EPRISE
EMPOWERING PHOTONICS

Go-To-Market And Opportunities Booklet

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PHOTONICS 21
PHOTONICS PUBLIC PRIVATE PARTNERSHIP

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1 INTRODUCTION

Photonics, as a cross-cutting technology strongly present in various industrial sectors, has been identified by the European Commission (EC) as one of six Key Enabling Technologies (photonics, micro/nanoelectronics, nanotechnology, industrial biotechnology, advanced materials, and advanced manufacturing technologies). They are drivers for the modernisation of Europe's industry, help tackle societal challenges, and thus foster Europe's competitiveness. Photonics applications in the Medical Technology, Pharmaceutical, Agriculture and Food markets, where Europe holds a leading position, have a high potential.

SMEs developing photonics-based products, processes or services for these markets face highly specific Go-to-Market challenges such as long timescales to market adoption and complex regulatory frameworks. They need market-specific advice from experts who can guide them through business-related (i.e. non technological) topics. They are also in need of support from public funding to cross the "Valley of Death" between the innovation-ready phase (Technology Readiness Level, TRL 4, where technology has been validated in a laboratory environment) and the investment ready phase (TRL 7, where system prototype demonstration has taken place in the planned operational environment and the technology has been sufficiently proven to get venture capital financing to bring it to the market). Thus, companies also require some non-market specific business support, e.g. advice about finance.

At the same time, photonics SMEs can benefit from networking with their European peers to share their experiences and jointly apply for public funding as well as from pitching their products at integrators, end-users, and private investors.

Photonics clusters can play a role in this context thanks to their technology understanding, connections with local policy makers, and experience in supporting companies and creating networking opportunities. Therefore, eight photonics clusters and a technology innovation center from eight European countries (France, the UK, Spain, Germany, Sweden, the Netherlands, Italy and Finland) conceived and delivered the EPRISE project ("Empowering Photonics through Regional Innovation Strategies in Europe"; an EU funded 30-month Coordination and Support Action from January 2017 to June 2019).

One of the key objectives of EPRISE was to assist photonics SMEs in accessing the Medical Technology, Pharmaceutical, Agriculture and Food markets by offering them expert advice.

The EPRISE partners conducted interviews with early, mid and late stage companies to find out their Go-to-Market challenges. In parallel, an EU-wide database of experts was set up to map the market specific expertise available in partner countries, and matching the identified needs. The database has been published on the EPRISE website at the end of the project.

SMEs also had the opportunity to gain knowledge about their target market, to obtain tailored solutions from experts, and to meet potential partners for collaboration and business development in the framework of the "European Photonics Roadshow" series (each event focusing on one target market).

This booklet provides an overview of the opportunities for photonics in the Medical Technology, Pharmaceutical, Agriculture, and Food sectors as well as information useful for SMEs to overcome market-entry barriers. It gathers the most relevant outcomes of the European Photonics Roadshow, including best practices, lessons learnt, takeaways and tips from experts.

Information consists of:

- general articles presenting target market trends and possible applications of photonics, and highlighting how the latter can contribute to solve societal challenges;
- technical articles dealing with both market-specific topics such as clinical trials and pharmaceutical clinical trials and cross-sectoral themes such as access to finance, Intellectual Property (IP), start-up support, internationalisation.

Finally, one case study per market has been selected as an example of challenges commonly faced by companies (scale-up manufacturing and regulatory strategy, access to large companies and IP strategy, recognition from end users, diversification).

The booklet mainly targets photonics SMEs entering the four target markets to help them enhance their business skills, but also integrators and end users to increase their awareness of the potential of photonics-based solutions in their sector. Printed booklets will be distributed amongst the members of the EPRISE partners (photonics supply chain) and their regional and national funding bodies to stimulate investment in photonics ventures. The booklet will be also available on the project website in the form of e-book. This will enable larger dissemination towards local sectoral clusters and photonics clusters not part of the consortium, and companies active in other technological areas (e.g. robotics) to foster collaborative projects in the target markets.

2 MEDICAL TECHNOLOGY MARKET

2.1 Market overview

Medical Technology is any technology enabling diagnosis, monitoring and treatment of human disease. It includes medical devices and in vitro diagnostic medical devices.

Medical Technology industry is an important player in the European economy. Key features and figures are listed below[1]:

- Highly innovative sector with about 13100 patent applications in the field registered at the European Patent Office in 2017;
- Medical technology companies are mainly SMEs (95% of about 27000 companies, most are based in Germany, the UK, Switzerland, Spain and France);
- More than 675 000 employees (Germany has the highest employment, the UK, France and Italy follow);
- Estimated market size in 2017 was about €115 billion (27% of the worldwide market after USA) with Germany, France and Italy having upper rankings;
- Average medical device market growth rate of 4,3% per annum over the past 10 years;
- Spending on medical technology amounts to 5-10% of the total healthcare expenditure, depending on the country;
- Estimated trade surplus of €19,7 billion in 2017;
- Cross-sectoral field involving physics, bio-chemistry, engineering, information technology and medicine.

2.2 Photonics for Medical technology

Europe already holds a leading position in healthcare photonics and a significant growth in this field is expected in the coming years. Photonics 21 Multiannual Strategic Roadmap indicates: a Europe's share of about a third of the worldwide healthcare market for optical technologies alone, estimated to be €23 billion in 2010; a share in the microscopy market larger than 50%; room for important expansion in the areas of medical imaging and laser therapeutic systems (market share about 30%) and for in-vitro diagnostic systems (below 20%)[2]. Market for healthcare photonics is expected to reach €50 million worldwide by 2020[3].

From a societal point of view, Europe currently faces challenges such as an annual death rate of 30 million people related to heart diseases, cancer, strokes, pulmonary diseases, and 10 million early deaths from diabetes and nutrition-related causes due to richer diet and sedentary lifestyles[3]. Additionally, age-related diseases like Alzheimer, dementia, macular degeneration, osteoarthritis and cancer are expected to growth proportionally to the fast population ageing. The number of citizens older than 65 is expected to double by 2030[3]. These demographic changes will have dramatic consequences for healthcare systems and annual spending that has already reached about 10% of the Europe's GDP[3]. Thus, it is crucial to develop new technologies, methods and processes to maintain health and treat diseases more efficiently at a lower cost.

[1] Source: « The European Medical Technology Industry in figures 2019 », MedTech Europe brochure
[2] Towards 2020 – Photonics driving economic growth in Europe – Multiannual Strategic Roadmap 2014-2020

Photonics may play a key role to solve these challenges and its main assets are:

- Its versatile nature (several health-related application fields such as preclinical research, oncology, ophthalmology, neuro-monitoring and imaging, infectious diseases);
- Its ability to provide solutions at different stages of disease evolution (from prevention to diagnostics, monitoring, treatment);
- The possibility of combining different technics to deliver at the same time diagnostics and treatment (for example multimodal imaging in combination with high-precision lasers to both identify and remove pathological cells).

The Photonics 21 Paper Vision also stresses that to fully exploit the potential of photonics in the Healthcare market it is necessary to address not only scientific challenges, but also to turn innovative technology into competitive products, services and business models. Main identified actions consist in opening this tightly regulated and quite conservative sector to new technologies, and making innovative start-ups and SMEs recognised as relevant market players.

One of the EPRISE aims was to support companies in this process and facilitate their access to the Healthcare market by focusing on business-related challenges.

2.2.1 The MedTech market: opportunities (and barriers) for Photonics

Figure 1: Anke Lohmann at the event in Marseille

By Anke Lohmann, Director at ESP Central Ltd., the UK

This article was based on a speech held by the author at the EPRISE Photonics Roadshow event in Marseille (November 2018). Anke is member of the EPRISE database of experts (scan the QR codes on the back cover to view her profile and the video of her presentation at the Roadshow).

Every year I need to have my eyes tested. I am strongly myopic (shortsighted) and at high risk of experiencing retinal detachment. This year's reminder to book my yearly eye test came to my surprise with a flyer telling me that my optometrist acquired a new instrument: an ultra-widefield high resolution retina imaging system. I happen to know the manufacturer of those instruments as well as the instrument that my optometrist bought and, I know that these systems make accurate diagnosis of a number of eye conditions that cannot be done in the traditional way. I also know that these instruments are complex photonic systems. They include lasers, scanning mirrors, fiber optic sub-systems, detectors and are combined with fast electronics and software that rebuilds images based on the understanding of light, the structure of the eye and how its layers interact with light. But, what is interesting is that these systems which have been on the market for some time and were bought mostly by hospitals, are now turning up in small surgeries and optometrists due to the reduction in cost and an increase in aging population with a number of age-related eye conditions.

[3] Photonics 21 Vision Paper, 2017

What I want to highlight with this example, is that photonics technologies are present in the MedTech market, that the changes in needs and advances in technologies are driving their uptake in the MedTech sector.

Applications of Photonics

Applications for photonics are broad. They range from diagnosing and monitoring conditions to the delivery of treatments. For example, diagnostic tools range from imaging technologies applied to the eye or skin, uses in endoscopes, digital advanced microscopes used in laboratories, to relatively simple photonics sub system that detect the presence of pathogens. Photonic based monitoring devices are deployed for example to measure blood oxygen levels or heart rate. One of the most routine photonics-based treatments is laser eye surgery with laser surgery gaining on importance in general, and, combined with real-time diagnoses which is also photonics enabled, becomes a powerful intervention approach in cancer surgery.

Photonics and human

The reason why photonics has something to offer to the MedTech market are the multiple ways that light interacts with tissue. This interaction is characterized by absorption and scatter, both bring advantages but also limitation. Understanding the characteristics is important when choosing the application.

Absorption spectra of human tissues are complex. In the medical sector they are used to identify the presence or absence of chemical components (blood oxygen for example) and in combination with fluorescence or photoluminescence could indicate whether cells are diseased or not. Increasingly interesting for diagnosis is also the use of photoacoustic signals, generated through laser pulses which create an ultrasonic signal. The advantage of photoacoustic imaging is that it penetrates deeper into tissue than just optical signals and that it can provide spectral information about the absorbing tissue which a simple ultrasonic image cannot.

Absorption also aids treatment. Exposing well defined areas with short pulsed lasers is used to remove cancerous tissue with a reduced risk of infection compared to standard surgery because of minimal direct contact with exposed tissues. Another area where absorption has a role to play is in photodynamic therapy where absorbed light acts like a switch, activating the chemicals that kill off diseased cells whilst keeping healthy cells alive. It is forecast that this is a high growth area for medical lasers.

The downside of absorption combined with scatter is the limitation on the penetration depth of light. It would be ideal could we image through a whole body without the use of X-Rays, but we cannot, at least not optically. Penetration depth varies for different wavelengths ranging from up to 100 µm for UV, blue and infrared light above 2µm to 3 mm for red to near infrared light. Increasing the power of light to overcome some of the limitation is not an option since it would burn cells unintentionally.

Trends

Technology developments are driven by an increasingly aging population that goes along with a higher prevalence of age-related diseases such as diabetes, cardiovascular conditions, cancer, dementia etc.. To keep people well for as long as possible and allow them to lead active lives requires early detection of the onset of conditions enabling early treatments and, potentially prevention.

Another key driver is the stratification and eventually personalization of treatments. This really requires an increased understanding of how individuals react to treatments and with it a potential need for diagnostic tests that can identify and guide appropriate treatment.

For a long time, people have been talking about point of care devices and real time diagnosis, where samples will be analysed where they have been taken and will yield almost immediate results, rather than having to send them off to a laboratory to be tested with results returned about a week later. This sounds good in theory but in practice has the complication that a doctor's surgery has to buy and hold a large number of devices which may be impossible to manage. It also requires training in handling the equipment and interpretation of the results.

Other trends that could be relevant for photonics is in the increased use of wearable technologies such a smart watch which have sensors already integrated monitoring vital signs. Or the integration of IOT enabled sensors in our homes. Whilst this is for the wellbeing market, it is likely to be translated into the MedTech market in the future.

And finally, machine learning and artificial intelligence will play in increasingly important part in medical technologies. Integrating this with photonics systems for diagnosis for example, will help doctors make a more accurate diagnosis and could be just an enabler to take that particular technology to market.

Barriers

The opportunities are vast. But, there are plenty of barriers and here are some of the important ones: other technologies that might just do the job, tightly regulated market, huge variations in reimburse models between countries, not knowing the MedTech sector and not understanding the real needs and forgetting the patient.

The MedTech sector for a start is very conservative. This is for a good reason: if things go wrong, it impacts a patient's live and wellbeing. This is reflected in the tight regulations this sector faces. The severity of the regulation depends on how much the patient would be impacted if things went wrong. A technology that is implanted or intravenously linked will be exposed to much tighter regulation than one that is external to the patient and does not even touch the skin. Important regulators for MedTech companies that sell internationally are the FDA from the US and the European's EMA.

Regulations usually result in longer time to market entry, especially if the technology is not developed with the regulations in mind early on. It is very important to be already aware of regulation during the product development cycle and companies who consider entering the MedTech sector are well advised to get expert input. This early expense can save significant costs down the line. Sometimes a company finds at the end of the R&D cycle, that it can't take the product to the market because it has not documented the R&D process in the required way, as far as the medical regulator is concerned.

Another thing that is very important is to understand who will pay for the product. This depends on the country the product is sold in and could for example be an insurance, a national health service or even a private individual. It is important to consider why these organizations would pay for the product and what benefits it brings for them. Often it is about how it will save money or attract customers.

The reimbursement model is also closely linked to where it will be deployed in path the patient takes from first symptoms to seeing the doctor to treatment. Is it at home, in a surgery, a hospital or a laboratory for example? How will it impact the treatment? One should have a good understanding of this path or paths when working on a new product.

And one last thing that I learnt in the last few years: it is difficult to sell a new diagnostic tool without a treatment for the illnesses it can diagnose.

