

The Internationalization Challenge – Enabling and Constraining Factors in the Medical-Technology Sector

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Abstract

SMEs in high-technology industries, such as life-sciences, face a fundamental challenge. On the one hand, high product development costs push companies into early internationalization to increase turnover and recover investments. On the other hand, internationalization is constrained, e.g. by financial and managerial resource limitations or the demand to follow local regulations. To date, little is known about how high-tech SMEs actually manage this challenge. This paper presents an in-depth case study of the internationalization process of a Swedish high-tech SME, to develop a better understanding of how the trade-offs related to internationalization are handled in practice. Combining insights from the process theory of internationalization with international new venture theory, our findings outline factors affecting the internationalization process specific to the medical-technology industry, the company and the founding team.

Keywords: Internationalization, Medical Technology, Born Globals, Networks, Strategic Entrepreneurship

Introduction

Small and medium-sized enterprises (SMEs) in many industries face an increasing pressure to start and/or to expand international operations (see e.g. European Commission 2003 Observatory Report). In addition, these companies are confronted with increasing international competition in their own domestic markets. Because of this increased competition as well as rapid technological developments, which have an impact on product development and marketing activities, more and more SMEs start their international operations already during their first years of operation, and a substantial share of their total sales is achieved on foreign markets. These types of firms have received different labels,

such as 'born global' firms (BGs) (Rennie, 1993) or international new ventures (INVs) (Oviatt and McDougall, 1994).¹

The medical-technology industry is of special interest when it comes to international development. Many previous studies have focused on internationalization in high-technology industries (e.g. Burgel and Murray, 2000; Jones, 1999; Keeble et al., 1998) including those belonging to the umbrella term 'life sciences' (more specifically referring to medical-technology, pharmaceuticals or biotechnology firms). As we will discuss below, a few studies have addressed the particularities of biotechnology firms, while medical-technology companies remain largely understudied. Yet, some fundamental dimensions distinguish the life-sciences industry, and especially medical-technology, from other high-technology industries, e.g. it is based on science-based knowledge and it aims at improving quality of life (Stremersch and Van Dyck, 2009). Purchasing decisions for life-sciences products are typically not made by the end-consumers, the patients, themselves, but by medical staff, and in many cases a third party, such as an insurance company, pays for the products.

Companies in the medical-technology sector face a fundamental challenge, which is especially aggravated for many SMEs with their limited access to resources. Namely, strong forces push the companies towards a global outlook, which is facilitated by the fact that these firms rely on high-technologies that are not culture specific. The need to amortize high research and development (R&D) costs pushes especially companies from smaller home markets to quickly expand across borders. At the same time, strong forces act as barriers to international business activities of SMEs. As the life-sciences industry is highly regulated, all international business activities need to comply to local demands. Also the financing of the life-sciences industry differs across nations. For example, in Sweden the healthcare sector is financed through taxes, while in the US it is mostly financed through health insurance. These factors make an international product launch a complex endeavour, providing challenges in scaling up marketing and sales, organizing clinical trials, including difficulties in getting access to hospitals and doctors, complying to regulatory demands, as well as financing the complete R&D process (KTH, KI and KUH, 2007).

Thus, the life-sciences industry provides an interesting arena to study the internationalization of SMEs, but so far has only attracted limited academic attention. In one of the few studies in this area, Orava (2001) has investigated operational modes in the internationalization of medical-service firms. Barnes et al. (2006) studied the export-marketing activities of 112 SMEs operating in international healthcare markets and identified the finding appropriate partners a key challenge. Another recent study has investigated the initial and continued internationalization processes of eight biotechnology Born Globals, integrating knowledge-based internationalization process theory and international entrepreneurship research (Melén and Nordman, 2009). A knowledge-based view has also been employed to study why SMEs in the biotechnology industry can achieve competitive advantage at an early stage (Gassman and Keupp, 2007). While providing important insights, these studies do not investigate how SMEs manage the challenge described above. To address this gap, the aim of this paper is to contribute to the understanding of the internationalization of high-tech SMEs by analyzing in detail how a company in the medical-technology industry handles the simultaneous forces which enable and constrain early internationalization.

¹ Despite this development, many firms still follow a more incremental and slow international development (Johansson and Vahlne, 1977, 1990).

The remainder of this paper is structured as follows. In the following section, relevant literature on internationalization is reviewed. After describing the method used in this study, an in-depth case study of the internationalization process of an SME from the medical-technology industry is presented. The subsequent discussion links the case findings back to the theoretical approaches reviewed earlier in the paper. Finally conclusions, practical implications and some ideas for further research are presented.

