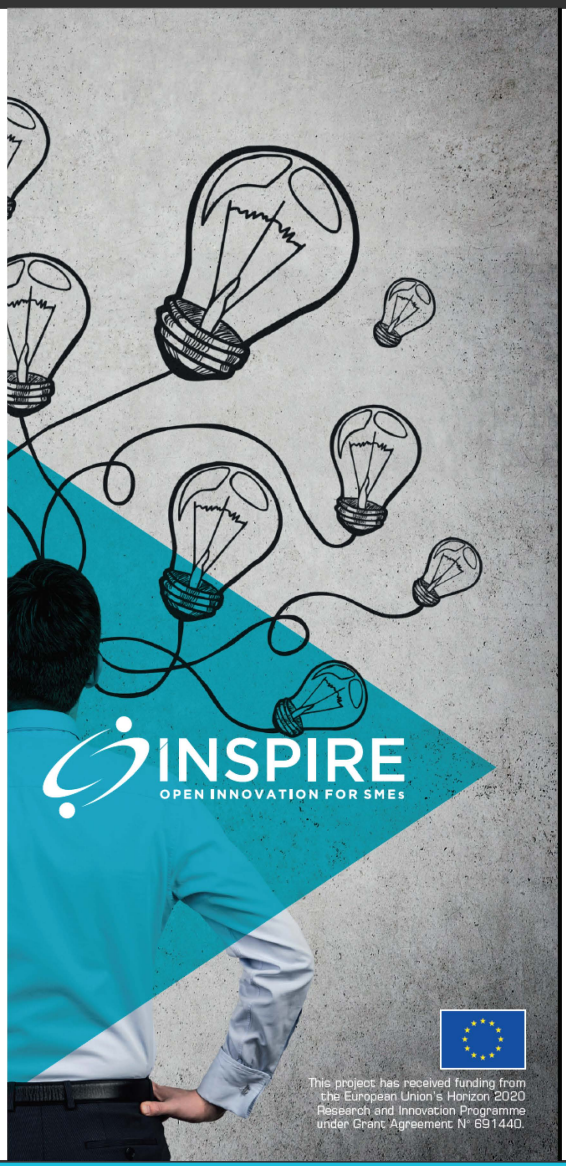

NOVOSANIS

Belgium, www.novosanis.com

A group of researchers made the transition to the business world by collaborating closely with a university and design and engineering company to commercialize a revolutionary medical diagnostic device

Executive Summary

Novosanis is a Belgian medical device start-up company that has developed a device platform that allows the collection of different pre-defined urine volumes for a range of medical applications (e.g. chlamydia, gonorrhoea and HPV, which can cause cervical cancer, as well as cancer biomarkers). From their first day of business the start-up has been working together with other partners. Their first commercial product (Colli-Pee) was developed with the help of the University of Antwerp and Voxdale (a design & engineering company). It is unique in that it provides a user-friendly, non-invasive sampling method intended for home-use by patients.

CASE N°: SD21

SECTOR: MEDICAL DIAGNOSTICS

TECH INTENSITY: HIGH-TECH

LIFE CYCLE STAGE: START-UP

INNOVATION VECTORS: PRODUCT, DISTRIBUTION CHANNELS

01 PARTNERS: PSR, OTHER SME

KEYWORDS: Diagnostics, medical, STD/STI, cervical cancer, detection, university, urine, market need, unique product

- BACKGROUND FRAMEWORK
- INNOVATION CHALLENGE & MARKET OPPORTUNITIES
- OI TRAJECTORY
- BUSINESS IMPACT
- LESSONS LEARNED

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BACKGROUND

Novosanis was founded on 12 March 2013 as a spin-off company from the University of Antwerp. Novosanis is funded by the company's management and a private investor, Taste Invest. At present, two medical device platforms are being offered: VAX-ID -a platform of devices suited for accurate intradermal drug delivery -and Colli-Pee - a device for guaranteed and standardized collection of first-void urine.

The creation of these two devices, which are at the heart of the company, was the result of multidisciplinary collaborations between the University of Antwerp (VAXINFECTIO and product development -the latter was formerly Artesis University College) and Voxdale (design & engineering company).

As Novosanis is still in a start-up phase they want to continue developing their platforms and products, and scale up with partners for their full entry into the market.

INNOVATION CHALLENGE & MARKET OPPORTUNITIES

The opportunity was identified by researchers at the Vaccine & Infectious Disease Institute - VAXINFECTIO - of the University of Antwerp. Among their testing of the effects of vaccinations, there was a need to detect the HVP virus in young adolescents. Following their research, the researchers involved the Innovation Manager who in turn set up a collaboration with the Department of Product Development at the Artesis College and formed a PPP with Voxdale, a design and engineering company based in Antwerp, to come up with a potentially marketable solution. They then decided to start their own company: Novosanis.

They saw an unmet medical need: regular detection methods (smear tests) for HPV cannot be performed by adolescent girls. They needed an alternative detection method for tracking the effectiveness of the vaccine. Through their existing knowledge they knew it was likely to be possible to diagnose using urine samples.

They also knew that home testing methods had much higher collection rates than clinical testing. Patients found self-collection and testing of urine and vaginal specimens at home easier, more acceptable, and generally preferred over testing at a clinic.

