2017.

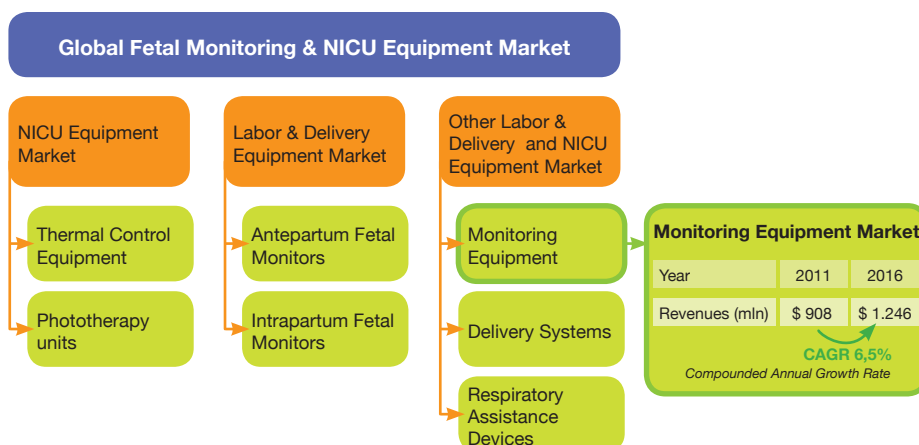
The trial phase is of great importance to accomplish the project's goal as well as the exploitation. That's the reason **why this last newsletter is dedicated to the market analysis in order to identify future business opportunities**. Fondazione Politecnico di Milano, having a vast experience in managing European projects, is studying a **go-to-market strategy**.

According to the new policies of the European Commission (to increase its level of innovation and to respond more effectively to societal needs), BabyLux project will have a strong focus on creating business activities.



The market!

To do that, we have to consider that BabyLux is positioned in a specific market segmentation: the global fetal monitoring & Nicu equipment market revenue, that is growing at a CAGR (compounded annual growth rate) of 6,5% during the 2011 – 2016 period (see the figure). Moreover the global labour and delivery NICU equipment market is worth over \$2.2 billion in 2011, growing to reach \$3.2 billion by 2016. The U.S. represents the biggest market, followed by Japan. These data are a consequence of a global trend: average age of maternal population across developed economies such as U.S. and Europe is increasing gradually and therefore the increasing number of premature babies is expected to increase the demand for fetal and neonatal monitors, which will reduce the mortality rate and resolve long-term problems of infants. The specific requirements of the preterm care babies, neonates, and infants, forces the manufacturers to develop devices and disposables which are small, non invasive and have a proper fit for the babies. Exactly what BabyLux is testing. The market is therefore in favour of such devices.



How to scale up

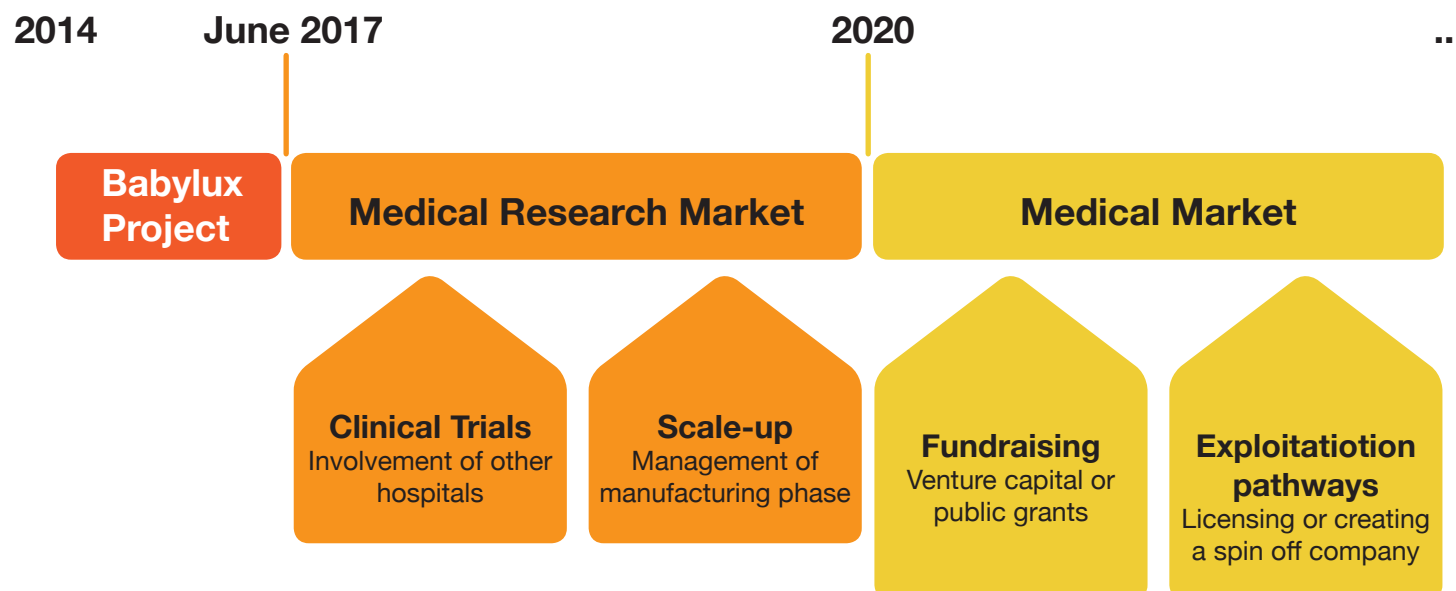
In order to exploit the competitive advantage of the BabyLux product, two different markets have been identified (see figure below) the medical research market and the medical market.