Literature Review

Internationalization of small firms

The development of small, national firms to become multinational has been an area of great research interest. One of the most important models in this field is the Uppsala Model developed by Johanson and Vahlne (1977, 1990). The model defines internationalisation as a process of increasing experiential knowledge (see Penrose, 1959). The model focuses on company development over time, including different establishment sequences in terms of markets and entry modes. According to the model, markets with successively greater psychic distance are entered. Psychic distance is defined as the factors preventing or disturbing the flow of information between firm and market – such as differences in language, culture, political systems, level of education, or level of industrial development (Johanson and Wiedersheim-Paul, 1975). The firm's international behaviour in a single market is suggested to be a consequence of successively greater learning and commitment. As the firm learns about the market, it commits more resources and goes through different steps, from sporadic export activities, via exporting through independent representatives to exports through sales subsidiaries, before establishing full-fledged manufacturing subsidiaries (Johanson and Wiedersheim-Paul, 1975).

The Uppsala internationalisation model and other process models has been criticized for being too deterministic (Bell, 1995; Reid, 1981; Turnbull, 1987). These models do not focus on discussing alternative international development strategies and factors that influence different strategic choices made by decision-makers. Later studies have shown that there are different alternatives for expanding internationally (Andersson, 2000; Bell et al., 2004) and that entrepreneurs can choose to internationalize rapidly and be global shortly after inception (e.g. Autio, 2005; Knight and Cavusgil, 1996; Oviatt and McDougall, 1994; Madsen and Servais, 1997).

Born Globals

A McKinsey study of Australia's high-value-added manufacturing exporters spotlighted the rise of numerous SMEs that successfully competed - virtually from their inception – against large, established players in the global arena (Rennie, 1993). These firms did not slowly build their way into international trade, contradicting earlier studies on firms' internationalization (Johanson and Vahlne 1977, 1990). Rather, they were 'born global'. The Australian study coined this term and has been followed by numerous studies on this phenomenon. There is growing empirical evidence showing that Born Globals are becoming more common and also becoming a more important phenomenon for the global economy (Rialp et al., 2005).

Knight and Cavusgil (1996) and Coviello (2006) outline several trends which have supported the emergence of Born Global firms: the increasing role of niche markets; advances in process and com-

munication technologies, as well as inherent advantages of small companies – such as quicker response times, flexibility, or adaptability. Born globals are typically founded by one or several strong entrepreneur(s) with extensive international experience in internationalized industries; the companies tend to be niche-oriented; with locations chosen based on the founders' and partners' previous experience (Madsen and Servais, 1997). The growth of Born Globals tends to be associated with innovation skills, including the ability to access effective R&D and distribution channels and to engage in close collaboration with international partners.

Much of the literature on Born Globals is related to newly emerging and/or high-tech industries (Crick and Jones, 2000). However, the phenomenon has also been found in “old” and mature sectors, such as arts and crafts (McAuley, 1999). A small home market can push even young ventures in those sectors into early internationalization (Madsen and Servais, 1997).

As internationalization can be defined as an entrepreneurial act, entrepreneurship theories can help to better understand internationalization processes (Andersson, 2000; Johanson and Vahlne, 2009). In the international entrepreneurship literature there are conflicting explanations of why early and rapid internationalization is possible (Keupp and Gassman, 2009). On the one hand, research based on the resource-based view of the firm portends that control of a certain resource endowment is needed for pursuing international growth (George, 2005). On the other hand, some researchers maintain that a lack of resources in the firm and on the home market can be drivers of international entrepreneurship (Matthews and Zander, 2007), leveraging social capital and networks for gaining access to knowledge and resources. Andersson and Wictor (2003) stress the role of entrepreneurs and their personal networks as most relevant factors for early internationalizing firms. This aspect will be discussed more in the following.

Importance of entrepreneurs/managers in small-firm internationalization

Different studies have identified an international orientation of the key entrepreneurs/managers as an important explanation of the international orientation of the firm (Andersson 2000; Andersson and Wictor, 2003; Madsen and Servais, 1997).

In a meta-study, Leonidou et al. (2002) identify managerial characteristics as an important factor for explaining successful exporting. Bloodgood et al. (1996) find that more international work experience among top managers is strongly associated with more internationalization of new high-potential ventures in the USA. Westhead et al. (2001) also ascertain that older founders, having more resources, denser information and contact networks, and considerable management know-how, are significantly more likely to be exporters. Industry-specific knowledge and experience were found to be of importance. Interestingly, Andersson et al. (2004) found a younger age of CEOs to be positively related to the growth of international activities. A younger generation of CEOs has been brought up in a more global world, with international networks from studies and travelling, and they can have a more positive attitude about the international environment and more easily see and take advantage of entrepreneurial opportunities in foreign markets.