"Women in the home testing group (60%) were more likely to self-collect a vaginal sample than women in the clinic testing group (42%, RR 1.4, 95% CI 1.2-1.7)"

"Home-based screening was up to 11 times greater than the testing rate with clinic-based screening."

OPEN INNOVATION TRAJECTORY

Concept development

The initial concept of a self-sampling test kit for the patient was conceived at the beginning of the project. Several adjustments to improve the design, production and usability have been made over the course of time. The University of Antwerp contributed to defining the medical testing concept based on their R&D experience in this field. The concept was based on the collection of first-void urine that allows the detection of Human Papilloma Virus (HPV), a virus which can cause cervical cancer.

The Colli-Pee device platform enables the collection of different pre-defined volumes for a range of medical applications. The Colli-Pee concept had several important feature requirements, namely:

- user-friendly
- compact - a device which is suited for postal delivery
- can be used by both men and women.

Their product engineering partner (Voxdale) helped with drawing up the initial product specifications for method of use, usability and materials.

The development process, IPR and competition strategy

Working closely with the University of Antwerp and Voxdale engineering company, a first injection-moulded prototype was developed. Several redesigns followed to match production and usability challenges, as well as to meet medical quality standards. Novosanis contributed with the product specifications and their medical knowledge, while Voxdale made the moulds and

product improvements. Students from the University of Antwerp assisted with usability and research. One of the former students was hired by the start-up company and is currently still working for Novosanis.

One difficult step they underestimated at the start of the project was the size and amount of clinical trials required for the development of the product. Even for a relatively simple mechanical concept a large number of expensive clinical trials were required before the product received its CE-IVD label.

The intellectual property is owned by Novosanis, with patents for Colli-Pee granted in Belgium, the Netherlands, the US, Japan and beyond.

Alternative testing methods in the labs of medical institutions (e.g. hospitals) are still a competitive option. However, thanks to the possibility of using the device at home, its being non-invasive and user-friendly, the Colli-Pee has the potential to reach more people than the traditional smear-testing. Novosanis is not aware of any other company offering solutions for use at home.

Commercialization and follow-up

Novosanis wants to expand its network: they are currently distributing through selected groups of laboratories, hospitals and diagnostics companies and are planning to grow this network. They also intend to expand their distribution network to pharmacies. An economics student from the University of Antwerp was initially involved in drafting the business plan for VAX-ID.

The beginnings of the start-up were very research-focused, but as the project advanced they had to acquire additional expertise: economics and sales-profiles, production partners. The production of the Colli-Pee has been outsourced to Denmark and China, but the assembly, packaging, labelling and shipping takes place at their Belgian facilities.

The company founders are very reliant on their personal network of connections to achieve success in the medical industry. There are two key aspects to breaking through in the market: spreading knowledge and demonstrating the reliability of the new solution. This is achieved primarily by presenting their product and results at medical congresses.

BUSINESS IMPACT

As the company started from scratch, new skills were continually acquired throughout the project: design, engineering, commercial. .. The Colli-Pee was a direct result of the OI collaboration and would not have been possible without the help of both the university and Voxdale. The knowledge provided by these partners was invaluable in the development process.

The company has extended its know-how in:

1. Integrated medical product development process: the company has learnt a lot about the medical product development cycle by working on the innovation process with partners. They will be able to apply this new knowledge in future projects as well.
2. Iterative product design approach: constraints on the design from a production, quality and usability standpoint required multiple iterations.

Currently, Novosanis has two products launched in the market:

- The Colli-Pee as a direct result of this project
- VAX-ID, which is an easy-to-use platform of non-pre-filled and pre-filled devices.

Both of these are patented, award winning products which are being marketed internationally. Now in the scaling up stage, Novosanis is earning revenue but is not yet profitable. They are currently still reliant on subsidies and private equity.

LESSONS LEARNED

This case shows how open innovation can initiate researchers to create a successful medical start-up. There are multiple challenges for researchers to make the transition from research to the business world. Partnerships and close ties to essential and dedicated partners from key stakeholder organizations (in this case a research institute and an engineering company) allowed them to make this transition.

The combination of aligning medical requirements with patients' tolerance while also designing a user-friendly and easy-to-manufacture device would not have been possible without close cooperation with different partners.

Main lessons learned:

1. Strong networks and trust are critically important for forming successful open innovation partnerships. This is especially true in the medical world since it is very hard to break into this market as an outsider. It would have been difficult to establish partnerships without personal contacts with the people who helped to open doors.
2. Partnering with universities can give access to a wide range of knowledge and expertise in fields which are lacking in start-ups and small companies. Working with universities provides access to good knowledge and skills. Thanks to the University of Antwerp's network, Novosanis was able to acquire key expertise which was missing at an early stage and at low cost (students). Having these students involved enriched the product development process.
3. Open innovation can help an SME to combine business, technology and user insights in a balanced way for the product development process. Especially in a research-driven start-up it tends to be a challenge to integrate all these aspects at the same time.
4. Unrelated to open innovation: The most important lesson was that the difficulty of clinical trials must not be underestimated. The company needed to attract extra capital for expensive and lengthy clinical trials throughout the process.