

Poland, www.selvita.pl

The business model of one of Poland's leading biotech companies is based on open innovation collaborations in which it positions itself as a commercialization intermediary working with both public research organizations and international big pharma

Executive Summary

Selvita is a drug discovery company and one of the leading biotech companies in Poland. It was founded in 2007 by two entrepreneurs coming from the IT industry. This case is not about a particular OI experiment, but rather it is about the OI system that was established in the company and how a pipeline of projects and a system to finance them was developed. The company in effect took on an intermediary role between public research and the established pharma companies. The concept explicitly relies on partnerships – it has OI in its design. The case reveals how their business model evolved by relying on partnerships of different kinds and by being flexible and creative. They developed a hybrid business model, which combines an internal pipeline and drug discovery services, to finance their long-term projects.

CASE N°: EE18

SECTOR: BIOTECHNOLOGY

TECH INTENSITY: HIGH-TECH

LIFE CYCLE STAGE: ESTABLISHED

INNOVATION VECTORS: PRODUCT, PROCESS, ORGANISATIONAL

01 PARTNERS: PSR, LARGE CORPORATION, OTHERSME

KEYWORDS: Drug discovery, business model, license in new technology, license out non-core technology, partnership agreement with large companies

- BACKGROUND FRAMEWORK
- INNOVATION CHALLENGE &
- MARKET OPPORTUNITIES
- OI TRAJECTORY
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BACKGROUND

In 2007, after a successful career in the IT industry, Pawel, who had been vice-president of Comarch, one of the leading IT companies in Poland, and Bogdan decided to set a new challenge for themselves – to manage a bio-tech company in their home city of Krakow.

Today Selvita is a company which provides its third-party partners with comprehensive solutions in the fields of chemistry, biotechnology and bioinformatics, enabling them to reduce the costs of innovative product marketing. The company is also carrying out its own projects aimed at developing original chemical molecules with a therapeutic effect. Currently, the company is working on substances intended for use in oncology (treatment of leukaemia, lymphomas and large intestine cancers), the treatment of Alzheimer's disease and of other central nervous system disorders, amongst others.

In 2011, the company took first place in the ranking of the rising stars of Deloitte Technology Fast 50 in Central Europe. In mid–July 2011, the company's shares debuted on the NewConnect market at the Warsaw Stock Exchange. Prior to its debut, the company raised just under PLN 15 million (€3.5 million) from a shares issue. At the end of 2014 Selvita's shares were tradid on the main market of the Warsaw Stock Exchange.

To develop the company, Selvita will continue to rely on international partnerships. Since 90% of revenues come from export sales, it is crucial to maintain this international focus. These partners include both medium-size biotech companies and large pharma companies around the world. The company intends to expand its research facilities in Krakow and Poznan.

By 2020, the company aims to have one thousand people working for Selvita (800 in services and 200 in the internal pipeline). They are also targeting fully owned Phase II programs in oncology and a market capitalization of roughly USD 415 million. They are planning 30% annual growth and significant advancements of their pipeline.

INNOVATION CHALLENGE & MARKET OPPORTUNITIES

few companies were active in the biotech industry in Poland. The founders had little experience in the bio -tech industry themselves. Their challenge was to develop the company's concept and find a viable business model.

There was also a positive side: the excellent bio-tech research in Krakow. Krakow is home to the best universities and research institutes in the country. They have the highest share of renowned publications on molecular biology in Poland, and many other areas. Here was an opportunity to take advantage of this scientific knowledge and turn it into a sustainable business.

OPEN INNOVATION TRAJECTORY

Concept development

Open innovation was at the core of Selvita's initial strategy and business model. The founders decided to rely on collaboration with research institutions and other partners in sourcing ideas and developing products. The idea was to select promising research results and to develop them to a stage where they would be interesting for big international companies – either to sell to or to initiate further collaborative research funded by the multinational companies. They saw themselves in the role of commercialization intermediaries between public research and the pharma industry.

In 2007–2008 Pawel and Bogdan launched a strategic search process for promising projects. In these early years, they selected two strategic projects. One of them, known as SEL 103, a compound for the treatment of Alzheimer's disease, was licensed in from the Institute of Pharmacology of the Polish Academy of Sciences (IF-PAN).

However, later on Selvita's strategy shifted. As they started hiring scientists, they developed research capabilities internally. They found that if they could generate project ideas in-house, there was no need to license in research results. Nowadays most of the projects in their pipeline originate internally. They also found that the value chain includes many other development companies downstream. Today their pipeline, in terms of development, is still very much early stage, which allows them to support many research programs at the same time, while remaining independent from the outcome of any single clinical trial.

The development process, IPR and competition strategy

Currently, Selvita has a relatively stable portfolio of about 10 internal projects. The development path for each project may be very different: they may be developed internally or they may be developed from some point in partnership with another company. These partners include both medium-sized biotech companies and large pharma companies from around the world.

As an example, Selvita's proprietary project SEL 103, a symptomatic treatment for Alzheimer's disease, has been developed since July 2010 in partnership with Finnish pharmaceutical company Orion. Under the collaboration agreement, Orion committed to fund the further development of the drug by Selvita over a period of two years. After that Orion had an option for the further development of the drug, i.e. pre-clinical and clinical studies, registration procedures and commercialization.

Selvita's deals with Merck Serano, as well as H3 Biomedicine are based on co-discovery collaborations. Selvita receives up-front and/or milestone and royalty payments.

In 2016 Selvita, together with Epidarex Capital established a joint venture, Nodthera, headquartered in Edinburgh, Scotland. Nodthera will take over the technology developed internally by Selvita. It has potential across several indications with high unmet need, such as cancers and non-malignant diseases like diabetes, rheumatoid arthritis and Alzheimer's disease. It is expected it will speed up the preclinical development.