Overall, different studies have indicated a positive relationship between entrepreneurs' international attitude, orientation, experience, competences and networks with a successful international development (Andersson, 2000; Kuemmerle, 2002; McDougall et al., 2003; Nummela et al., 2004;

Preece et al., 1998; Westhead et al., 2001). However, the role which individual entrepreneurs play as the internationalization process unfolds is still not very well researched.

Networks

Different studies have shown the importance of international networks, on both an individual and an organisational level, for understanding a firm's international development (e.g. Coviello, 2006; Majkgård and Sharma, 1998). Yet, most studies on networks are based on established firms and focus on processes, routines and systems at company level (e.g. Håkansson, 1982; Johanson and Vahlne, 1990). For start-ups, personal networks tend to be highly relevant, with many new relationships being created (Kock and Galkina, 2008). New firms are dependent on relationships with, for example, financiers, suppliers and customers (Oviatt and McDougall, 1995). Both, social and business aspects of networking are of importance (Johannisson and Mönsted, 1997). Knight and Cavusgil (1996) emphasize that formal and informal networks are important, and they are used in a formal and planned way (McAuley, 1999). Networks can be an important tool to acquire, create and leverage resources (Chetty and Campbell-Hunt, 2003; Coviello and Cox, 2006). Not only international networks are important for understanding a firm's international development, but also local networks play a key role (Johannisson, 1994). How these different types of networks interact and influence the internationalization process remains to date understudied.

To contextualize the in-depth case study presented in this paper, we will next introduce the specificities of the medical-technology industry.

The medical-technology industry

Generally speaking, medical-technology products can in different ways extend and improve life. Examples of medical-technology products are wheelchairs, pacemakers, insulin pens, oxygen masks, dental floss, surgical instruments, and syringes. The industry can be briefly characterized as in Table 1 below.

Medical technology industry
Relatively young industry
80% SMEs
500,000 products in 10,000 generic product groups
Innovation occurs in result of clinicians' insights
Investment recovery period can be as short as 18 months for medical devices with incremental improvements
Rather high distribution costs
Rather high training, education and service requirements
Efficacy and efficiency more difficult to prove; results obtained depend on skills and experience of the physician and quality of the hospital

Table 1: Industry characteristics of the medical technology industry.

Source: based on Eucomed (www.eucomed.org)

The strict regulatory regimes for medical devices (e.g. EU directive 93/42/EEC) force the manufacturers to carefully document their manufacturing processes and raw materials used (Sidén, 2003). Before launching a product in a European country, the product needs to be CE marked, ascertaining that the law on medical devices is followed. To enter the largest market worldwide, the USA, every medical-technology product must be approved by the Food and Drug Administration (FDA). Once the product is approved by the FDA, the chances that a product will be accepted by clinicians are higher than in Europe (SwedenBio et al., 2005). In fact, the market-acceptance process has been characterized as an industry-specific challenge, with three critical factors (SwedenBio et al., 2005):

- *clinical acceptance*; after receiving the CE marking, the product's clinical efficacy will still be evaluated in each market, before local physicians and caregivers accept the product. This poses an enormous challenge to a young company, which has not yet achieved brand recognition and built its reputation among customers.
- *reimbursement*; hospitals and clinics are hesitant to invest in medical-technology products where there is no track record of reimbursement by third parties (such as insurance companies).
- *cost efficiency*; products aimed at an aging population should not only show solutions with improved clinical effect, but should also provide cost efficiency for the care-giver.

Figure 1 below illustrates a number of specificities of the life-sciences industry. It provides an overall image of the complexity in the healthcare market, and positions the industry/producer in relation to different stakeholders. The interaction among the different actors (such as users, buyers, and end-customers) differs from other industries in that medical and other professions are involved in using, prescribing and recommending medical devices (Sidén, 2003). Thereby, the decision to use a certain product is typically not made by the end-consumers themselves.