However, these barriers should not stop companies from entering the MedTech market. Many people have done this before and we are seeing an increase in products entering the sector. On a recent visit to a biophotonics tradeshow I was talking to a number of exhibitors who usually sell optical components and subsystems into the research market and have told me that they see increasing demand from the MedTech sector which goes along with tighter tolerances and a guarantee that its performance will last over a long period of time.

Takeaways

- Understand reimbursement model for your product
- Understand where your technology will fit in the patient pathway
- Understand the users and what they are looking for
- Do not overwhelm the user with information
- Take into account that there are competing technologies

2.3 Clinical evaluation of a medical device

Figure 2: Tom Beale at the event in Berlin

By Tom Beale, Commercial Development Manager at CPI, the UK

The author was a speaker at the EPRISE Photonics Roadshow in Berlin (October 2018). Tom is a member of the EPRISE database of experts (scan the QR code on the back cover to access his profile).

Under European regulations, medical devices are required to be tested for safety and efficacy prior to placing on the market. This document outlines how a medical device manufacturer might undertake this testing, and what the implications are for manufacturers.

In May 2017 the Medical Device Directive and Active Implantable Medical Device Directive was replaced by the Medical Device Regulations (MDR). These regulations come into force in totality following a three-year transition, therefore after May 2020, all medical devices on the market in the European Union must comply with the MDR. There is no 'grandfathering' therefore any devices already on the marked, must be re-certified under the MDR to remain on the market. This document will refer to the requirements of the MDR.

CE Marking

A medical device is required to be CE marked prior to placing on the market. In order to CE mark a medical device, the manufacturer must show that the device is safe, and that its performance meets that claimed in the CE marking documentation. The manufacture will put together a dossier of information or 'technical file' that contains evidence showing that the device meets all of the 'General Safety and Performance Requirements' as detailed in Annex 1 of the MDR. This technical documentation must include a report of the clinical evaluation (Article 61, MDR), which will typically require some kind of clinical trial in order to gather evidence for the efficacy of the device. As this is required for CE marking, you are therefore required to use a non-CE marked device in order to gather this information. This can only be done through a Clinical Investigation.

Clinical Investigations

Clinical Investigations enable the use of a non-CE marked device within a clinical trial. At this point in the development of the device, the manufacturer would have all of the relevant safety data for the device, and have performed all pre-clinical testing (i.e. benchtop testing, possibly animal testing), but will have little or no clinical efficacy data. As with any clinical trial, a clinical investigation requires appropriate ethical approval, and when using a non-CE marked medical device, a summary of the technical information must be sent to the competent authority for approval (in the UK this would be the MHRA). The competent authority will then evaluate the technical information and assess the safety of the device for use within that clinical investigation. It may also be necessary to obtain other country or healthcare provider related permissions.

Upon successful permission from the competent authority, the device can be used within the clinical investigation, thereby enabling the manufacture to gather efficacy evidence, however its use of the device is strictly limited to within the clinical investigation

Designing a clinical trial for a medical device is not simple. There are two main types of clinical evaluation, an observational study, and a randomised control trial (RCT). Under an observational study, a measurement is taken, a change in a patient clinical pathway is made, and a second measurement is taken. This type of study has the disadvantage that other changes might be happening in parallel to the intended change in the care pathway, which may affect the results. For example, under an observational trial, a new piece of early stage diagnostic equipment may be introduced. The diagnostic rate might be measured prior and subsequent to the introduction of the equipment. However, this might happen to coincide with a change in the weather that makes the patient symptoms more obvious, thereby affecting the result of the trial and making the diagnostic device appear more or less efficacious than it actually is.

The aim in the design of clinical trials is to reduce bias, and this is the fundamental thinking behind an RCT. Here the trial has two patient groups, one for whom the patient care pathway is changed, and the other where there is no change. The efficacy of the intervention (i.e. the use of the device), is measured through the differing outcomes between the two groups. This type of trial does not completely remove bias, as the patient and the clinicians will know who is using the device, and there may be a subconscious bias to be more (or less) conscientious when treating this patient group, however it minimises temporal effects.

The disadvantage of RCTs is that they tend to be expensive to run, almost by definition they require twice the patient cohort size, as one group is needed as a control and the other for the intervention. If the device is for a very specialist (and therefore small patient group), this may be problematic.

It is worth considering the entire rationale behind clinical evaluation from the outset. It is unlikely that the clinical trial is purely for collating evidence for CE marking, it may be used for approvals in other jurisdictions (i.e. FDA or MDSAP approval), and it might well be used for demonstration efficacy and cost-effectiveness for adoption. This could be through a formal process (i.e. a NICE evaluation) or for demonstrating to private buyers or trade purchasers. At this point it is essential to assess how a clinical trial fits in with a health-economic model and what your measurement parameters are. For example, if your health economic model is set up to demonstrate cost effectiveness of your device when used in primary care, then this is where your clinical evaluation should be. The efficacy of your device may well be different when used in a specialist hospital and a primary care centre. A manufacturer may want to measure different parameters for different purposes, i.e. a device may improve the speed of healing, however it might also improve the quality of life of the patients – this may be just as important both for manufacturer and patient. Multiple measurements can be built into a single trial, and this will almost always be more cost effective than running multiple trials.

Once a manufacturer has all of the safety and performance data, and meets all of the requirements of the MDR, then they can place their product on the market (involving a Notified Body for the higher risk devices). It maybe however, that in order to speed up commercial income, a manufacturer will use a lower claim for their CE mark in order to place the product on the market quickly, then perform a further clinical evaluation (this time of a CE marked device) to gather evidence to support a higher claim.

Post-Market Clinical Follow-up

Once a manufacture has placed a medical device on the market, their obligations for clinical evaluations have not ceased. Following Part B of Annex XIV of the MDR, the clinical evaluation is a continuous process through the lifetime of the device, and this is known as Post-Market Clinical Follow-up. A plan should be developed to continue to gather evidence for the efficacy of the device throughout its use. This may be through additional trials, or could be generated through efficacy use of the products in service. The level of this will depend on the nature and risk of the device.

Best practices to overcome barriers to medical device RCTs

- **Timing**

  Choose the most appropriate time for clinical evaluation.

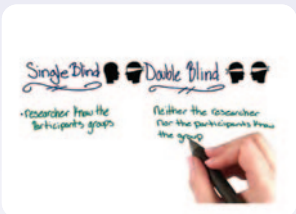
  MDs undergo frequent changes in device design after their first introduction in humans, and a new device will be allowed to replace older products only when it is proven to be more effective and/or safer.

- **Acceptability**

  Conduct a qualitative study to take into account the interplay between staff members (surgeon, nurse) before starting RCTs. Together with surgical expertise, it can affect the results of the procedure.

- **Blinding:**

  When RCTs cannot be blinded by procedures that prevent participants in the study and caregivers from knowing which intervention was received, *plan to blind the outcome assessors (data managers, adjudication and safety committees, conclusion drawers) and chose them amongst experienced and trained staff.*



- **Choice of comparator group:**

  Ethically, the more invasive the procedure is, the harder it is to justify exposing patients in the control group to risks without any expected benefit. Therefore:

✓ make participants aware of the overall benefit of the trial;

✓ standardise the trial framework, including preoperative care (patients or equipment), perioperative care (duration of procedure, instruments, manipulation, or treatment allocation), postoperative care and rehabilitation.

- **Learning curve:**

  When designing an RCT, *analyse training and learning level of surgeons and trial staff.* This will allow you to reassure patients that the new MD is effective and safe regardless of the experience of the caregivers.

Figure 3: Mattia Nuti at the event in Newcastle

By Mattia Nuti, Chief Executive Officer at International Checks Group, Ireland

The author was a speaker at the EPRISE Photonics Roadshows events in Florence (May 2018) and Newcastle (April 2019). Mattia is member of the EPRISE database of experts. The text above is based on the speech held by the author in Newcastle (scan the QR codes on the back cover to view his profile and the video of his presentation at the Roadshow).

2.4 Case study

2.4.1 Re-engineering for manufacture and clinical testing

Company profile

Start-up, innovation ready (TRL 4) with <10 employees

PROBIOMEDICA
PHOTONICS & ROBOTICS

https://www.probiomedica.it/

Activity field: Medical technology based on phototherapy.

Product: "CapsuLight" – an ingestible capsule for the photodynamic elimination of Helicobacter pylori in situ for the treatment of Helicobacter pylori associated pathologies. It has shown significant and valuable results in pre-clinical testing in animal model.

Team and partners: Complementary expertise in optics, photonics, electronics, microbiology and biochemistry.

Location: Florence, Italy

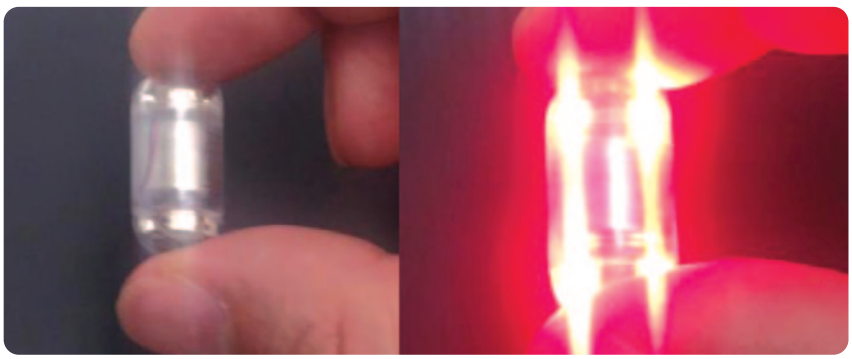


Figure 4: CapsuLight. Credit: Probiomedica.

The company presented its product and Go-to-Market challenges at the European Photonics Roadshow event in Marseille (November 2018) where met and started a collaboration with the expert Deepan Shah.

Market barriers and needs

Medical device development is a high-risk venture with a high chance of failure:

- Development cycle is long and expensive with complex processes that take years to accomplish.
- Healthcare systems are risk-averse and very slow to adopt technical innovations unless they show greater than incremental functional or cost improvements compared to prevailing methods.
- Complex IPR landscape with large corporations holding wide-scope patents that may block innovative new entrants.
- Complex international regulatory and healthcare reimbursement environments with differing requirements for evidence of efficacy, safety and health economics.

Expert profile

Deepan Shah, Bid Proposal Development Manager at CPI, the UK

Deepan Shah is an experienced Biomedical Scientist with 10+ years' experience in Biomedical Device development. He works with companies in the photonics-enabled medical device, and in vitro diagnostics sectors. CPI is a non-profit RTO with multidisciplinary teams providing SMEs with assistance in product development and scale-up for manufacturing as well as with compliance, quality, and regulatory-related challenges and commercialisation strategy (UK, Europe).

Proposed solutions cover re-engineering of device for better performance; and scale-up manufacture as well as regulatory strategy, technical files for CE marking, quality management system and relations with clinical centres.

Feedback from the expert

General comments

The challenge here is to progress from a laboratory prototype to an improved-function device designed for scale-up manufacture that is compliant with medical-device regulatory framework; and with robust data, pre-clinical and clinical, showing efficacy, safety and a health economics case that strongly supports adoption by healthcare systems.

To meet the technical, commercial and environmental challenges the following need to be considered:

- How to maximise light output with the necessary size and power restrictions of the device
- How to manufacture the devices at scale and within a reasonable cost
- How to ensure safety and integrity of the device whilst in use
- How to classify the device and achieve compliance with the required regulations and directives
- How to dispose of the device after use.

Probiomedica have a clear understanding of these challenges and are pro-active in securing the required funds and expertise both locally and further afield. Probiomedica have expertise and experience in the technical development of the device but will require professional guidance regarding, regulations, standards for manufacturing, clinical trial design and execution, and disposal/recovery strategies. They have carried out meaningful pre-clinical studies in a mini-pig model which provided strong justification for further development. The CapsuLight device would eliminate the need for antibiotic treatment of stomach infections due to Helicobacter pylori; as such it is strongly aligned with WHO and national healthcare systems' drive to reduce the use of antibiotics owing to the rise of antimicrobial resistant organisms – this would be a great impetus for the adoption of this technology.

Tailored solutions

Maximisation of light output and scale up: The current design can be modified to increase the numbers of light-emitting diodes within the device. Probiomedica already have a conceptual design with such improvements and require a design/prototyping organisation with some level of scale-up manufacture capability to help with the detailed design, prototyping and production of enough numbers of the final design to carry out pre-clinical and clinical trials. There are numerous design houses and CROs in Europe that can provide such services. A design using flex-rigid PCB with LEDs arrayed using automatic pick-and-place would serve the purpose and be scalable. This assembly can then be packaged into the current transparent material with the power supply to create the ingestible device.

Safety in use: This is a critical issue that requires careful consideration. Probiomedica have taken considerable steps to address the safety features of the current form of device and it is proven to be safe in a mini-pig model. The main risks are a possible overheating of the device, mechanical failure of the outer casing resulting in exposure of internal parts to stomach acids with subsequent exposure of patient to potentially harmful substances from the device, and overspill of light treatment into the duodenum causing collateral damage to normal gut flora. Any new design and form factor will require stress testing to ensure integrity throughout alimentary canal transit.

Regulatory Compliance: Early engagement with a notified body for medical device regulation is advisable. CapsuLight will be subject to EU Medical Device Regulations (EU/2017/745). It will be important to define the Intended Use and Classify the device according to the Regulations and expertise in this and other relevant regulations and standards will need to be accessed by Probiomedica.

ISO13485 regulatory compliance should be involved during the re-engineering of the device so that regulatory constraints are integral to product design phase. Engagement with clinical expertise and clinical trial specialists should be sought to facilitate design of experiment for trials to generate evidence of efficacy through Phases of clinical trials.