Selvita has established yet another type of partnership with Felicitex in Cambridge, MA. Selvita uses its expertise in medicinal and computational chemistry to optimize the acquired lead series. The ultimate aim of the joint project is to deliver clinical candidates for unmet oncology indications. The companies will plan joint projects on other targets related to cancer quiescence in the future. Selvita will also receive from Felicitex guaranteed research funding and a value share in joint projects, which may in the future be monetized through milestone payments from Felicitex or a portion of revenues from programs partnered by Felicitex.

Two of Selvita's projects, SEL24 (a dual PIM/FLT3 kinase inhibitor) and SEL 103, were licensed in from Polish research institutions. Later, when the company's research group became stronger, the projects were generated internally. However, know-how from development partners is important.

In terms of the Polish market, Selvita is a very unique company. There is no other company in Poland with a similar profile of activity and accomplishments. The company has a hybrid business model which allows for the research and development activity to be financed from the revenues from the drug discovery services sector.

Selvita's business relies on three pillars: The first pillar is its own series of innovative drug development projects which involve original small molecules. The second pillar involves contract research services for innovative and generic pharmaceutical companies, i.e, medicinal chemistry, custom synthesis, in vitro screening and other analyses. In this case they do not take the financial risk for the project but dedicate expertise and a scientific team to its implementation in accordance with the contractor's specified requirements.

The third pillar of Selvita's business consists of IT solutions for laboratories. They offer the implementation of IT solutions from leading developers of laboratory information management systems. This division was spun-out in 2015 to form a new company, Ardigen.

The owners find Selvita's hybrid business model very advantageous. First, they can use the same laboratory equipment in contract research services and their own innovative projects. The economy of scale pertains also to sales, as they can promote all of their activities. Furthermore, the model is advantageous when human resources are involved, both in appropriate staff recruitment and the exchange of knowledge when people working on diverse projects share their experience with colleagues and use it to consult with clients. Finally, the hybrid business model is advantageous in maintaining business stability.

Selvita is an R&D company with its projects in pre-clinical research (some of them reaching the clinical stage). As biotech research has long life cycles, it is important to secure funding. Selvita funds its research pipeline from several sources. One of the sources is drug discovery and other service contracts. Contract research is fiercely competitive, but a rapidly growing market and Selvita's lower cost benefits make it well placed to compete. Other funding sources include(d) shareholder capital, emissions on the Warsaw Stock Exchange and other investors funds.

Currently they have sufficient cash to fund their projects. To succeed in R&D, Selvita increases its research capacity by investing in new laboratory facilities and hiring new research staff. They also use partnerships to complement their research gaps and acquire knowledge. Their SEL24 and SEL 120 projects are potentially unique when compared to other clinical stage competitors and may offer advantages in terms of efficiency and safety.

Commercialization and follow-up

On the drug discovery side, Selvita does not roll out production, rather they aim to reach the clinical trials stage.

As an organization Selvita is evolving all the time. It started by licensing in the first technologies. Then they started relying on their own research capabilities. They rented laboratories and now they are establishing their own research facilities. Following their business model, they divided drug discovery services from their own project pipeline. Now they are looking to organize clinical trials.

For the drug development companies, the main strategy is to find as early as possible a big pharmaceutical company that can fund further research and take over the results when it is completed. The biggest problem for these companies is to fund long development cycles. Currently, they can support 2–3 years of development work and would like to increase it to 5 years when more convincing results can be shown. Selvita relies on participating in dedicated events to show their capabilities and attract interest from potential partners. IPR is also exceptionally important.

In 2016 Selvita opened a new laboratory in Poznan. Ultimately, the facility in Poznan is meant to be the "second heart of Selvita", providing both contract services, as well as actively participating in internal R&D projects. They opened a subsidiary in the US in 2015 and signed a collaboration agreement with the University of California in 2016. These moves further increase their research capabilities, project generation and growth.

BUSINESS IMPACT

In the early years Selvita acquired IP from public research. Later, they built in-house research capabilities by hiring scientists who generally came from public research institutions. Partnerships with big pharma like Merck or other well-known companies, such as H3 Medicine, validates proof of concept, and raises their visibility to the rest of the pharma world. Selvita derived its reputation from this very important intangible asset.

Partnering contracts with foreign strategic investors give access to the extensive know-how of major organizations, their knowledge of the pharmaceutical market, market players, and determinants and customs, thereby facilitating the search for potential licensees and their selection. Selvita learned from partners what kind of assumptions they make, what is important for big pharma when they are actually investing in the early development of compounds, what is a no-go for them, what are the criteria for taking the project further. In partnerships scientists exchange practical experience with scientists in other companies, thereby enhancing the probability of the R&D project's success. Scientists also exchange practical experience with scientists in other companies.

Selvita broke-even in Q4 2013; it is a fast growing company in terms of revenue and employment. It is estimated that the value of the company exceeds PLN 577 million (\in 134 million).

LESSONS LEARNED

This case presents the example of a company which has built its business model around collaborations. The issues that such R&D companies face are rather universal – how to combine long-term development and short-term cash flow needs, the need to focus on priority areas and the acquisition of new knowledge. This case shows the importance of an entrepreneurial spirit in establishing one of the first biotechnology companies in Poland, starting from scratch.

Main lessons learned:

- 1. PSR can be the source of ideas for a sustainable business.
- 2. Licensing in technology can be the stepping stone to developing a company's own core skills a later stage.
- 3. Strategic collaborations may have different forms; it is important to learn how to manage them.
- 4. IPR is important in collaborations.
- 5. Reputation is an important asset in setting up collaborations.