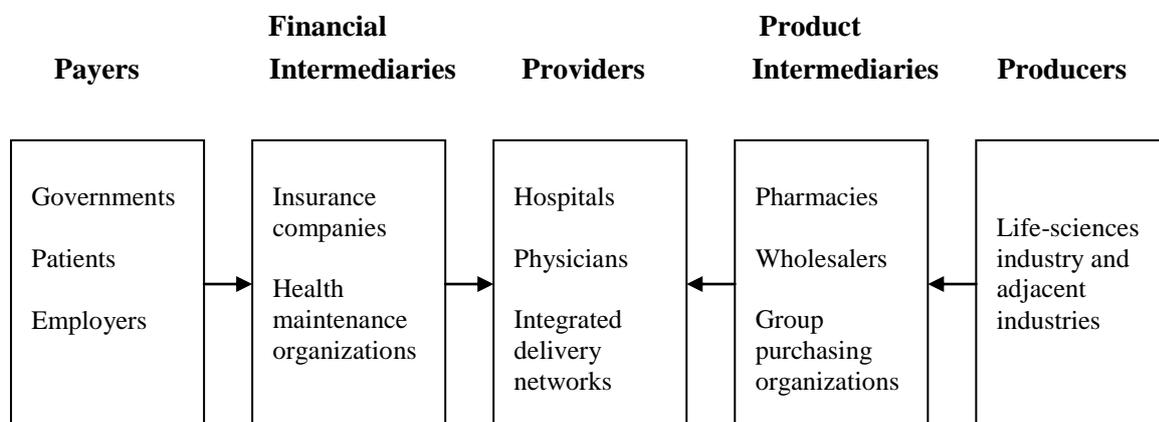


Figure 1: Relevant actors and their roles in the life sciences industry (based on Stremersch & Van Dyck, 2009)

In addition, intermediaries are often involved in the payment as well as the product-distribution sides. Payment flows from the payers (who not necessarily are the end-users themselves) via financial intermediaries to providers, while the products flow from the producers, often via product intermediaries, to the providers (who also make the purchasing decision). Different systems exist in different countries.

Not only this diversity, but also the intermediated process provides additional challenges for medical-technology SMEs when internationalizing, as we will further explore in this paper.

Method

A longitudinal, in-depth case-study approach was chosen to catch the complexity of the internationalization process in the medical-technology sector as it unfolded. We focus on a single case, which is appropriate when new aspects of a phenomenon are studied and conflicting explanations have been brought forward. Of course, we do not aim to generate statistical generalizability, but rather want to achieve analytical generalization (Yin, 1994).

We chose the case company, Redsense Medical, for two main reasons. Firstly, it was presented in media as a successful medical-technology company. The company was awarded with a Frost & Sullivan best practices award and the 2008 European Hemodialysis emerging company of the year award. Secondly, it is part of a local network in the medical-technology sector in Sweden, the Healthcare-Technology Alliance, which is situated in Halmstad as a non-profit organization. This membership allows us to study the impact of both, formal and informal, networks for SME internationalization. The aim of the alliance is to help the region to become leading in developing products and services within healthcare technology (www.halsoteknik.com). Around 50 companies, the local university, local authorities and other organizations can be found among the approximately 60 members.

The case-study is built on personal interviews, and complemented with secondary data (mainly business magazine reports, annual reports and internal documents). Several interviews have been conducted with all individuals personally involved in the decision for and implementation of the company's internationalization, lasting approximately 90 minutes each. In addition, the other employees as well as important stakeholders were interviewed. The interviews have been transcribed and checked for accuracy by the respondents. More than 36 hours of empirical data have been compiled continuously over a period of 18 months so far, longitudinally following the company's internationalization process as it unfolds as well as reconstructing the initial company development before embarking on this longitudinal research. Moreover the research team has participated in different practitioner-oriented seminars within this industry to extend and deepen the knowledge about this sector's logic. Specific themes addressed in these seminars were, for example, export possibilities and internationalization, investment possibilities, innovation possibilities for healthcare technology and finally legal issues of the medical technology directive.

A semi-structured interview guide is used, covering the company's internationalization process, the roles of different actors and networks in this process, as well as specific industry factors. Following Eisenhardt's (1989) recommendations, the analysis includes several iterations between theory and data. Based on the analysis of our empirical material, we develop in this paper a model that includes the specific characteristics of internationalization in the medical technology sector.

Redsense Medical

The background: Origin of the business idea and founding of the company

Redsense Medical (RM) was created in 2006. However, the original idea for the development of its product dates back to 2001, and a contact between the county hospital and Daniel Engvall, now Chief Technology Officer (CTO) at RM, who was then working for a another medical-technology company. The medical technicians at the hospital faced the problem that during hemodialysis the needle could

dislodge, implying a risk for the patients who could in the worst case bleed to death. Dialysis machines have to be equipped with a surveillance system for protecting the patient against blood loss in case of needle dislodgement. Today this is obtained through a built-in venous pressure alarm. However, the change in venous pressure can be too small for the alarm to react in case of blood loss, making this method unsafe.

Based on this problem formulation, Daniel Engvall initiated an exam project at Halmstad University involving two Innovation Engineering students. When it became evident that fibre-optical sensor technology might provide an appropriate solution to this problem, he contacted Anders Andersson, an expert within fibre-optic technology. In collaboration with him, a prototype sending an alarm when blood is detected was developed.