Disposal after use: Capsulight will be ingested, perform its function in the stomach, transit through the gut and be voided with normal digestive waste and then either be recovered for disposal, or more likely, be flushed into sewerage system. Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) provides an exemption for "medical devices and in vitro diagnostic devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices" (Part 2 8 (g)). The CapsuLight is likely to fall under this exemption but this should be confirmed with the relevant authorities in different territories – with "likely to be infective at end of life" as a potential point of contention.

3 PHARMACEUTICAL MARKET

3.1 Market overview

The pharmaceutical sector is an industry focused on discovering, developing and manufacturing drugs.

According to the European Commission, the pharmaceutical sector is one of the strategic sectors for the European economy[4] . Key features and figures are listed below[5] :

- Highly innovative sector with €36,500 million invested in Research & Development in 2018;
- 0,765 million people employed directly and about 3 million employed indirectly;
- 17,7% share of global market (second place, after USA with 65,2%);
- €105,000 million trade balance (€410,000 million export, €305,000 million import);
- Pharmaceutical industry is the high technology sector with the highest added value per person employed (15%);
- Countries with the largest pharmaceutical production (in million EUR): Switzerland (44,944), Italy (31,2000), Germany (30,555), France (21,900).

SMEs are vital for the Pharma industry. They are often real specialists in their field and have a wider appreciation of the use of new technologies as they often align with academia and more fast- moving industries. Pharma industry has typically tended to use traditional manufacturing methods often based on existing capability and known and trusted technologies. However, this is changing due to the fact that there is an expectation to continually drive down manufacturing cost but maintain the highest quality. Regulators are also expecting to see data driven quality systems and patients and healthcare providers are demanding improved product security. The digital platforms accelerating enhanced manufacturing across all industries reach into pharma but so does Pharma industry's opportunity to use these enablers to research and develop new molecules in new ways. SMEs are important partners as the Pharma industry's paradigm changes.

3.2 Photonics for Pharmaceuticals

Figure 5: Gregor Anderson at the event in Newcastle

By Gregor Anderson, Managing Director at Pharmacentric Solutions Limited, the UK

The author was a speaker at the EPRISE Photonics Roadshow in Newcastle (April 2019). Gregor is member of the EPRISE database of experts (scan the QR code on the back cover to access his profile).

[4] Source: European Commission (2014). Pharmaceutical industry: a strategic sector for the European economy. SWD (2014) 216 final/2.
[5] Source: EFPIA (2019). The Pharmaceutical Industry in Figures. Key Data. Brussels: EFPIA.

Current and future market trends

In the Pharma industry, photonics has traditionally been used in areas such as process analytical technology (PAT), Quality by Design (QbD) and Quality risk management (QRM). Specific examples in QRM include for example raw material inspection (to identify correct composition) and importantly used as a tool to enhance supply chain integrity checks (to identify counterfeit ingredients and confirm the authentic ones). Instruments using methods such as Near-Infrared spectroscopy or Raman spectroscopy are available and more recently terahertz spectroscopy has been successfully introduced. There is a continued trend towards solutions that lower initial and ongoing costs and provide simpler to operate (and maintain) instruments which should drive further accelerated uptake into the Pharma market. In-line process control versus off-line process control may also be a future need driver, especially with new medicines such as Advanced Therapy Medicine Products (ATMPs). However, there are also other parts of the manufacturing process where photonics in the form of machine vision or laser cutting/welding/processing may be of continued benefit due to the decreasing cost and ability to offer technical solutions to complex manufacturing challenges as photonics can be applied to production systems and their suitability for high speed and high volume automation.

Photonics can be utilised within pharma stretch across the whole end to end supply chain. It can be used in the actual manufacturing processes but also add considerable value and opportunity down to individual pack (and patient) level. Photonics systems and processes are proving to be reliable and robust and these factors are absolutely critical within pharma where quality is a given. Examples include:

Laser printing and marking

Photonics offers a cost-effective tool to mark a whole range of materials used in the pharma industry. Several more recent requirements have driven the need for new technology, such as for example the highly accurate high-speed marking of dose wheels on respiratory device counter components through to the 2D printing codes used to enable the serialisation of all medicine types. Serialisation (this is essentially the unique printed 'fingerprinting' of each medicine pack produced) has been established to protect patients and pharma companies from counterfeiting. Counterfeiting is one of the major global issues within pharma and it is estimated that at least 10% of all drugs in the market are fakes and this extends to beyond 33% in emerging markets, with deaths from these recorded in hundreds of thousands.

Serialisation is so important that it is being mandated for every pack supplied into Europe and is set to revolutionise pack security and patient safety with an expectation that it will roll out globally over the next decade (it is already in place in countries like China). Photonics technology enables the highly accurate printing on each pack and is utilised in the hardware that reads the data, all at the high volumes expected by the industry and the customers throughout the supply chain (including wholesalers, retailers and hospitals). Serialisation is a game changer and photonics plays a key role in its introduction.

Complex delivery formats or packaging

Laser drilling has been utilised by the pharma industry to introduce minutely controlled holes (or cavities) for some various purposes. One is to enable slow release from tablets/capsules where an osmotic effect drives active product out at a controlled rate. Another opportunity is to use these cavities (if positioned in a line) to make packaging that is child resistant but remain senior friendly. Introduction of 'break lines' into glass ampules is another example where this technology offers accurate high-speed solutions to genuine technically challenging problems that enhance not only the medicine itself (such as tablets) but also the packaging that they are stored in.

Personalised Medicines

With the advent of more Personalised medicines having the capability to enable the medicines to be uniquely identified (even down to a single dose level so as to ensure maximised traceability and security). Photonics can be used to mark a whole range of platform formats and this extends from the serialised secondary pack mentioned above to the potential to mark the individual dose. This technology can be applied from high volume small molecule medicines through to low volume complex medicines. Photonics offers the ability to safely print directly onto the medicines and also then for this data to be read and provide a route for automated data acquisition. This data capture is critical as it enables better management of the taking of medicines and this in turn can improve adherence with the patient and demand management with the pharma supply chain.

ATMP/Cell and Gene Therapies/Complex Medicines

These therapies are another area where photonics can play an exciting role. Equipment used can be marked, identified and verified throughout the whole process. The technology enables a robust methodology that can meet, for example, the challenging storage temperatures where labelling isn't completely secure. Photonics could also be used as part of the inspection process during manufacture through enhanced specialist vision systems to ensure that there is no contamination of product.

With the increasing growth in biological and complex medicines, the packaging formats are typically supplied in glass syringes and vials. Photonics has added considerable value is this area in several ways. Firstly, lasers are used to mark the primary pack materials such as glass (with serialisation 2D codes for example) without damaging the surface. Secondly lasers are used to inspect these components for imperfections at high speed and this capability extends to vials and even clear polymer syringes and vials. Ophthalmic markets are going to expand as the world has an aging population and these products frequently are supplied in syringes and other sterile platforms.

Reimbursement by outcomes

There is a move towards extended evaluation of medicines post launch to prove effectiveness in 'real world' settings. Having the ability to track and monitor packs in the patient environment will be a beneficial requirement in the near future. This covert and overt tracking will be enabled by not only the effective marking of medicines but also the ability to acquire automated data using coding and scanners. These will be supported by wearable technology platforms that will be part of the solution when monitoring patients in these 'real world' trials. Photonics will be used as part of this capability and the scope to incorporate sensors, diagnostics and even vision systems will all be technology enablers as we move into this new challenge of proving outcome-based reimbursement, especially with diseases like Chronic Obstructive Pulmonary Disease and dementia.

Faster new drug discovery cycle

Every day a drug isn't on the market can easily cost the originator several million dollars. The development process for a new chemical entity can typically take eight years so every day counts when you consider that these medicines have a limited patent life once launched. As such, accelerating the clinical development phase through to commercial supply is imperative. Photonics can play an important part in reducing these time scales in several ways. High throughput analysis using laser-based systems ensures the right product quality is assured. Vision systems also check quality at high speed and with high accuracy and this data can be used to control production parameters thus enabling absolute confidence in medicine manufacture. Transferring this data and capability from pilot to scaled up production again can be verified and validated using photonic tools.

3.3 Pharmaceutical Clinical Trials: an overview of the state of the art

Figure 6: Giulia Iardella at the event in Newcastle

By Giulia Iardella, Associate at International Checks Group, Italy

This article is based on a speech held by the author at the European Photonics Roadshow in Newcastle (April 2019). Giulia is member of the EPRISE database of experts (scan the QR codes on the back cover to view her profile and the video of her presentation at the Roadshow).

Around the world, pharmaceutical companies conduct clinical trials to evaluate the safety and efficacy of their drugs. These studies are a necessary requisite to obtain regulatory approval so that drugs can be made available to patients. But, how exactly do drugs progress from concept to approval?

According to the World Health Organisation (WHO) a clinical trial is defined as 'any research study that prospectively assigns human participants…to one or more health-related interventions to evaluate the effects on health outcomes' – these 'interventions' include drugs, as well as biological products, medical devices and surgical procedures, among others. Every drug that can be prescribed for patients around the world has been approved by national regulatory authorities, such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA), after successfully completing all required stages of clinical trials.

Pharmaceutical clinical trials start with pre-clinical studies and progress through phase I, phase II and phase III. Occasionally phase 0 studies are carried out before phase I, and phase IV studies are performed after the drug has been approved and launched on the market.

Pharmaceutical Clinical Trial Phases

Phase 0

Phase 0 trials aim to learn how a drug is processed in the body and how it affects the body. A very small dose of the drug is given to about 10 to 15 people.

Phase I

Phase I trials aim to find out the best dose of a new drug with the fewest side effects. The drug is tested on a small group of 15 to 30 patients. Investigators start by giving very low doses of the drug to a few patients. Higher doses are administered to other patients until side effects become too severe or the desired effect is observed. The drug may help patients, but Phase I trials are dedicated to test drug safety.

Phase II

Phase II trials further assess safety as well as efficacy. The drug is often tested among patients with a specific type of cancer. Phase II trials are conducted with larger groups of patients compared to Phase I trials. Often, new combinations of drugs are tested. Patients are closely monitored to check if the drug works. However, the new drug is rarely compared to the current (standard-of-care) treatment.

Phase III

Phase III trials compare a new drug to the standard-of-care drug. These trials assess the side effects of each drug and which drug works better. Phase III trials enrol 100 or more patients.

Trials are often randomized. Patients are assigned to a treatment group, called trial arm, by chance. Randomization is needed to make sure that people in all trial arms are alike, so that trial outcomes are a consequence of the treatment and not of differences between the groups. A computer program is often used to randomly assign people to the trial arms. Treatment groups can be more than two. The control group receives the standard-of-care treatment. The other groups receive a new treatment. Neither patient nor physician can choose the group. In addition, patients don't know which group they belong to until trial ends.

Every patient in a phase III study is closely monitored. The study will be stopped early if the side effects of the new drug are too severe or if one group obtains much better results than others. Phase III clinical trials are often needed before the Regulatory authorities approve the use of a new drug for the general public.

Phase IV

Phase IV trials test new drugs approved by Regulatory authorities on several hundreds or thousands of patients. This enables in-depth investigation of short-lived and long-lasting side effects and safety. For instance, some rare side effects may only be discovered in large groups of people. Physicians can also learn more about how well the drug works and if it's helpful when used with other treatments.

	Pharmaceuticals (ICH-Guidelines)	**Medical Devices (EN ISO 14155:2011 and others)**
Standardisation of clinical development phases	Highly standardised (phase I, II, III)	Not standardised, it depends. Review of Clinical Investigation Plan (CIP) is paramount
Methods for pivotal trials	Highly standardised (double blind, randomised, controlled)	Not standardised, it depends. Review of CIP is paramount
Irreversible effects on study subjects	Rare	Very common. Review of CIP is paramount. Challenges affecting informed consent, vulnerable patients, many of the study procedures of the CIP.
Research in vulnerable subjects	Easier to detect	Good Checklist needed
Size of companies involved in research	Mostly Large	Large to very small, many start ups
Know-how	Easier to build up	More difficult to build up

Table 1: Comparison between Pharmaceutical and Medical Device Clinical Trials. Authors: Giulia Iardella and Mattia Nuti.

Challenges: interviews with companies (by Giulia Iardella)

Complexity of Trials

- Designing trials "that give the right answers, in the most simple and unobtrusive way for patients, that are acceptable to regulators and payers".
- Focussing on the best study design' for "very complex modern clinical trials" to meet primary endpoints.

Regulations

- Guidelines are difficult to follow;
- Requirements vary between different regulatory bodies;
- Need of understanding new sets of requirements when looking to emerging markets in other countries.

Spiralling Costs

- Complexity and regulation result in an all-time high cost of clinical trials;
- "Need for resources to implement and control every step"

Patient access

- Patient recruitment and retention are major challenges for investigators: "increased burden for patients throughout the study, without an adequate return of investment in the form of personal benefits'". As result, patient centric approaches prevail in today's research.

Staff Roles & Responsibilities

- Hiring and training the right staff is getting tricky as complexity and rate of change in trials increase: "working in a constantly dynamic environment in and out of the company means that roles and responsibilities are evolving'; "increasingly remote nature of teams has an impact on how we manage and retain staff";
- "Obtaining experienced clinical research professionals in developing countries" is an additional challenge as trials become more and more geographically diverse.

Technology

- Technological progress is improving many aspects of the trials and, at the same time, resulting in new challenges: "With regard to technology, so much is happening so fast! the question is how to select and use the RIGHT technology, and to gain the acceptance of patients, healthcare professionals and regulators for that technology."

Governance and oversight

- Coordination and management of strategic partnerships, vendors, study sites, CROs which are playing a more important role in almost every aspect of trials.

New drugs

- New classes of brand drug require different ways of running trials. "Cell therapies, genomics, personalised treatments and whatever next breakthrough is" make more difficult to demonstrate clinical effectiveness.