The medical research market can be quickly addressed. This segment is made by professional users such as hospitals and research centres that are interested in evaluating the performance of the BabyLux innovative solution. This market is small, but there are no particular threats to be addressed. During this phase, the involvement of other hospitals around Europe could improve the significance of the results and allow the BabyLux consortium to collect valuable feedbacks and information. There will be a first phase of 'scaling-up' to manage the bill of material with suppliers and the manufacturing phase, to appoint some managers in charge for the customer relationship, to collect valuable information from the early users.

On the contrary, it is more complex to serve the larger medical market (i.e. the general market made up by any possible user of the device), because of certification issues (the CE mark, above all). A startup company can experience troubles in this phase, because of lack of competences and funding.

Therefore it will be particularly important to find partners. Moreover, clinical trials must be completed, this allowing the BabyLux team to fully exploit the opportunity of the market in 2020. In the medium run the most relevant investment will be devoted to the development of the commercial network and to marketing expenses. Funding could be provided either from venture capital investors or from public grants. It will be worth submitting the business opportunity to venture capitalists around Europe, focussing on life sciences and medical market. This will also allow the partners to access to a broader audience of potential customers and to benefit from synergies with other investee ventures. Funding from public entities (i.e. European Union or national governments) is also welcome, in order to take the business project to an advanced level'.

In relation to the exploitation of the device it is recommended to carefully examine potential exploitation pathways, i.e. licensing, creating a spin-off company. It is also recommended to further investigate if the BabyLux consortium has the freedom to operate in the existing IP landscape.



With us in this issue!

Read the interviews with our partner Udo Weigel, CEO of Hemophotonics, and Paul Borm, Chief Sales Officer Nano4imaging.

Spin-off of the ICFO-Institute of Photonic Sciences, **Hemophotonics** will draw up the exploitation plan, the DCS system customization and the control software adaptation to commercialize and further develop the final prototype.

Nano4imaging, who has a great experience in medical devices, is a startup company based in Aachen. Its focus area is minimally invasive medical devices. It plays the same role as Hemophotonics in other EU financed projects. One of them is **Openmind** – On Demand Medical Devices – a Horizon2020. As an end user, Nano4Imaging will on the one hand support the development of a practicable process model and on the other hand give guidance on the implementation and demonstration.

Udo Weigel, CEO of Hemophotonics



At what stage is the project?

At the present stage, all the technology is still a prototyping technology, which is of course an advantage in terms of flexibility, but it is less competitive and much more expensive per unit. To be scalable, we should look to a large scale production and consider many more units. It means exploiting the cost factor arising from building this many times.

What are the next steps?

The next step is to collect the data from clinical doctors, because this is the standard that should be measured. Our target is that of providing valuable information to them. So we need to take these data and see if we really can give this contribution. The technology is there and the data acquisition has to prove now that these are valuable data, that maybe in the future they can change the situation of premature babies and give them a better outcome in the long term.

From research to the market. Is it a big challenge?

It is, because that's the challenge that we basically started out with. But for a commercial device phase, we need high volume production as well as the necessity of selling many units. Actually, there should be some people who pick up the technology earlier than others and do some research with this device. This way might help us and the credibility of the technology to evolve to the medical market. So from research to commercialization is certainly possible, but it is a long way and a lot of work!

Paul Borm, Chief Scientific Officer Nano4imaging



Challenges and difficulties in the medical market

There are many challenges and many difficulties. The most important one is to stay alive. First of all, you have to take care of your financial situation and make sure it is as robust as to survive the certification procedures. As a matter of fact, especially for these products (surveys and intensive care unit market), you have to manage with a high competitive market and with vulnerable patients. Certification will take a lot of time. Therefore you have to be sure that your company has good supplies for that period.

What would you suggest to BabyLux partners?

I notice that BabyLux is a highly innovative product. It is for a very specific market: neonates and intensive care units. So my advice is to partner up with companies that are in the same situation. It is necessary to make a real business plan and rely on someone who has experience in this market (intensive care and preterm babies), like a CEO. Don't forget to make a couple of plans with also fall back scenarios in case something goes wrong financially or with certification.

From research to the market. Is it possible for BabyLux?

It is possible. It can be done. You need to involve the key opinion leaders, you need to have the clinical drivers that are right behind you to make things happen and then you have to find people supporting you financially. Then you'll be able to create the evidence you need for the certification.

Next events



1-4 April 2017

28th Symposium on Cerebral Blood Flow, Metabolism and Function.

13th Conference on Quantification of Brain Function with PET

Berlin, Germany

The abstract "Baseline haemodynamic and optical properties of the newborn brain and the reproducibility of the measurements: a preliminary report from the BabyLux project" will be presented in the "Cerebral ischemia: clinical" session on April 3rd 2017. BRAIN & BRAIN PET 2017 will cover numerous aspects within the area of neuroscience research.

28 April 2017

BabyLux, final event

Milan, Italy

Further comments about the project and the outputs are expected during the final event. We look forward to seeing you at Politecnico di Milano!

The conference will be dedicated to both scientists and doctors to comment on the project outcomes and on the optical methods for diagnosis and brain monitoring. The event is free of charge and open to the public.



BABYLUX

Talks

Watch the video interview

Episode #9



This project is partially funded under the ICT Policy Support Programme (ICT PSP) as part of the Competitiveness and Innovation Framework Programme by the European Community

Subscribe to the **newsletter**
on our website www.babylux-project.eu