Yet, even though Daniel Engvall continued to further develop the prototype in his spare-time, nothing dramatic happened with it until around four years later, when Patrik Byhmer, now CEO of Redsense Medical, was asked one day before Christmas 2005 to investigate its market potential. The original project had belonged to a company, where Engvall worked and Byhmer was a board member. That company had decided to focus on consultancy, and as part of that re-orientation revisited old projects. Byhmer assessed the results of the original project work for a period of two weeks. He ascertained that there was a problem with needle dislodgement, but as hardly anything was written about this phenomenon, a more precise market estimation was difficult to make. Due to the possible potential, he suggested to continue the project. A company was founded and seed-money invested. Next, a prototype was developed which already 'looked like' a product. Byhmer visited hospitals in Toronto and Seattle, where he had previously established contacts, to gain a better understanding of the market. A professor at the University of Toronto confirmed the problem of needle dislodgement, especially during night-time hemodialysis.

Byhmer carried out a market study, phoning different clinics, in order to further investigate the need for this product. At the same time, Redsense carried out clinical trials with the help of Jarl Ahlmén, an Associate Professor of Nephrology and now also Chief Medical Consultant at Redsense. Thanks to the initiated clinical trials, the company could apply for CE-marking in 2007.

The next step taken was to assess how much could be charged for the product. The potential price was found to depend on market acceptance, which still needed to be developed – requiring additional funding. A first step taken for gaining that acceptance was to exhibit at a fair in the US. Though positive feedback was received, Redsense was not yet allowed to sell the product in the USA due to missing FDA clearance. This was applied for during the summer of 2007, and obtained in October 2007.

At the same time, it was realized that more competence in marketing and sales was needed, and Susanne Olauson, who had long experience with internationally-oriented tasks in the pharmaceutical industry, was employed as Sales and Marketing Director in April 2007. With the product approved in Europe and the USA, appropriate test centres needed to be found, where potential customers could try the product and evaluate it.

In March 2009, the sales of Redsense's product started with a big order from a clinic in Glasgow – approximately two years after contacts had first been established with that hospital. A patient had died there after a needle dislodgement, enhancing the interest of the clinic in the Redsense alarm. Such long lead-times turned out to be a major challenge for the company. As at many hospitals doctors and nurses are not even aware of the risk of needle dislodgment and the false security with the existing built-in venous pressure alarm, the sales process requires to first make potential customers aware of

the need to then persuade them of the advantages of Redsense's product. Before making a purchasing decision, the finance department of the potential customer then needs to approve of the budget, which can easily take another year. Thus, the process of gaining new customers is very expensive, and strategic questions for an SME in this situation are whether this should be conducted in-house or outsourced, and which markets should be tackled.

Redsense faces an interesting competitive situation. It largely has one competitor only, Fresenius. This company is the worldwide market leader for dialysis products, both for hospital and private use. Their product differs from that of Redsense in that the alarm does not specifically react to blood and that it is not a disposable product. Redsense claims that it looks upon this competitor as an opportunity, due to the market need which still has to be further developed. In addition to Fresenius, a number of other companies producing hemo-dialysis machines exist. Instead of merely focusing on developing a sales and distribution structure for its disposable product aimed at hospitals, Redsense is working on persuading one or several of these companies to integrate the alarm device into their machines. This innovation would not only make dialysis safer, it would also free Redsense from the need to further develop their own sales and distribution structure (which has proven to be a lengthy and costly process), as they would only have to deliver to the dialysis-machine makers.

The internationalization process

The CEO of Redsense realized early that it would be difficult to reach break-even focusing on the small Swedish market only. In contrast, there are around 1.6 million dialysis patients worldwide, and about 200 million dialyses are conducted per year, taking between four to five hours each. He asked himself in which country the product could be launched in the easiest and fastest way, and the UK was selected as the first target market – as it is close to Sweden, has a high population and is densely populated. Moreover, Redsense wanted to choose a country where business could be conducted in English. In addition, the liability which hospitals have both in the UK and the USA was taken into account as an important factor for market selection: If hospitals are liable when something goes wrong with the treatment, the risk of being sued can increase the willingness to invest in an alarm that reacts immediately to blood if the needle dislodges. Thus, for Redsense an important aspect when choosing a foreign market is to analyse how the healthcare system is organized and how it functions.

In the UK, a distributor was chosen out of different companies recommended by Jarl Ahlmén, Associate Professor of Nephrology. However, Redsense changed this distributor rather quickly, as the cooperation did not work well. At that stage, Redsense had established an awareness of its product in the market, mainly through participating in different congresses. By now, it is rather common that distributors contact the company directly to show their interest in representing the Redsense product in their own country. Moreover, Redsense asks local hospitals to express their opinion about which distributor they believe might be most appropriate. This was also done before changing distributor in the UK.