3.4 Case study

3.4.1 Challenges and barriers for a service provider when entering the Pharmaceutical market

Company profile

Start-up (TRL 4-9 depending on market segment)with 5 staff and 2 students

https://xploraytion.com/

Activity field: Xploraytion facilitates access to non-destructive X-ray based analytics at the highest sensitivities and spatial resolutions.

Product: Bridging the gap between highly advanced laboratory and synchrotron-based analytics and industrial R&D demand, they offer consulting services and a comprehensive all-round package.

Team and partners: The key expertise lies in the analysis of bio materials such as bones and implants.

Location: Berlin, Germany

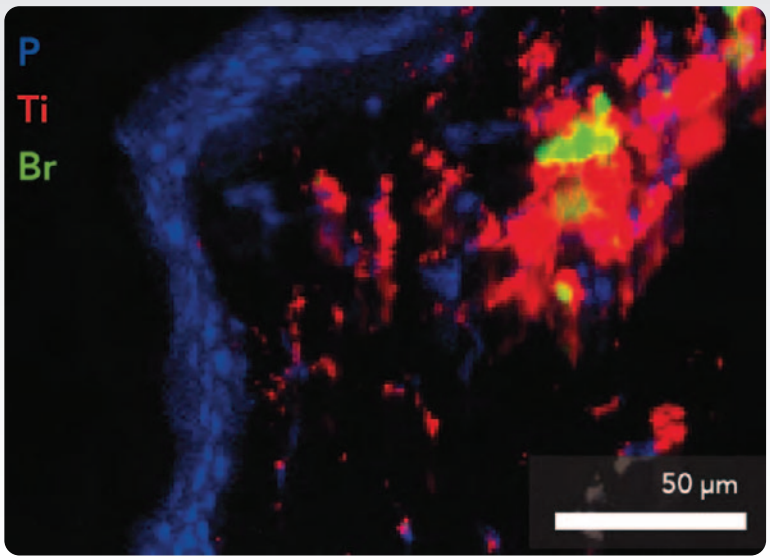


Figure 7: Tattooed human skin tissue section. Synchrotron micro X-Ray fluorescence mapping reveals presence of bromine (organic pigments) and titanium (inorganic pigments). Epidermal cells are visualized through the X-ray fluorescence intensity of phosphorus (phosphorus in blue; titanium in red; bromine in green). Credit: Xploraytion.

Market barriers and needs

While Xploraytion is getting more and more established as commercial analytical research organization in the field of bio-materials, including a growing turnover rate, the expansion to other markets is still challenging. Xploraytion's analytical tools and expertise potentially match the needs of R&D departments of big pharma companies. Thus, they consider Pharmaceuticals as a high potential target market but are facing the following issues:

- **How to identify the relevant contact person in pharmaceutical companies?**

R&D of pharmaceutical companies is not very transparent about their research demands and challenges due to confidentiality issues. As a new company it is therefore difficult to introduce new analytical tools and services to them. However, from previous experience with larger pharmaceutical companies it was learned that once the right contact persons are identified, a collaboration may be initiated and become very fruitful for both sides.

- **How to cover the relatively high costs of proof of concept studies to successfully convince pharmaceutical companies?**

To establish and foster new contacts and to convince large companies about the potential in collaborating with a young service provider, some initial investment in terms of time and money is required on the SME side. This can include kick-off workshops, presentations and free analytical tests requested by big pharmaceutical companies, and potentially even the service offer has to be tailored to match the clients need. These studies can have high costs. Investments only pay back once a longer lasting collaboration is established because the analytical services become more efficient thanks to the initial adjustments of the services and tools provided.

- **How to address IP issues and legal aspects about patenting when new technology is being developed by consortia?**

To stay in the forefront of synchrotron analytics applied to the target markets, Xploraytion has to constantly improve its methods and tools. Improvement of analytical methods requires constant study of latest literature and participation in relevant conferences which is costly and time consuming. One efficient tool for SMEs to develop new technologies is to go through local, national or EU funding. In Berlin, ProFit is a very interesting instrument through which to receive funding for the development of new technology. Normally, the funded development is realized through collaborations with other companies or public institutes or universities and IP and patent issues come up.

Feedback from the experts

Issue: Contacts to decision makers in pharmaceutics and medicine

Expert profile

Dirk Voelkel, General Manager Innovation at GE Healthcare Life Sciences, Sweden

He manages the R&D and technology portfolio of GE Life Sciences and Life Science innovation activities. Together with his team, he ensures great design and user experience for customers, R&D portfolio management, innovation coaching for R&D teams as well as support of manufacturing and R&D with data analytical tools.

Xploraytion was introduced to Dirk Voelkel during the European Photonics Roadshow in Stockholm.

Dirk was very interested in the services provided by the company and participated in a workshop organized by Xploraytion and Charité University hospital in Berlin only few weeks after the Stockholm event where new joint projects were discussed. The fact that a famous institute such as the Charité was involved in the workshop helped to also involve representatives from large pharmaceutical companies into the workshop.

In addition, Xploraytion presented its needs during a pitch at the roadshow event in Newcastle. In the following discussion and during the networking breaks, new and promising contacts were made with local hospital representatives.

Not only are these contacts helpful to establish new projects, they also potentially help to link with pharmaceutical companies as there are normally tight connections between them and key opinion leaders, i.e. clinical experts (in the medical field aligned with their products) who lead clinical trials crucial for the drug or influence the clinical practice guidelines.

Issue: External investment to access new markets more quickly

Expert profile

Edward Schneider, General Partner at Spirit Ventures, Switzerland

He has 30 years of investment experience, including 22 years managing technology funds in both quoted equities and venture capital. Prior to founding Quan Management LLC (2000), he was a Geneva-based fund manager for Lloyds TSB Bank, where he managed equity mutual funds as well as an external venture capital portfolio.

Xploraytion met Edward Schneider at the European Photonics Roadshow in Stockholm.

He confirmed what was already experienced in earlier discussions with external investors. Xploraytion is at a "too early" stage to receive investment. It should be proven that company's services are indeed scalable to address bigger and new markets. One suggestion was to change the business model from project-based into a subscription-based model, meaning that the clients pay a monthly fixed price over a fixed period of time and in turn get access to a certain amount of analytical services. This may potentially make cash-flow more stable. Xploraytion is considering a subscription-based model for their customers in the future.

Issue: How to protect new technologies

Expert profiles

Christian Sandweg, Partner at Vossius & Partner, Germany

European Patent Attorney with a scientific background in solid state physics, he supports Vossius& Partner clients and attorneys in the field of intellectual property, in particular patent prosecution, opposition, invalidation and patent infringement cases.

Robert McDougall, Director at Keltie LLP, the UK

R&D engineer/physicist turned patent attorney specialising in photonics, quantum technologies, optics, optical fiber, telecommunications, and electronic engineering. His experience in the IP field is both from an IP attorney and an engineering view point, being co-inventor on a number of photonic patent applications and co-author on various peer reviewed papers.

Intellectual properties related to new pharmaceuticals and medical technologies were intensively discussed during the European Photonics Roadshows in Berlin and Newcastle with Christian Sandweg and Robert MgDougall, respectively.

It was explained how crucial it is to protect new methods and technologies at earliest stages. In particular, Xploraytion is currently developing a new measurement device together with the Fraunhofer Institute. The development and prototyping are supported through a local funding. Whether or not patenting is required before submitting the idea within a grant application is not a trivial question. However, those questions must be addressed before submission to avoid regret at a later stage.

4 AGRICULTURE MARKET

4.1 Market overview

There are about 11 million farms in the European Union and 22 million people working regularly in farming (44 million people are employed in the entire EU food supply chain)[6] . Farmers are the first link in the food production chain. EU is the leading exporter of agricultural products (mostly processed and high-value-added products) which amount to the 8% of Europe's overall exports in 2015[6]. Farmers are thus important strategic and economic players.

Nevertheless, farming is a major source of pressure on the environment (agriculture is responsible for 70% of the planet's water use[7], 24% of greenhouse gas emissions and environmental degradation on a planetary scale[8]) and farmers face multiple risks, such as a more unpredictable production and harvest due to climate change, increased price volatility, frequent animal/plant health incidents. Moreover, a rapidly growing global population (expected to reach 10 billion by 2050) will dramatically increase the demand in food production. Therefore, new practices, technologies and methods are required in order to implement a sustainable management of natural resources, manage climate exchange, and ensure a viable food production.

Europe will play a central role in meeting these challenges, due to its technological leadership in the Agriculture sector and, in particular, in the vanguard of high-tech precision farming. The global market for precision farming equipment and services is expected to grow from USD 3.3 billion in 2016 to USD 5.9 billion in 2021[9]. Agri-photonics is already a fast-growing discipline in precision farming and environmental management. Relevant photonics devices and techniques include LiDARs (Light Detection and Ranging), sensors, energy-efficient LEDs, spectroscopy, laser scanning, multi and hyperspectral imaging.

The Photonics21 Vision Paper stresses that the Agriculture sector is resistant to the adoption of and investment in new technology. Three policy responses are identified to enable Agri-photonics to fulfil its potential:

- Policy makers and industry associations should leverage existing agricultural extension systems (designed for application of scientific research and new knowledge to agricultural practices through farmer education) to help farmers access new technology, and to assist them with investment decisions;
- Regulation should protect consumers and ensure food safety without hindering the introduction of new farming techniques and processing technology;
- Facilitating technology uptake by smaller farms by providing technology-focused support and leasing or sharing of equipment.

[6] European Commission Publications: "Agriculture, A partnership between Europe and farmers", manuscript updated December 2016
[7] http://blogs.worldbank.org/opendata/chart-globally-70-freshwater-used-agriculture
[8] www.epa.gov/ghgemissions/global-greenhouse-gas-emissions-data#Sector
[9] Photonics21 Vision Paper, 2017

4.2 Photonics for Agriculture

4.2.1 Societal challenges and market segments

Figure 8: Jacques Cochard at the event in Florence

By Jacques Cochard, Founder and Associate at TEMATYS, France

The author was a speaker at the EPRISE Photonics Roadshow in Florence (May 2018). Jacques is member of the EPRISE database of experts (scan the QR code on the back cover to access his profile).

The challenge for modern agriculture and breeding is to increase food production by *70% within the next 30 years* in order to cope with the increasing world population, while *reducing global impact upon ecosystems* and meeting the transparency requirements in the field of food safety.

This increase in production should be carried out without expanding the current agricultural surface, because the majority of arable land is already cultivated, with no additional fertilizers to increase yield and with *fewer phytosanitary products* to limit production losses.

Faced with these challenges in the area of productivity and transparency, farmers and breeders today need the appropriate diagnostic tools providing two types of information – e.g. spatial and temporal information about the daily state of production – *which can facilitate decision-making process* and help with engaging in the appropriate actions. Consequently, this leads to *higher quality of production* while preserving the *competitiveness of EU actors* vis-à-vis their competitors from non-EU countries (Australia, South America and China).

In economic terms, the *low margins* of the sector and the *price pressure* from wholesale distribution and the consumer itself also oblige the producer to optimize margins and to sell a product, whose quality is - by nature – variable, at the best price. Development of *post-harvest or post-slaughter sorting tools* could drive the quality of production towards the most appropriate consumer and recycling industry for the farmer.

Since photonic technologies provide non-contact, potentially long-range, real-time, sensitive information on various parameters including the *plant's shape, size, colour, hydration, metabolism as well as its chemical composition* (proteins, sugars, water, vitamins ...), photonics-based devices provide suitable solutions for the above-mentioned challenges, be it in the fields or in an industrial or artificial environment of agricultural production. This market of *agronomic and on-line sensors today represents €2 billion*, mainly generated by tools for measuring sugars and proteins developed by major players in the analysis industry: Bruker, Thermo-Fischer, FOSS, Zeiss and Chauvin-Arnoux.

The *expected growth* related to the development of *agricultural robotics and control processes* is expected to be above 15% in the next 10 years.

Figure 9: Sensor measuring anthocyanin on grape bunches. Credit: Force-A

Along with the analytical dimension - sensors and imaging - *photonics also allows to grow vegetables with the help of light* in greenhouses, urban and vertical farms and to process agricultural products by X-rays or by UV illumination based on lamps and/or LEDs. These products contribute to the development of both urban and "dry" production, without solvents or effluents.

On one hand, the *on-going revolution in photonics miniaturization* - integrated photonics, micro optics, freeform optics - will *increase reliability, ease of use, and lower cost of products*, resulting in decreased operational and capital expenditures. On the other hand, in order to transform *raw data into reliable diagnostics, modelling tools and artificial intelligence* will have to be developed in parallel.

Market segment	**Application**	**Technology**
Agriculture & farm equipment	• Phenotyping, variety innovation, plant protection, biocontrol • Management of large crops and vineyards, including machinery and agricultural robotics • Remote sensing and spatial information systems	• 3D laser scanning, hyperspectral imaging, Terahertz imaging (hydration), thermal imaging (evapotranspiration), NIR-MIR spectroscopy, Raman spectroscopy, Surface Plasmon Resonance spectroscopy, high-resolution machine vision • Visible cameras, portable NIR/UV spectrometers, multispectral and hyperspectral cameras, UV lighting, biosensors • LIDARs, Vis/NIR/MIR imaging, high-resolution satellite imaging
Agriculture in artificial environment	• Greenhouses, vertical farming, urban farms	• LED Lighting (UV-Vis), Fibre Optic Lighting, Fibre Optic sensing, various spectroscopic techniques
Breeding & Aquafarming	• Animal feed, additives • Precision breeding • Veterinary science • Abattoirs	• Portable/on-line spectroscopy • Conventional cameras, holographic interferometry (fish farms) • Biosensors • 3D imaging, UV lighting, spectroscopy

Table 2: Photonics technologies in Agriculture market segments.

