OI INSPIRATIONAL CASES

THE IMPORTANCE OF RESEARCH AND BUSINESS NETWORKS FOR OPEN INNOVATION

Novosanis is a spin-off from the University of Antwerp which has been driven by collaboration between multidisciplinary research institutes and a design & engineering company. Their user-friendly and game-changing medical devices, which offer self-sampling and drug delivery solutions, have been able to impose themselves in the market and attract a Nasdaq-quoted medical devices company, which acquired the SME at the beginning of 2019.

- Novosanis was launched on 12 March 2013 as a spin-off company from the University of Antwerp. Funding was provided by a private investor Taste Invest, together with subsidies from the Flemish Government and research funding from the European Commission.
- The company's main two offerings are medical device platforms: VAX-ID - a platform of injection devices suited for accurate intradermal drug delivery - and Colli-Pee - a platform of self-sampling devices for volumetric and standardized collection of first-void urine.
- The creation of the two devices was the result of multi- disciplinary collaborations between university departments and a design & engineering company.
- Since January 2019 Novosanis is a wholly owned subsidiary of OraSure Technologies Inc, based in Bethlehem, Pennsylvania (USA).

The Origin of the Open Innovation

The origins of Novosanis are to be found in two research projects at VAXINFECTIO, the Vaccine & Infectious Disease Institute of the University of Antwerp. In both cases, the cross-disciplinary involvement of students from the Master Program in Product Development of the Faculty of Design Sciences led to the development of the medical devices which went on to become Novosanis' core offering.

In September 2010, Wouter Coemans (a Master student in product development) started work on the VAX-ID (formerly 'Vaxintradermal') project as the subject of his thesis. The idea for an intradermal vaccination device came from VAXINFECTIO's key researchers who had identified the lack of sufficient vaccine during the H1N1 flu pandemic. Intradermal vaccination allows for smaller volumes to be used while leading to an improved immune response. That year, Koen Beyers, CEO of the design and engineering company Voxdale, based in Antwerp, became involved in the creation of the VAX-ID through his role as Wouter Coemans' industrial supervisor. Koen Beyers went on to become CTO of Novosanis.

In 2011, the VAX-ID project was continued by three Master students with different backgrounds: Ruben Camerlynck (product development), Charlotte Reypens (applied economics) and Timothi Van Mulder (nursing and obstetrics), who investigated the industrial design, clinical applicability and market potential of the device. Their academic supervisor and the VAX-ID project coordinator was Vanessa Vankerckhoven, at that time Innovation Manager at VAXINFECTIO, and now CEO of Novosanis. Timothi Van Mulder went on to become Clinical Affairs Manager and Quality Manager at Novosanis.

In September 2011, Lara Biekens, who was studying for a Master degree in product development at the University of Antwerp, started developing a device for the non-invasive collection of first-void urine, now known as Novosanis' Colli-Pee. As with the VAX-ID project, the concept was inspired by VAXINFECTIO's researchers who had discovered that first-void urine can be used for the detection of HPV infection (human papillomavirus, the most common sexually transmitted infection which can cause cervical cancer). The VAXINFECTIO researchers recognized that regular detection methods (smear tests) for HPV cannot be performed by adolescent girls, but their existing knowledge told them that it was likely to be possible to diagnose using urine samples. They also knew that home testing methods had up to 11 times greater collection rates than clinical testing.

In 2012 therefore, this project was continued by three master students with different backgrounds: Hanne De Bauw (product development), Tina Van Hove (nursing and obstetrics) and Ragnar Dienske (sociology), who each focused on a different part of the development process. Hanne De Bauw's work was supervised by Koen Beyers and his Voxdale team, while Tina Van Hove's research was supervised by Timothi Van Mulder. Again, Vanessa Vankerckhoven was responsible for the coordination and academic supervision of the Colli-Pee project.

Open Innovation Journey

The initial concept of a self-sampling test kit for the patient was therefore conceived at the beginning of the Coll-Pee project and several adjustments to improve the design, production and usability of the invention were made over the course of time by the team of Master students and designers/product engineers from Voxdale. By enabling the collection of different pre-defined volumes for a range of medical applications, the Colli-Pee concept offered 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 regarding its method of use, usability and materials. Working closely with the product development unit at the University of Antwerp and Voxdale engineering company, Novosanis commissioned a first injection-moulded prototype. 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, assisted by the multidisciplinary team of students who carried out research and testing of its usability and other features.

One difficult step that the Novosanis team underestimated at the start of the project was the size and number of clinical trials required for the development of the product. Even for a relatively simple mechanical concept like the Colli-Pee, a large number of expensive clinical trials were required before the product received its CE-IVD label (EC conformity for in-vitro diagnostic devices).

On the strength of their invention, Novosanis was able to file a patent for Colli-Pee which is valid in Belgium, the Netherlands, the US, Japan and beyond. Alternative testing methods in the labs of medical institutions (e.g. hospitals) still remain a competitive option, but 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-test. And no other company is currently commercializing such a testing solution for use at home.

Impact of the OI Collaboration

The ability to add new and complimentary skills – design, engineering, commercial - to develop the two medical devices that were to become the value proposition of Novosanis was fundamental for the creation of the company itself. The Colli-Pee was a direct result of the OI collaboration and would never have matured as a product without the help of other university departments and Voxdale. Novosanis went on to patent its award-winning products, Colli-Pee and VAX-ID, which are currently being marketed internationally and have already convinced a number of customers from Europe and overseas. Now in the scaling up stage, Novosanis took one more step towards profitability in January 2019 when it became a fully-owned subsidiary of OraSure Technologies, Inc, a US-based producer of medical devices and diagnostic testing kits, including OraQuick, the first over-the-counter home HIV testing kit.

Novosanis' open innovation experience demonstrates how researchers can go on to create a successful medical start-up. There are multiple challenges for researchers to make that transition from research to the business world, but strategic collaboration and close ties with essential and dedicated partners from key stakeholder organizations (in this case a research institute and an engineering company) set them on the path to commercial success.

STRONG NETWORKS AND TRUST OPEN DOORS

They are critically important for forming successful open innovation partnerships, especially in the medical world where it is hard to break into the market as an outsider.

UNIVERSITIES AS A SOURCE OF CROSS-DISCIPLINARY EXPERTISE

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. 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). The students' contribution was essential for the product development process.

OPEN INNOVATION = RIGHT COMBINATION

Open innovation can help an SME 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.

CONTACT DETAILS
VANESSA VANKERCKHOVEN, CEO
NOVOSANIS
BIJKHOEVELAAN 32C – 2110 WIJNEGEM, BELGIUM
TEL. +32 3 485 50 16, WWW.NOVOSANIS.COM

The INSPIRE project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 691440 – INSPIRE.