The second target market was the USA, the world's largest market. Both the CEO and the Marketing Director had direct contacts with different hospitals there. Redsense wanted to identify four clinics with which they could maintain sales contacts directly, in order to gain a thorough understanding of how the health system and, correspondingly, the sales process works. By maintaining direct responsibility for a few large customers in the USA, Redsense thought to be able to establish a better negotia-

tion position, e.g. when appointing distributors at a later stage. Due to the large market size, Redsense decided to be selective rather than to try to cover the entire market at once. A potential distributor was identified, but withdrew from the negotiations, as in result of the worldwide financial crisis that company preferred to focus on its existing product portfolio.

This process underlines the strategic challenge of deciding on a distribution structure. One alternative for an internationalizing SME could be to negotiate with a global player to become part of their world-wide sales portfolio. If working well, this would lead to rapid market penetration and increased sales for the SME. However, such strategy bears two risks. Firstly, the product might not be prioritized by the sales staff, remaining a minor product. This risk is especially high when awareness-building and training is needed to sell the product. Secondly, rapidly increasing sales could overstretch the capacity of the SME to handle large orders, leading to an immediate loss of trust in the brand and product.

The choice of entry modes has been topic of extensive discussion within Redsense. For now, distributors are preferred to agents, as the company can first gain a feeling for the market and then select distributors, who tend to care about the product, as they take on a certain risk by including it into their portfolio. An in-house sales force could increase sales, but for the time being Redsense does not have enough resources to cover the high costs agents would imply, as they would have to be recruited, trained and paid for before even starting their sales activities. By now, Redsense has distributors in the Netherlands, Belgium, Austria, Finland, Norway, Denmark, and Ireland. A future option could be to establish own sales subsidiaries in the main markets.

The internationalization activities are not limited to marketing and sales. Redsense has even established a manufacturing plant in Malaysia. Despite searching for eight months for a subcontractor that could manufacture their product, Redsense could not find a company which had experience with fibre optics used in disposable products. To manufacture the product turned out to be more challenging than anticipated, as when making disposable products, it is crucial to keep production costs down. Through building a greenfield factory, a positive aspect was seen in gaining know-how of in-house production and a former colleague of Redsense's CEO was willing to run the factory, reducing the perceived risks.

For further internationalization, Redsense has now even chosen to experiment with a different mode for finding partners. For entering the large and important markets of Germany and France, Redsense collaborates with the Swedish Trade Agency in the "business opportunity project", where the company and the agency jointly cover the costs, and the agency supports Redsense in identifying suitable partners.

The internationalization process described so far demonstrates that Redsense does not perceive going international as something threatening *per se*. The Marketing Director explains: "...we have been out there, and we know that it is nothing dangerous". The key people responsible for internationalization brought with them extensive international experiences and contacts, especially the CEO. Within Redsense it is believed that without this experience internationalization would have been slower and more step-wise. Regarding the speed of internationalization, Redsense appears to be in favour of opening up as many markets as possible. The limit for this is "as much as you can manage", as the Marketing Director states, as it takes time to support and inspire the different distributors. Still, it is a continuous strategic question whether to enter many markets at once or to focus on a limited number of distributors to later broaden the scope, for example once positive cash flow is reached. As lead-times

in this industry are very long, both to get clearance from the healthcare authorities but also to establish customer contacts, this is a crucial issue.

The role of networks for Redsense's business development

A number of different networks have been important for the development of Redsense and its product, as well as its internationalization process. Informal, personal networks on a local level were important for the formation of the original business idea, through contacts between the county hospital and Daniel Engvall. The internationalization process was facilitated by informal contacts in the medical industry which helped establishing international contacts for example in Canada, the UK and the USA.

Participation in fairs and congresses, mainly in the US and in Europe, are considered as an important means for becoming known to the specific target group of decision-makers in the medical sector – a crucial step for achieving sales. Such brand-building activities have helped the company create many contacts, which have led to many inquiries from interested persons and companies. In addition, Redsense has cooperated with an external consultant with experience of working internationally with public relations. The aim was to place articles and press releases in journals and other media, e.g. aimed at patient organizations, to enhance awareness of the product and its need.

The Redsense management team believes also that it is important to be part of different associations, as long as they provide some kind of benefit to the company, e.g. by providing further access to a well-defined target group (such as nurses or nephrologists).

The formal network of the Healthcare Technology Alliance has played a crucial role at start-up, as it helped to match the business idea and key actors in the project. However, for internationalization it has played a minor role. Being a successful player in a small network in the region of Halland has created positive media attention for Redsense. The local network was especially important for financing matters, as it helped in the process of finding local funding. Still, securing continued financing is currently proving to be a major challenge, due to the world-economic crisis.