4.2.2 The enlightenment of Agriculture

Figure 10: Per Frankelius at the event in Amsterdam

By Per Frankelius, Agtech 2030 at Linköping University

This article was based on a speech held by the author at the EPRISE Photonics Roadshow in Amsterdam (February 2019). Per is member of the EPRISE database of experts (scan the QR code in the back cover to access his profile).

Figure 11: The iXtra LiFe is responding to photonics data by liquid fertilizing. Credit: Kverneland.

In *precision field work* many things have happened. About 20 years ago, the company Patchen came out with a product, WeedSeeker, on the market where IR cameras were used to identify chlorophyll, i.e. growing plants. At present photonics is paving the way for so-called see-and-spray concepts. Cameras detect every weed plant and then direct spraying towards each detected spot, but not elsewhere.

Still more is happening: by means of camera-aided row-crop cleaning, for example, farmers today can achieve high performance organic cultivation. One pioneering company in this area is Gothia Redskap with its "System Cameleon".

The science of light generation and detection – photonics – is paving the way for a broad spectrum of applications in agriculture. One main area is *remote sensing and analysis*. It includes soil and crop analysis by means of satellites, drones, ground-based sensors, vehicle-borne sensors, and hand scanners. Farmers use this for yield forecasting, nutrient management etc. Hyperspectral sensors from Glana and other companies will pave the way towards more precision in the art of isolating different spectral signatures to real biological phenomena. However, to make use of precision data it is important to have machines that can respond to it. Kverneland, for example, has developed a liquid fertilizer concept with smart pumps, RTK-GPS-guidance and ISOBUS machine-to-machine communication.

Figure 12: The camera-aided Cameleon machine means precision. Credit: Gothia Redskap

Figure 13: The SeedEye concept was presented at Agritechnica 2017. Credit: Väderstad

Photonics also revolutionizes seeding. Väderstad presented in 2015 a concept making possible analysis in real-time of each seed. The concept is called SeedEye. Many more field applications exist. The farmer Axel Lagerfelt at Tolefors farm, for example, proposed, in 2019, a bird detection system, because some birds like lapwings tend to build their nests in crop fields.

In animal management area photonics is used for analysis of cows, pigs and other animals. The company BMP Innovation, for example uses infrared cameras and smart digital technology to provide many monitoring services. Sometimes photonics is used also outdoor and beyond sight. One special animal application is the concept of weight detection of pigs by means optical sensors and artificial intelligence. Such a concept was presented by Smart Agritech Solutions and IBM at Eurotier 2018.

I could have mentioned many more photonics applications. But one thing is clear: Agriculture has entered a new era – an era of high-tech enlightenment.

4.3 Case study

4.3.1 Introduction of new technologies in a conservative market with both small end-users and large competitors

Company profile

Start-up, innovation ready (TRL 6-7); 4 employees.

http://www.bmpinnovation.se

Product: Detection of oestrus, pregnancy and parturition in livestock or detection of fungal infections & aflatoxins in plant species. Diagnostic solutions for "smart farming" using IR/UV camera-based systems to provide a range of non-invasive diagnostic tools.

Team and Partners: Optronics, mechatronics, imaging, IoT product development

Location: Stockholm, Sweden

Figure 14: IR-image of cows from testing setup. Credit: BMP Innovation.

Market barriers and needs

BMP will reach the end-users, i.e. farmers (small farms) via distributors, but has to acquire a good knowledge of their needs and working conditions. The introduction of new technology is problematic because of economical and practical reasons. First, it is difficult to adopt new solutions during a large part of the year without interrupting seasonal production. Second, farmers' margins are low and investments long-term.

How to convince farmers of the benefits of investing in new photonics-based solutions?

Regarding competition, some large companies control large parts of the market and can be resistant to the introduction of disruptive technologies.

The company is dealing with regional support centres offering "people skill training" as well. These centres are important for their marketing activities.

Expert profile

Per Frankelius, Agtech 2030 at Linköping University

Per Frankelius is a senior lecturer at the department of management and engineering of the Linköping University. The recurrent theme in his research is innovative processes, investigating the interaction between innovative processes and outside world factors. One important conclusion from his research is that marketing and external factor analysis are natural parts of innovation. Per's current research is focused on a try to understand and stimulate innovations in agriculture to meet several societal challenges.

A contact between Per Frankelius, and BMP innovation has been established during the European Photonics Roadshow in Amsterdam via the EPRISE partner PhotonicSweden. Per has identified farms in Sweden suitable for collaboration and offered help to get in contact with them.

Figure 15: Team BMP Innovation, Gabriel Korduner and Graham McCarthy, together with Staffan Tjofnhammar from Photonics Sweden during the Photonics Roadshow in Amsterdam. Photo by Per Frankelius.

Feedback from the expert

The company BMP Innovation uses infrared cameras and smart digital technology to provide many monitoring services. It is an interesting Agri-tech company based on innovative ideas and a lot of technical skills. However, this company like many others faces a lot of barriers on the road to international markets.

From research about barriers to innovation one can learn that an important barrier is *market knowledge*. That includes understanding of price elasticity among potential customers. It also includes one obvious thing, namely to *find the right prospects* in different countries. The *value proposition* can also be a barrier. Some companies think they have the right offer but have not. One common problem is that some prospects want to see a *reference product* before they decide to buy. For a new company that means a hen-and-egg problem.

Of course, *business model aspects* such as "product selling" vs. "function selling" is part of the success factor package. But research also pinpoints some "hidden secrets" regarding success factors. That means aspects not common in the business literature. One such secret is *mingling competence*. That includes not only how to talk with people, including "elevator pitch competence", but also dress codes etc. Another success factor is trade fair management, which includes not only stand design but also pedagogical models to describe the value of the product.

Figure 16: Success factor package. Author: Per Frankelius.

5 FOOD MARKET

5.1 Market overview

The Food sector consists of ten main subsectors: Meat, Fish (fish, crustaceans, molluscs), Fruit-Vegetable, Oil (animal oils and fats), Dairy, Cereals (grain mill products, starches, starch products), Bakery (bakery and farinaceous products), Beverages, Spirits and other food (Sugar and Confectionery)[10].

According to the European Commission, Food and Drink industry is the largest manufacturing sector in the EU[11]. Key features and figures are listed below[12]:

- Estimated market size is €1,109 billion with 4.57 million people employed and 13,8% of household expenditure;
- Sustained growth over the 10 past years;
- Most of the food and drink companies are SMEs (99.1%) with €538 billion turnover and 2.8 million employees;
- The biggest national markets within the EU (turnover in billion EUR) are: France (179.8), Germany (171.3), Italy (133.1), the United Kingdom (118.2) and Spain (96.4);
- 17.9% EU share of global exports, with €35 billion positive trade balance (€110 billion export, €75 billion import);
- Larger trading partners are North America and China
- Sustained level of R&D investment (€2.9 billion in 2016/2017).

5.2 Global trends in a fast-changing consumer market

Figure 17: Ivo Ploesgma at the event in Amsterdam.

By Ivo Ploesgma, FoodTechBrainport, the Netherlands

This article is based on a speech held by the author at the EPRISE Photonics Roadshow in Amsterdam (February 2019). Ivo is member of the EPRISE database of experts (scan the QR code on the back cover to access his profile).

The global food industry, a huge opportunity for high-tech solutions

Characteristic for the global food industry is that it is non-cyclical in its totality. Non-cyclical applies to products that people will always need, such as food. The global food industry is also characterized by a very high annual volume (>5 trillion US$), a globalizing market place and is driven by a consumer market with a stable growth but also a pressing demand for change.

[10] Source: ECSIP Consortium (2017). The competitive position of the European food and drink industry. Final report. Brussels: European Commission.
[11] Source: https://ec.europa.eu/growth/sectors/food_pt (30.04.2018).
[12] Source: DATA&TRENDS (2018). EU FOOD AND DRINK INDUSTRY. Brussels: FoodDrinkEurope

Global trends

It took 200.000 years for the world population to reach 1 billion and only 200 years more to reach 7,7 billion. The current estimate is that by 2050 we will have 9 billion consumers on our planet. A growth of 1,3 billion in only 30 years.

Country	1950 Urban population as percentage of total	2010 Urban population as percentage of total	2030 Urban population as percentage of total (estimate)
Argentina	65,3	92,4	93,2
Australia	77	89,1	91,9
Bangladesh	4,2	28,1	39,9
Brazil	36,2	86,6	91,1
Canada	60,9	80,6	84,4
Chile	58,4	89,0	92,3
China	13,0	44,9	60,3
Egypt	31,9	42,8	53,9
Ethiopia	4,6	17,6	27,1
Finland	31,9	63,9	68,9
France	55,2	77,8	82,9
Germany	64,7	73,8	80,0

Table 3: Urban population. Data source: Citymajors.

Besides this huge growth of the world population urbanisation will also have a large impact on the food industry. The table shows the urban population as a percentage of the total population for several countries from 1950, 2010 up to 2030. This growth of the urban population will shift the centres of economic activity and will increase the demand for (healthy) food by (critical) consumers enormously. How to feed a 30 million people metropole on a daily basis?

Healthy, Safe and Affordable Food for every human being living on our planet should be one of the most important goals of our food industry. Production should be sustainable, using our scare resources in the most efficient and cost-effective way.

And here is still a lot of work to do. We live in a world of big opposites, on one hand poverty and hunger and on the other hand overweight as an extreme example. Obesity has reached epidemic proportions globally. In the past only associated with high-income countries, obesity is now also prevalent in low- and middle-income countries.

Consumers nowadays demand for more healthy food products, search alternatives to animal-based proteins (e.g. plant-based materials), and want to see more transparency in the food chain (e.g. consumer trust) based upon accurate data. The Food Industry (producers and retailers) want to offer more choice and variety in food products, the easy of e-commerce, personalised food instead of mass production…….because technology enables all of this…..

Figure 18: World of opposite. Credit Shutterstock

Sustainable development goals for our planet

The Sustainable Development Goals defined by the United Nations and illustrated in the figure below are the blueprint to achieve a better and more sustainable future for all. They address the global challenges we face, including those related to poverty, inequality, climate, environmental degradation, prosperity, and peace and justice. The Goals interconnect and in order to leave no one behind, it is important that we achieve each Goal and target by 2030. To reach all these goals it might be clear that it should start with the primary necessity of life for all the people living on this planet, the availability of clean drinking water and sufficient food, produced in a sustainable way.

Figure 19: The global goals for sustainable development. Credit: UN.org

About 30-40% of the potential output of food production is currently wasted and the world population is growing fast. If we continue as we are working now then we would need three planets to feed the world in 2050. Only little time left to find the right answers on the question “How to feed 9 billion people in 2050?”

Take away (and call for actions)

Feeding the (whole) world with safe, healthy and affordable food in a sustainable way is our shared challenge.

Opportunities:

- Anything accelerating measuring, sensing, automation, datafication, and enhancing technologies;
- Food waste (reduction) step changes, and enabling technologies
- (International) collaborations, cluster approach

Challenging:

- Close the business gap between Food Industry and High-tech (from projects to shared goals and solutions);
- Supply chain approach from farm to consumer;
- Joined (powered) approach from Multinationals, SMEs, Academia and Government to address the needs
- Create shared FieldLabs to facilitate and accelerate new products and processes to market

Is Photonics one of the key technologies for the Food industry? The answer is yes and the EPRISE-project is a good example of closing the gap between Food Industry and Hightech and how to stimulate the collaboration in the whole value chain from farmer to end user on an international European level.

5.3 Photonics for Food

5.3.1 Opportunities and Go-to-Market strategies for Photonics in Agri-Food industry

By Jacques Cochard, Founder and Associate, TEMATYS, France

Agri-Food industry refers to the manufacturing sector processing raw materials and semi-finished products issued from Agriculture (by extension including Forestry and Fishery). A large part of agricultural production undergoes a more or less extensive transformation process between the stages of harvesting and consumption.

Optical methods mainly perform two functions within this process:

- Food safety, to ensure the absence of pathogens, foreign bodies and chemical contamination, which can represent a health risk;
- Food quality, to guarantee organoleptic (flavors) and mechanical properties (crispness, melting) as well as the conformity of raw materials and end products.

Beyond these two well-established functions relating to raw materials and processed products, there is a third function related to the transformation processes itself: the real-time process control.

The first function - Food Safety - is first and foremost a regulatory challenge. The launch of a new optical product is subject to the approval of the method. A product reaches the market only when regulations are put in place and enforced by a regulatory body. Beyond this, the competition is also strongly constrained by the costs, e.g. a Petri dish costing a few cents is still the reference for many controls. These three drivers - cost, approval time and adherence to proven methods and standards - make this market fairly difficult to penetrate and therefore largely managed by large groups with strong financial basis.

The field of process control is mostly driven by manufacturers themselves, with short-term opportunities for innovative products. Industry is facing major economic challenges and has little or no margin when negotiating with raw material producers and distributors on purchase and selling prices, respectively. Therefore, any production control tool that can significantly reduce - at a steady cost – an unnecessary loss of raw products through a failed transformation process, and/or can guarantee a necessary quality level of an end-product, can find a place in the Agri-Food industry.

Until recently, photonics remained outside the scope of these applications. This can be explained by three factors:

- Multitude of application niches where it is expensive to develop an ad-hoc product and software;
- Difficulty of implementing optical systems in harsh environments (vibration, moisture, hot temperature ...);
- Difficulty of exploiting the multiparametric information issued from photonic sensors within industrial processes based on empirical methods that rely on a few simple parameters (temperature, pressure, acidity);

In the quality control field, the entire photonic spectrum can be used. Quality-control solutions for packaging and labels were initially developed with industrial vision in the visible spectrum. Few years later, NIR spectroscopy allowed the analysis of protein and lipid content of agricultural raw materials before processing. UV fluorescence methods can also detect and quantify very specific molecules such as anthocyanins, polyphenols, and other antioxidants.