Discussion

To a certain extent, the internationalization pattern of Redsense resembles that proposed by the Uppsala model, namely to first enter those countries perceived to have low psychic distance for the top management of the company. Due to personal experiences of the team mainly from living and working in the UK and the US, these countries were considered natural choices as business there could be done in English. In line with Johanson and Vahlne (2009) it seems that the relevant analytical level regarding psychic distance has moved from the national to the individual level. Also, the structure of the healthcare industry was crucial for deciding which markets to enter. Thus, in addition to the company-internal factors of cultural and language knowledge, the external factor of industry conditions was decisive for the choice of markets. However, it was not the similarity with the home market that was important – rather the hospitals' "risk of being sued" makes a market attractive.

The decision to set up a manufacturing plant in Malaysia illustrates one shortcoming of the Uppsala model, which assumes that foreign direct investment (FDI) takes place after substantial learning from activities in that market augmented in a step-wise approach. Due to their personal international expe-

periences, Redsense was not scared to enter an Asian market through FDI at an early stage of company development. Thereby, they could generate an ownership advantage by developing production competences in-house, which is relevant for being able to offer the product at a reasonable price (cf. Dunning, 1988). Malaysia's low labor costs contribute to a localization advantage, and an internalization advantage was realized as no adequate subcontractor was identified, leading to lower transaction costs when producing in-house. This example shows that the management team's international experience not only influences the firms outward activities (e.g. sales), but also other strategic activities such as sourcing and production (cf. Holmlund et al., 2007).

Johanson and Vahlne (1977, 1990) argue that experience-based knowledge is critical for conducting activities on foreign markets, as well as for identifying new business opportunities. Before deciding on how to enter the USA as the largest market world-wide, four influential clinics there were targeted in order to develop a thorough market understanding. Only then, the company started to search for suitable distributors, committing further to this market. The Redsense management team could also draw on experience-based knowledge and managerial capability by quickly learning from the internationalization journey, adjusting the subsequent entry modes to context specificities and experimenting with new solutions. While specific market knowledge might not be directly transferable across markets, learning from potential challenges and how to solve them could be: For example, the process of selecting distributors was improved based on experiences made, but the strategy of working with distributors was largely maintained, as these provide important access points to relevant networks, and especially contacts to dialysis clinics.

The Redsense top management team acts highly entrepreneurial and Redsense appears almost a prototypical example of the international entrepreneurship of a born global firm (Autio, 2005; Oviatt and McDougall 1994; Madsen and Servais, 1997): Internationalization was started soon after inception, production as well as sales take place outside the home market, and individual experience and entrepreneurial vision drive international commitment decisions. Strong entrepreneurs have extensive international experience from relevant industries (cf. Andersson and Wictor, 2003). Additional entrepreneurial know-how is brought into the company by the chairman of the board who has experience of starting around 20 companies. Through the complementary skills of the top management team, Redsense manages to create a marketing and sales focus for its technological innovation (cf. Andersson, 2000). Redsense follows a proactive strategy, characterized by supply push combined with creating market demand.

As pointed out in the literature review, different types of network linkages had been proposed to be relevant for SME internationalization. For Redsense, the local healthcare technology alliance played a decisive role for its start-up, as it helped to team up the county hospital and the initial project team. Even for financial matters, local network linkages were crucial for receiving financing in the local vicinity, confirming the importance of the local network for the development of new products and financing (Johannisson, 2009) and how networks can be for acquiring, mobilizing and developing resources (Chetty and Campbell-Hunt, 2003; Coviello and Cox, 2006). However, the role of the healthcare technology alliance has *not* played a specific role for internationalizing. Instead, the international experience and contact networks of the top management team were important, and helped to avoid a typical challenge of SMEs in the life-sciences industry – namely the difficulty to get access to hospitals and doctors. Fruitful contacts were established with key actors in different clinics who had expe-

rienced needle dislodgment as a problem during hemodialysis and who were therefore willing to provide access to their own contact networks, mainly in the US and Canada.

Conclusions, Practical Implications, and Ideas for Further Research

We find Redsense's internationalization process to be driven by an entrepreneurial team using social capital and networks as important tools for gaining access to knowledge and resources (cf. Sarasvathy, 2001). The chairman summarizes the approach to entering new international markets as follows: "The easiest way is to start with what you know and where you have a network, and to try to reuse it in different ways. Sometimes it will work and sometimes it will not. If you do not have that, then there are more open channels, such as the Trade Council and similar organizations which can help to find collaboration partners and to build networks. Or you simply have to use companies that exist on this market and see if they can help. You have to use all available means and all available methods. If nothing else works, then you have to take the plane and go there, and go around and knock on the doors. It is not more difficult than that".