New real-time measurements by VIS-NIR hyper-spectral ultra-compact cameras, MIR spectroscopy based on integrated photonics and recent advances in the field of real-time terahertz imaging can broaden the scope of new applications, e.g. detection of organic contaminants in an organic matrix, non-destructive monitoring of moisture in dry and granular products, certification of the origin of the products, etc…

Beyond these industrial applications, photonics could play an important role in restoring some of the trust in consumer-producer relationship, affected by a series of recent food scandals. Consumers increasingly want to know what they eat and numerous handheld spectroscopic devices - some of them based on smartphones - are today enabled by extremely compact and inexpensive components. Thanks to this consumer-driven demand, the time-to-market for photonics products in the near future will be much shorter. These new markets will be much easier to access for SMEs and start-ups, as it was the case in the medical sector with the appearance of the "well-being" market.

In conclusion, there are a lot of applications opening for photonics in the Agri-Food market, which require different go-to-market strategies. The challenge is to choose the right one with the right technology!

Market barriers and needs

Market segment	Application	Technology
Agri-food Manufacturing	• In-line and on-line control • Rapid microbiology methods (particle detection/identification/ characterization) • Foreign body detection	• Infrared spectroscopy (NIR, MIR, UV), hyperspectral imaging, Terahertz imaging, photonic integrated circuits (PICs), machine vision • Cytometry, Plasmonics, Raman spectroscopy, Surface Plasmon Resonance spectroscopy, unconventional imaging (holographic, speckle), PICs • X-rays, Terahertz imaging
Distribution	• Warehouse and retail outlet control (freshness, ripeness)	• LED Lighting (UV-Vis), RGB imaging, Hyperspectral/Terahertz/NIR imaging

Table 4: Photonics technologies in Agri-Food market segments.

5.4 Case study

5.4.1 Pathway from Healthcare to Food industry: ups and downs

DIAFIR
Innovative Diagnostic Solutions

Company profile

SME, investment ready (TRL 5-6); 7 employees

http://diafir.com/en/home/

Activity field: Infrared Diagnostic Solutions

Diafir develops a versatile and easy to use fiber optic diagnostic platform primarily dedicated to the Healthcare market. The strategy is now to extend its application towards other market sectors, e.g. biocide detection in rinse water for the Food industry.

Product: Diafir SPID 1 spectrometer, a minimally-invasive medical device integrating an infrared photonics source and a chalcogenide fiber sensor.

This device provides additional comfort to the patient by avoiding injury or unnecessary hospitalizations. It also helps practitioners to deliver a rapid and robust diagnosis following an easy-to-use medical practice for a growing range of pathologies:

- fast diagnosis of septic arthritis
- diagnosis of non-alcoholic steatohepatitis (NASH)
- analysis of tumoral tissues

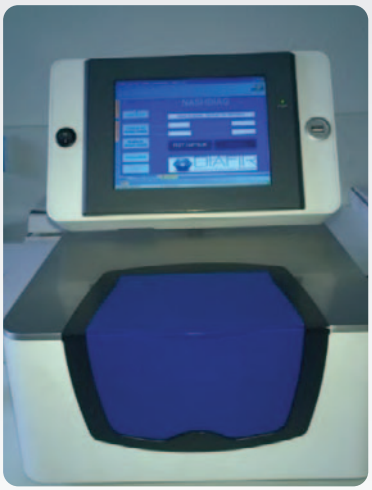


Figure 20: Daifir SPID 1 spectrometer. Credit: Daifir.

Figure 21: Disposable fiber sensor receiving a sample drop. Credit: Diafir.

Team and Partners: Complementary expertise ranging from photonics and electronics to biology and public healthcare.

Location: Rennes, France

The market barriers that Diafir has to overcome for succeeding in its diversification strategy can be summarized by the following questions:

Q1 ***Which are the funding opportunities available to carry out a state-of-the-art technology analysis and verify the technological feasibility?***

Q2 ***How to identify and approach complementary actors e.g. system integrators able to industrialize prototypes and market them?***

Q3 ***How to find a common language between photonics specialists and end-users in the Food industry?***

Q4 ***How to adapt the product to the target market and validate its capacity to ensure optimal operation before offering it to end users?***

Diafir presented these topics at the European Photonics Roadshows in Barcelona (May 2019) as well as the challenges faced in product application to in-vitro diagnostic at the European Photonics Roadshows in Marseille (November 2018).

1st Expert profile

Guillaume Briend, "Digital & Agriculture – Agribusiness" project manager at Bretagne Development Innovation, France

Bretagne Development Innovation's (BDI) mission is to participate in the transformation of the Brittany economy by anticipating and accelerating the deployment of economic policy and regional innovation.

Organized in project mode, BDI brings together multidisciplinary skills at the crossroads of priority regional sectors, e.g. "Digital and electronics for industry and services of the future".

A first contact between the company and the expert was established during the regional EPRISE event in Rennes (Mars 2018) organized by the EPRISE partner Photonic Bretagne. Guillaume Briend was a speaker at the European Photonics Roadshow in Florence (May 2018) as well.

Feedback from the expert

Big data, internet of things, artificial intelligence, measurement and control sensors, automation and robotics are all technologies mastered by companies, mainly SMEs, in the digital sector that can be used to improve the competitiveness of the Agri-Food industry.

The regional AGRETIC program aims to develop the use of digital technologies in the regional Agriculture and Food sectors. The main challenge addressed by this program is how to turn company competitiveness issues into experimental projects to reach new markets.

Funded by the Brittany Region in 2011, the AGRETIC program is managed by BDI in collaboration with the Chamber of Agriculture and the Valorial Food cluster.

Tailored solutions

- **Answer to Q1:** Support for selecting the most appropriate funds for financing Proofs Of Concept (POCs) or collaborative projects (see extract from the Dr. Briend's presentation at the European Roadshow in Florence below). Thanks to this support, DIAFIR benefited from regional funding in the framework of AGRETIC to successfully carry-out its POC programme on a dairy pilot line.
- **Answer to Q2:** Access to a database gathering more than 150 food equipment suppliers.
- **Answer to Q3:** Organisation of B2B meetings and demonstration of the Diafir prototype to potential integrators and end-users during the "Food Plant of the Future Booth" at the Food CFIA 2018.

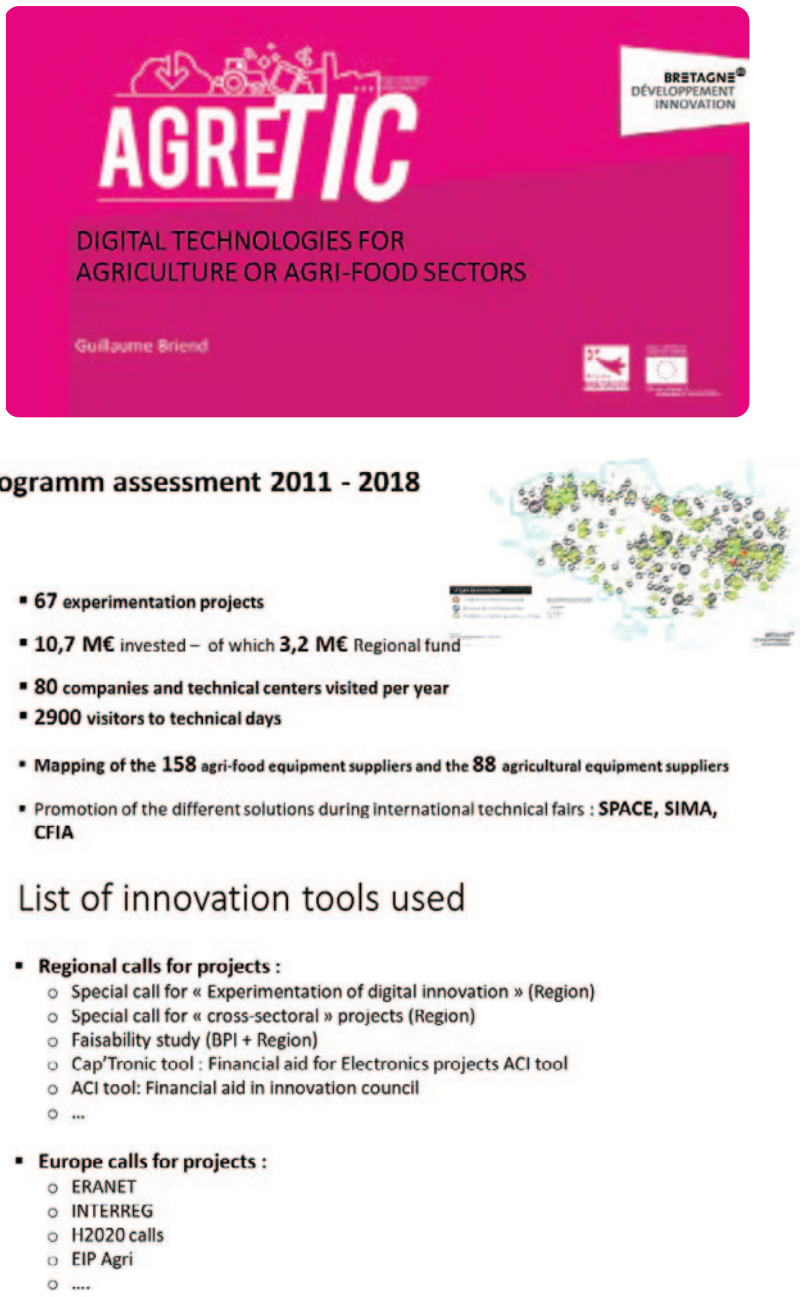


Figure 22: Extract from the Guillaume Briend's presentation at the European Roadshow in Florence

2nd Expert profile

Hedwige Verherbrugghen, Project Manager at "Pack4Food", Belgium

Pack4Food is a consortium of 68 companies, universities and research centers active in the food-packaging interaction field, and network organizations. Pack4Food aims to stimulate innovation in food-packaging, both at the food producer and supplier level (packaging producers, filling machine producers...) and to support companies in their everyday packaging challenges. Pack4Food launches and coordinates research projects, offers networking, training and advice.

Hedwige is project manager at Pack4Food in charge of assessing and identifying the future developments needed to ensure food packaging safety based on the needs identified across all sectors in the food chain.

A contact with Hedwige Verherbrugghen has been established during the European Photonics Roadshow in Barcelona (May 2019) via the EPRISE partner Photonic Bretagne.

Feedback from the expert

During the B2B exchange carried out at the Barcelona Roadshow, Hedwige described the general needs of the food packaging sector. Diafir presented its SPID 1 product and the plan to develop a specific device or process for application to the Food industry. He pointed out the need of finding pilot lines not only dedicated to dairy but also to various food products in order to test such new sensing technologies.

Answer to Q4: Hedwige suggested that Diafir's technology might be used to:

- analyse cleaning water to assess if it can still be used or needs to be purified/refreshed by other water to - at the end- save on water usage for e.g.
- cleaning certain packages (re-usage or recycling process)
- cleaning vegetables or fruits (during production process)
- analyse beverages (milk, smoothies, sauces etc.) during production or on finished products in store
- detect the potential presence of hazardous (allergens?) or nutritious compounds.

She stressed that, if these ideas are viable, the technology will have to be affordable as well. Despite being the largest manufacturing sector in Europe, the margins in the Food industry are very low and incomparable with the Healthcare market.

If e.g. hand held, small size, easy to use analysis equipment could do the work at an affordable price, more companies and food laboratories might consider buying and using it.

In addition, to help establish suitable contacts for testing on pilot lines and with CIP (Clean In Place) systems integrators, Hedwige has forwarded request and information about the Diafir's technology to some colleagues at the university and Food clusters in Belgium. As a result, Flanders' Food, which coordinates S3FOOD, a H2020 Innosup project aiming to develop smart sensor systems for food safety, quality control and resource efficiency in the food processing industry, has identified the DIAFIR's sensing technology as a very promising solution in the field.

6 LEARNING FROM EXPERTS ON CROSS-SECTOR TOPICS

6.1 Venture capital funding for Photonics Start-ups: problems and solutions

By Ed Schneider, General Partner at Spirit Ventures, Sweden

This article is based on a speech held by the author at the EPRISE Photonics Roadshow in Stockholm (June 2018). Ed is member of the EPRISE database of experts (scan the QR codes on the back cover to view his profile and the video of his presentation at the Roadshow).

Figure 23: Ed Schneider at the event in Stockholm

Photonics creates an enormous amount of value. Photonics and other Key Enabling Technologies (KETs[13]) empower today's smart phones, electric vehicles, and other products.

Figure 24: Credit: European Commission, High-Level Expert Group on Key Enabling Technologies, Final report June 2011

Despite their vast potential, limited venture capital (VC) funding has been available for photonic and other KET startups. KETs accounted for only 1.8% of European VC technology funding since 2008. VCs have been avoiding KETs because they require too much investment, take too long to mature, and require expertise that they may not have. The alternative Information Technology (IT) investments in software and internet companies are a better fit for most VC funds' time horizon and capital base.

[13] KETs: Photonics, micro/nanoelectronics, nanotechnology, industrial biotechnology, advanced materials, and advanced manufacturing technologies.

Number and Aggregate Value of Venture Capital Deals* in Europe, 2008-2019 YTD (as of 18.03.2019)						
	Hardware (i.e. KETs)		Internet		Software	
	No. of Deals	Aggregate Deal Size (€mn)	No. of Deals	Aggregate Deal Size (€mn)	No. of Deals	Aggregate Deal Size (€mn)
2008	7	17,0	240	556,9	187	464,0
2009	4	5,7	208	383,5	168	223,1
2010	5	3,7	294	547,5	194	262,4
2011	6	28,0	403	1119,1	207	308,8
2012	7	41,2	559	1487,4	289	467,3
2013	13	14,9	615	1272,6	442	656,9
2014	16	68,0	659	2391,7	494	1030,2
2015	27	139,6	654	5250,9	504	1408,6
2016	27	134,8	704	3158,3	605	1701,7
2017	41	162,6	729	4914,4	740	3050,5
2018	22	113,2	751	5353,9	768	3303,1
2019 YTD	7	33,2	126	1079,1	155	1549,7
Subtotals	182	761,8	5942	27515,4	4753	14426,3
% of Total	1,7%	1,8%	55,6%	65,6%	44,4%	34,4%
Avg Deal Size		4,2		4,6		3,0
*figures exclude add-ons, grants, mergers, venture debt & secondary stock purchases (source: Preqin)						

Table 5: Venture capital in Europe. Source Preqin

KETs require investments of €70M to €120M over a period of ten years or even more. The few European VC funds that have invested in KETs applied the same internet and SW funding metrics in terms of deal size. Thus, they underfunded their KET portfolio companies with small investment rounds and fund lives that were too short.

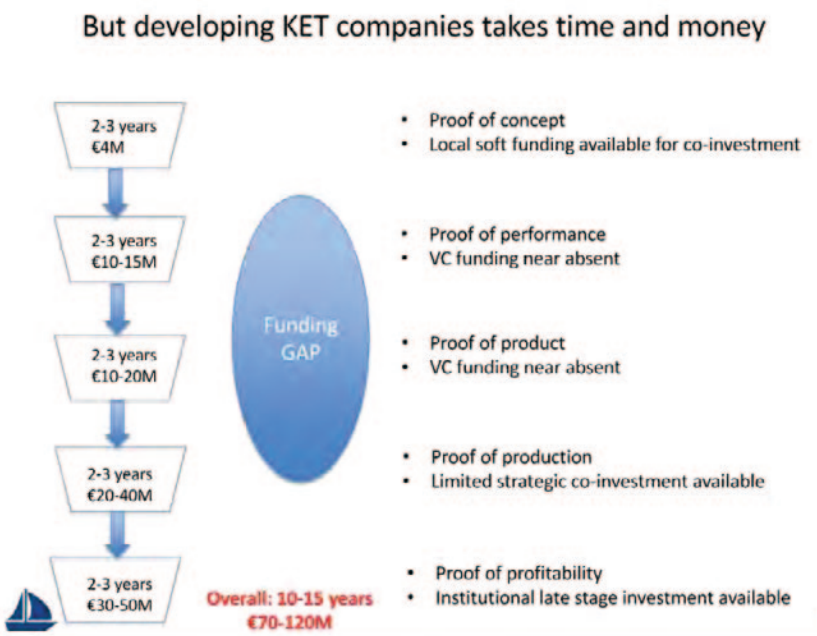


Figure 25: Extract from Ed Schneider's presentation at the event in Stockhom

New funding solutions, however, are emerging for photonic startups today. A new KET fund being formed - Spirit Ventures (www.spiritvc.se) - proposes a larger fund size and longer fund life to match the capital needs and time horizons of its portfolio companies. Furthermore, the Spirit team has extensive KET operating and investment experience to assist its portfolio companies in building and globally commercializing their technologies.

The European Commission (EC) created a KET division, focusing on support for KET companies (http://ec.europa.eu/research/industrial_technologies/index_en.cfm). The EC's Horizon 2020 plan has supported over 250 KET projects over the last three years.

Beyond Horizon 2020, the EC is doubling-down on its efforts to support KETs vis-à-vis the Horizon Europe program (https://ec.europa.eu/info/designing-next-research-and-innovation-framework-programme/what-shapes-next-framework-programme_en). Horizon Europe plans to invest €100B from 2021-2027 in research and innovation including KETs. This budget includes a lab-to-fab initiative, which will help KETs scale-up production.

The problems that photonics startups are solving are not trivial. They take time, patience, and a lot of hard work. But the differentiated solutions ultimately created at the end of this process provide value for the company and society for years to come. Hopefully, KET funding gap issues will be resolved by appropriate VC structures and EC support, enabling photonic startups to realize their potential.

6.2 How to become investor ready

Figure 26: Alex Buchan at the event in Newcastle

By Alex Buchan, Investment Director at Northstar Ventures Ltd., the UK

This article is based on a speech held by the author at the EPRISE Photonics Roadshow in Newcastle (April 2019). Alex is member of the EPRISE database of experts (scan the QR codes on the back cover to view his profile and the video of his presentation at the Roadshow).

Introduction

Northstar Ventures is a VC firm based in Newcastle that specialises in investing in early stage technology businesses. During the 15 years we have been investing we have seen a huge range of businesses across multiple sectors and invested in over 200 in amounts ranging from £10k to £2m. This paper briefly describes what we look for in investment opportunities and what we believe management teams should explore to make themselves attractive investment opportunities with the right balance of risk and reward for our funds.

Firstly, at the stage we are investing it is unrealistic to expect management teams to either be complete or have all the answers. What we are looking for is the ability to analyse and understand the issues facing their business and make realistic assumptions about how to proceed.

To set the scene, a brief outline of what we hope to achieve by making an investment. Investing at the stage we do is high risk; eight out of ten businesses fail and the rough statistics of a company reaching unicorn status (valuation of >$1bn) are 10,0000:1. Consequently we look for a very high level of return on the companies which do succeed. As a general rule we need to be able to convince ourselves that we can achieve a return of at least 10 times the amount invested. To do this we are prepared to invest pre-product and pre-revenue at a point where traditional sources of finance won't touch it.

Success factors

At all stages you need to convince investors that the following stack up:

- The idea / technology
- The team
- The market
- The customer
- The competition
- The funding journey

All of these are important but above all else it is the team which is the critical success factor.

To run through each of these in a bit more detail:

The idea / technology - Investors need to understand what it is you are proposing and what it takes for it to become ready to sell. This is not just the technical development required but any other hurdles (e.g. regulations) that need to be overcome. As important is the understanding of what you need to do to convince people the technology works and is of value to them.

They will also want to see that you have considered routes to market and have sensible strategies in place to sell the product. Last but not least they will want to understand the IP position; this is not just patents but all the other defences that can built (brand, knowhow etc.) to protect your place in the market.

The Team – Who are you? And who does what? These are the first critical questions. We want to see a clear structure of roles and responsibilities so that all the jobs get done. We want to see both that the team has the requisite skills and the understanding of the skills that are lacking. Investors can help fill the gaps.

We look for an open collaborative approach with a readiness to seek advice. One of the most telling aspects of a team is the ecosystem of advisors providing ad hoc support. Above all we are looking for passion and commitment and a real sense of a team rather than a collection of individuals. Building a business is tough and you need to rely on each other.

The Market – at this stage investors are looking as much at the way you analyse a market as at the data you present. We want to see that you have investigated it thoroughly and have a clear understanding of what the Total Available Market (TAM) might be as well as the segment you can address with the product in its current form (Serviceable Available Market – SAM). To do this you need to be dispassionate about your product and segment the market to understand where you really fit.

A fundamental mistake that start-ups often make is to assume they can take a small share of a large market simply because it is a large market (they won't). If your product is as good as you think it is it should be able to take the lion's share of the market segment where it really fits. Ideally, we want to see new product in a fast-growing market or a disruptive product which can overturn an existing market.

The Customer – Investors want to understand who really buys the product and who influences the buying decisions. One of the critical mistakes start-ups make is to try and sell to the wrong person. You need to find out who is the end customer (for example is it the Doctor or the patient), who has control of budgets and what are the buying cycles. For larger ticket items where there are multiple stakeholders you need persuade someone to be your champion within an organisation. Companies in general and start-ups in particular mostly don't talk to their customers enough. You need to persuade investors you do and that you are responsive to continuous customer feedback.

The Competition – Do not make the mistake of thinking that there is no competition even for a new and disruptive product. By default, the status quo is the competition. Teams are generally bad at analysing competition, overestimating the strengths of their product and underestimating the strengths or positioning of competitors. You have to be objective and global in your analysis (even if your initial market is local). The classic comparison matrix where your product is all ticks and the competition always has multiple crosses always feels like a fix rather than good analysis. You really need to understand your USPs and more importantly make sure they actually matter to your customers.

The Funding Journey – One critical issue to investors is what is required to get the business self-sustaining and ideally on a fast growth trajectory. This is likely to involve multiple rounds of funding, so the company needs to raise sufficient capital at each stage to achieve the milestones to take it to the next round. This means the teams need to understand their costs in detail and be realistic about what can be achieved for a given amount of cash. Early stage funders are particularly vulnerable to this requirement as generally they take their investments only so far. The overall funding requirement is therefore critical to any decisions investors make on whether they can or how they might participate in a round.

Hopefully this has given some pointers as to what investors look for in the propositions they see. As I mentioned above, we are looking to see that teams can think through these issues and pull out the key issues facing them, not that they have all the answers. The journey of a start-up is never a straight line so how you deal with setbacks and the changes in positioning you will need to make is key.

6.3 Innovation and entrepreneurship in high technology

By Steffen Terberl, Head of Profund Innovation, FU Berlin, Germany

The author was a speaker at the EPRISE Photonics Roadshow in Berlin (October 2018). Steffen is member of the EPRISE database of experts (scan the QR code in the back cover to access his profile).

Figure 27: Steffen Terberl

Founders from the scientific sector and innovative SMEs often face similar dilemmas and challenges, such as: Which business model is best to address the market? What is the market size for my novel product, and how can I convince investors of the value of my project?

A good team, with the necessary network, creating barriers to market entry (through patents, for example) and convincing presentation are the key prerequisites to tackle such challenges. In the medical technology and pharmaceutical sectors, investments in research and development and the purchase of equipment and laboratory infrastructure are often additional factors. Without taking these factors into considerations, investors are doubtful about spending money without a reliable expectation of Return on Investment (ROI).

It's the classic chicken and egg problem: without top management, investments in IP rights and a professional corporate identity, there's no capital. Without capital, there's no opportunity to make the relevant investments.

Tips

"Minimum Valuable Product", "Lean Startup" and "Bootstrapping" are new German terms taken from English. Often heard in the start-up scene, they are becoming increasingly established methods to solve the chicken and egg problem, even in the high-tech segment. Loosely translated:

- Test out your product idea as soon as possible with the customer directly and with as little outlay as possible.
- Concentrate on the core business and outsource as much as possible to specialised partners.
- Earn money on the side with consultancy and services that don't generate fixed costs. But be careful!
- Make sure not to give away too much at an early stage, as you may risk that your technology becomes public, damaging its novel nature.

In Germany, founders from higher education institutions and research centres, as well as innovative SMEs, enjoy privileges which help to survive without bootstrapping. For patenting inventions, patent offices offer their expertise and financial support to higher education institutions and WIPANO-certified agencies. For founders of all genders there are the EXIST programme[14] and the Berliner Startup Stipendium (Berlin Start-up Scholarships[15]) , and for SMEs there are support programmes such as ZIM and KMU Innovativ (SME Innovative) which are low on bureaucracy and also offer access to the expertise and infrastructures of higher education institutions and research centres. Incubators such as Profund Innovation, scientific centres such as Berlin Partner and networks such as OptecBB offer (free) support with the application process.

Following the company pitch session of the European Photonics Roadshow in Berlin and based on my own organisation's experience of working with local start-up companies who have now become established, I observe that innovative SME companies throughout the EU face very similar challenges to each other.

The more specialized the topics which the company is interested in, the more important it is for them to engage with experts from abroad. There is currently no critical mass of actors to sufficiently address market-specific challenges of photonics SME in life sciences, if one searches for answers in the local region only. Especially the EU is a great place to initiate and establish such networks because the distances between regions are rather short and the value system and culture is similar between different regions.

Berlin is one of the top-destinations worldwide to setup or establish a start-up, especially within the EU. The barriers for entrepreneurs from outside Germany to found a start-up in Berlin are quite low. Berlin is internationally oriented; it has a very good and favourable ecosystem for founders from inside and outside of Germany. The numerous Berlin Universities and Institutes are contributing significantly to this phenomenon: They are not just open to innovative start-ups but also offer funding (e.g. the Berliner Start-up stipends) and supportive infrastructure (e.g. access to expertise and qualified employees). In the near future FUBIC will potentially become the major place to go for laboratory-oriented business: the planned Business and Innovation Centre next to Freie Universität Campus (FUBIC) is part of an innovation park occupying about 50,000 square meters where space is also being set aside for established high-tech companies to take up residence in buildings of their own.

http://www.exist.de/EN/
http://www.startup-incubator.berlin/en/startup-center-of-the-hwr-berlin/

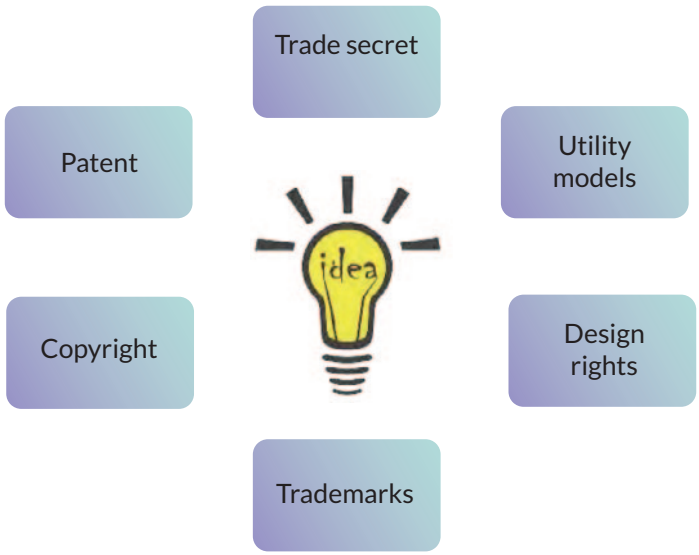
6.4 Intellectual Property Rights for Photonics

Figure 28: Viola Prifti at the event in Florence

By Viola Prifti, PhD in law & economics, University for Applied Sciences and Economics, Germany

The author was a speaker at the EPRISE Photonics Roadshow in Florence (May 2018) and in Barcelona (May 2019). Viola is member of the EPRISE database of experts (scan the QR code in the back cover to access her profile).

Every company that invests in photonics technology and develops new products and processes can add value to its business by adopting several types of intellectual property rights (IPRs). This brief will outline the main types of rights that can be used in medical technology, pharmaceuticals, agriculture and food as well as a few considerations on activities that can help photonic companies increase profits and expand their market.



Trade secrets protect valuable information that gives the company a competitive advantage. In order to have a trade secret, the information should have commercial value and it should not be disclosed to the public at large or to experts in the sector. The company should also take adequate steps to protect the information such as sign non-disclosure agreements and store the information in a safe deposit box. Trade secrets can be especially important for protecting know how and any other information that cannot be easily discovered by competitors (a particular molecule, a recipe, list of suppliers and clients, manufacturing processes, or early-stage inventions).

Patents protect any invention that gives a technical solution to a technical problem. Patents are important instruments to signal the potential commercialization of an invention and attract investments. In addition, they allow companies to recoup the initial costs of research and development, and grant monopoly power for a maximum of 20 years. All companies that invest in photonics should consider patenting their new technology in order to obtain competitive advantage. If companies decide to license their rights, they should do so strategically.

For example, when a company does not have the technological and financial capability to further develop the technology, they can license their patent rights to another company. In this case, the choice between exclusive and non-exclusive licensing should be carefully pondered and the licensing agreement wisely drafted in order to guarantee a return on investment.

Utility models are similar to patents because they confer exclusive rights on an invention, but they do not require substantial examination. This makes them low-cost and fast to grant. There is no uniform law in the European Union on utility models. While some countries (Germany, Austria, Denmark, Poland, Italy, the Czech Republic, Finland, France, Spain) grant utility models, others do not. Utility models are usually granted for minor inventions such as improvements of existing technologies.

Copyright protects the expression of ideas in fixed form. It grants to the owner the exclusive legal right to produce, reproduce, publish, or perform a work. Copyright is relevant for companies that work on photonics when they use computer programs and codes, compilations of data and graphics and other products that can be covered by copyright. Copyright is an important asset for the company and contractual terms with end users and third parties should clearly specify permitted use. Even when companies are not the owners of copyright, they should have policies incorporating third-party copyright use because they may even inadvertently infringe other's IP rights.

Trademarks consist of a combination of letters, words, sounds or colors, or designs that distinguishes one company's goods or services from those of others in the marketplace. A good trademark strategy helps companies differentiate their products and services from competitors and establish a strong reputation in the market.

Design rights protect the appearance of a product that results from a combination of its features such as color, shape, material. They can protect, for example, the appearance of a photonic sensor and/or that of a drone where the sensor may be incorporated. Design rights do not protect the function of a product and they can be granted for a maximum of 25 years in the European Union.

How to make the best use of your IP rights?

A company that develops a new product and enters a market should certainly try to use the wide range of IPRs strategically in order to maximize its profits. Different types of rights can be applied to the same product, but the choice of rights should be strategically thought. Although rights such as copyright, trademarks, and design rights arise without the need of registration, it is advised to register such rights in order to better protect inventions against any type of infringement.

Intellectual property is both a resource and a cost for companies. Patents, in particular, involve considerable application and maintenance fees. A patent should not be maintained if it loses its commercial utility. Looking for patents, monitoring, enforcing, and developing IP can be particularly cumbersome for small companies. However, information on different types of IP is available online either through private databases or publicly accessible databases on the websites of national and international patent offices. Information on patents can be found on the websites of the European Patent Office[18] (EPO) and of the World International Patent Organization[19] (WIPO). WIPO and the European Union Intellectual Property Office[20] (EUIPO) offer rich information on trademarks.

The information and the rights provided by these organizations have different territorial scope. When a company decides to apply for protecting its intellectual property, it should assess whether it is worthwhile to obtain protection at national, European, or international level. In addition, a company that intends to enter a market should also take into consideration existing proprietary technology and whether it is beneficial to license IPRs from existing players in the market.

[18] https://www.epo.org/index.html
[19] https://www.wipo.int/portal/en/index.html
[20] https://euipo.europa.eu/ohimportal/en/home?ld=BRFRNF

Takeaway

An adequate protection and IP strategy for the technology involved in research and development as well as for the final products will help companies maximize their profits and expand their markets. Companies should clearly define and protect their IP and establish clear agreements on IP rights between third parties to manage risk.

6.5 International Business Development for Photonics Companies: Focus on North America

Figure 29: Jabril Bensedrin at the event in Marseille.

By Jabril Bensedrine, Managing Director at The Triana Group, Inc., USA

This article is based on a speech held by the author at the EPRISE Photonics Roadshow in Marseille (November 2018). Jabril is member of the EPRISE database of experts (scan the QR codes on the back cover to view his profile and the video of his presentation at the Roadshow).

The author thanks the EPRISE project and contributions from David Sejourne and Dr. Paul Sohmer.

Market highlights

Photonics companies enjoy a high-potential market in North America. $3 billion for medical laser systems, for example; $600 million for technologies such as Coherence Tomography (OCT), Hyper Spectral Imaging (HSI), Near Infrared Spectroscopy (NIRS) and Photo- Acoustic Tomography (PAT), which are growing rapidly in fields such as ophthalmology, oncology, neurology, and dermatology. There is still substantial room for growth within the larger scientific and technical instruments sector (est. $19 billion) and medical devices sector (est. $160 billion), both of which represent 40% of the world's market. Applications in agriculture, food-processing and industry quality control might be smaller, but promising[21].

Numerous photonics ecosystems exist around the nation: Rochester Regional Photonics Cluster, Inc. for example, includes 150 large notable companies (Xerox, Bausch and Lomb, Kodak, Corning…) and the University of Rochester, Rochester Institute of Technology. Other rich photonics ecosystems include Arizona; California (Silicon Valley and Los Angeles); Carolinas; Colorado; Florida; Michigan; New Mexico; Massachusetts; Washington DC (detailed map, descriptions and contacts are available upon request).

However, as a member of The Optical Society of America (OSA) explained, "it is not very helpful to speak of the overall sector. Assessments vary greatly among segments." The same is true for business development strategies: one size does not fit all.

[21] The Triana Group estimates based on data from Ibis World, Grand View Research, Technavio, SelectUSA

How to approach the market

In business development, we found that the "lean startup" process provides the right balance between market discovery, planning, and agile action. On one hand, investing too quickly is dangerous and can lead to waste of resources. On the other hand, the other extreme is also counter-productive: "you should assess the market and plan carefully but avoid the Analysis-Paralysis Syndrome", said the CEO of several successful US subsidiaries of European photonics companies. "Taking initial steps can increase your market knowledge and serve as stepping-stone for next phases in a way that analysis alone can't."

Our sources

This article is based on 59 brief case studies of technology companies, 10 in-depth case studies of photonics companies, and hundreds of conversations. Examples of significant interviews include: several presidents of regional photonics clusters; active members of the Optical Society of America (OSA); experts for the National Science Foundation; scientists and engineers in prominent research labs; senior engineering execs in photonics companies; senior executives in large US and global scientific instrumentation companies; division heads of the US subsidiary of European photonics companies; etc.

Short stories of success

To illustrate this article, we chose three short stories of photonics companies that expanded successfully. We also share a broader list of recommendations and food-for-thought based on a larger review of successes and failures.

Case 1: The North American CEO of a European bio-photonics company that is now well established in the US summarizes his key success factors as follows:

- Came with breakthrough product that people started to recognize in scientific publications
- Started with a reseller then acquired the reseller
- Developed additional collaborations with local partners to open new market access
- Digital strategy and twitter "were a big thing for us in America."
- Went to all conferences where they could meet actual end-users and start discussions

Case 2: A European manufacturer of photonics sub-components that is now well established in the US, summarized its development as follows:

- Started in the US with just sales partners
- Gained traction then acquired a local manufacturing operation to reinforce its presence
- Focused on successful integration then became appealing to a large acquirer, and got acquired

Case 3: A university spin-off in the photonics / medical imaging space, managed to establish itself as a technology leader in the US thanks to the following combination of activities:

- Constantly growing portfolio of patents with proven track record in global licensing deals
- Active leadership in a $15 million R&D consortium with a dozen collaborations
- Aggressive beta sales program and free trials, leading to a solid footprint

One size does not fit all

The right business development options vary from segment to segment and from company to company. It would take much more than an article to examine each potential situation, but here is an example of heterogenous advice that you might hear.

Working with Key Accounts:

The CEO of a successful company told us, "although we don't ignore direct buyers, those buyers purchase individual units and infrequently, whereas integrators and Original Equipment Manufacturers (OEM)'s buy dozens and sometimes hundreds of units per year so we put a lot of effort in signing those large customers." An additional benefit of working with OEMs is that they can often be approached globally. However, other companies are deterred by the OEM channel because of long sales cycles, dependency concerns, and lower margins... "For example, one customer is buying 75 cameras per year. Prices for higher volume buyers can be up to 50% discounted."

Working with Distributors:

We often hear "we recommend selling through distributors. Given that this market is relationship driven, distributors could drive a strong ramp to volume." Decision criteria to choose the right distributor include: deep relationships with buyers; ability to provide the required level of expertise; strong ability to collaborate with key accounts on integration matters. However, don't expect a hands-off relationship: you should plan to work very closely with distributors. You should catalyse market awareness and sales by collaborating with key opinion leaders such as Principal Investigators on research projects leading to publications and conference presentations. In a highly specialized "niche" market, this means that you might as well, sometimes, develop the market yourself rather than leave 50% of the margin to a distributor. But it depends on your capital and commercial team.

Collaborations:

Some US counterparts complain that "international R&D collaboration are difficult to implement. Each of them is managed on a case-by-case basis." Since a lot of photonics research is funded by the Department of Defense, anything connected to that is even harder, if not practically impossible, said the CEO of several photonics companies. However, certain sectors are very different. "Healthcare applications are a very dynamic space where there are a lot of acquisitions, M&As, and strategic alliances. There is potential to engage in strategic collaborations very rapidly." Another CEO explained that collaborations with startups are the best catalysts. He said: "our best paying clients are established companies, but our most cutting-edge and innovative work is with startups. We work together with startups and universities where ideas can't be pursued with off-the-shelf equipment but instruments that can be tailored to what they do."

Sales and business development toolbox;

Companies reported the following sales development methods as particularly productive:

- presence in trade shows jointly with partners;
- sales to Original Equipment Manufacturers / integrators;
- active participation in industry associations (including end-user associations);
- direct marketing campaigns to well-qualified contacts;
- webinars promoted with partners; technical publications along with partners;
- increasingly, digital marketing and promoting products on multiple websites (company, distributor, partners, other);
- roadshows with partners (in-person workshops in key cities for live demos.)

Key takeaways

In summary, the key challenges and "must do's" of business development, especially at an early stage, can be summarized as follows:

- Realistic analysis of competition
- Solidifying/Affirming IP position
- Ecosystem (collaboration, partnerships, modes of market entry)
- Positioning, business model, offering
- Resources: capital and personnel

This article outlines our presentation at the EPRISE's European Photonics Roadshow, but a lot of its content applies to a broader range of technology companies. Many points couldn't be addressed here due to space constraints, but we hope this provides some insights to innovative companies interested in optimizing their business development both domestically and internationally.

Lessons learned on factors influencing success and failure

Factors that most often hindered business development:

- Approaching the market as a "test" is a double-edged sword
- Under-capitalized / lack working capital
- Capitalized but high burning rate
- Competition / status quo
- Insufficient market interest (need for a "10x factor")
- Positioning, adaptation of business model & offering
- Isolation (no ecosystem, lack of local partnerships)
- Distance management, lack of follow-through
- Home country priorities or issues, reallocated priorities
- Insufficient teams and resources
- Factors that most often facilitated business development:
- Realistic analysis of local competition
- Objective (re)analysis of user needs and practices
- Solid team with "hybrid" people and the right balance of locals and expatriates
- Trial & errors, learning process, strategic vision
- Part of global strategy (not US vs. home country)
- Cross-pollination at the international level (ideas, joint-projects, etc.). New division not just a sales channel but a contributor to the global R&D and value chain of the company
- Working capital; ability to support long cycle
- Major partnerships & combined modes of entry (not falling in the trap of "one" mode of entry). Development of a rich ecosystem.

EPRISE has bought nine European photonic leaders together to support SMEs working in the Photonic Industry and overcome the market barriers.

SMEs developing photonics-based products, processes or services for the Medical Technology, Pharmaceutical, Agriculture, and Food markets face highly specific Go-to-Market challenges such as long timescales to market adoption and complex regulatory frameworks. They need expert advice on business-related topics, such as, taking the Healthcare market as an example, clinical needs, health economics, clinical trial planning, access to clinicians.

This booklet offers an overview of the opportunities for photonics in the four markets and provides SMEs with information on how to overcome market entry barriers. It is a compilation of best practices, lessons learnt, takeaways, tips, and case studies issued from the European Photonics Roadshow, a series of events organised by the EPRISE partners in seven European countries from May 2018 to May 2019.

The EPRISE consortium thanks all the experts for their valuable contributions to the booklet as well as the following companies: Probiomedica, Xploraytion, BMP Innovation, and Diafir for their involvement in the case studies.

Videos of the presentations delivered by experts at the European Photonics Roadshow can be found here:
https://www.youtube.com/channel/UCeJx04jqCuWUbblxIFTa4hQ

Presentation documents from the Roadshows can be found at
https://eprise.eu/media
The market expert database, which profiles many of the contributors in the booklet can be found here:
https://eprise.eu/experts/