This highly entrepreneurial approach to internationalization appears to be key when trying to resolve the major challenge of balancing the need for early internationalization with reducing its hindrances, outlined at the beginning of the paper. Just like a typical born global company, Redsense is built on providing one niche product (see Madsen and Servais, 1997). The small home-market pushed the company towards internationalization at an early stage in order to facilitate reaching break-even. However, the actual 'going international' did not turn out to be a major issue, as the top management team relied on its relevant industry and international experiences. Therefore, internationalization was never interpreted as a threat. A much bigger challenge for Redsense is to build demand for its product, since many people working with dialysis are not aware of the risk of needle dislodgement during hemodialyses and the false security of the existing built-in venous pressure alarm. Creating a market need in a foreign country requires a thorough understanding of the market and its key actors, which is a tedious, lengthy process. Regulations and healthcare systems are very different across countries, and an intimate knowledge of the specificities is crucial, when trying to enter the market directly. Entering many international markets at the same time made the company financially vulnerable. The solution to this part of the challenge is to try to overcome financial constraints by searching for different kinds of deals which could reduce the financial risk and burden carried (e.g., by working with distributors rather than agents, by signing a deal with the Swedish Trade Council, by producing in a low-cost country, and by attempting to integrate the product as a component into dialysis machines), and they draw extensively on their personal networks to leverage their limited managerial capacity (Chetty and Campbell-Hunt, 2003). Access to the healthcare systems – especially hospitals and doctors – is secured via personal networking linkages. External aspects of the challenge are mainly regulatory affairs and clinical trials, which further increase the lead-times to customer orders. Here, the company attempts to proactively work with government and other relevant agencies upfront to facilitate the process.

To summarize, this paper has drawn on the case of a born global SME from the medical-technology sector to explore how the company manages the internationalization challenge and the factors enabling and constraining internationalization. A number of key success factors for its internationalization process were identified.

Theoretical implications

An important discourse in theories about firm internationalization is the creative tension (Autio, 2005) between the Process Theory of Internationalization (PTI) (Johanson and Vahlne 1977, 1990, 2009) and International New Venture Theory (INV) (Oviatt and McDougall, 1994). This study aims at contributing to that discourse by arguing for complementing the PTI perspective with a further development of the INV perspective. Important differences between the two perspectives are that INV focuses more on the entrepreneurs, the very early internationalization process (including individual experience before start-up) and enabling factors, while the PTI perspective focuses on organisations, does not explicitly discuss international start-up and is focusing on constraining factors (Autio, 2005; Johanson and Vahlne, 2009). To understand the early internationalization of a small firm in the medical-technology sector, a more fine-grained analysis is possible drawing on concepts and models from the INV tradition. Johansson and Vahlne (2009) maintain that their model is suitable also to explain the development of international new ventures. This shows an important difference in the scope of the two perspectives. The PTI is a model on an aggregate level, broadly covering the development in firms – aiming to be a ‘theory of the firm’. In contrast, the INV tradition has a more narrow scope, focusing on the development of early internationalizing firms. In line with earlier research, we see a demand for different models explaining different types of international development in firms (Bell et al., 2004). Earlier research has pointed out that there is a need for different models to understand internationalization in different industries (Andersson, 2004; Manolova et al., 2002). Following earlier research and our empirical study we have developed a model that combines the two traditions to fit the aim of this study, focusing on the medical technology industry.

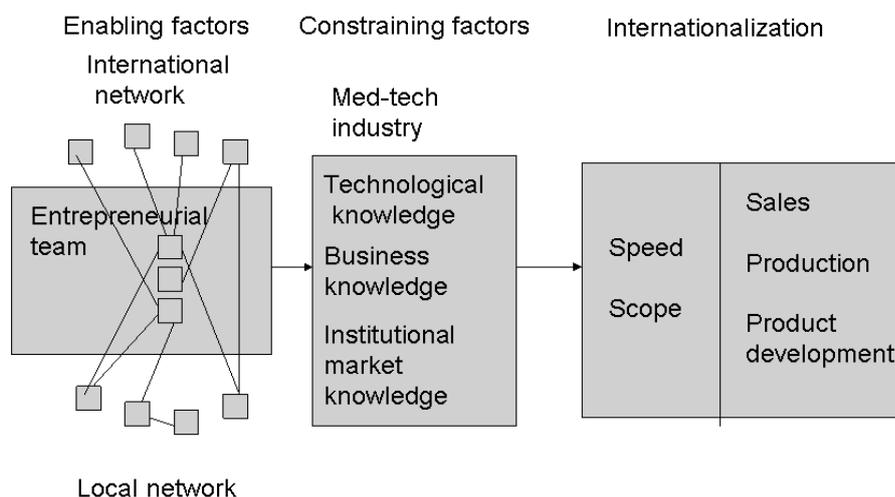


Figure 2. Internationalization in the med-tech industry

The starting point in the internationalization in the med-tech industry model (figure 2) is the entrepreneurial team and their personal network. These factors are enabling factors for succeeding with the international expansion (cf. to the INV view and Sarasvathy, 2001). In the industry, nation-specific constraining factors exist which can be overcome through learning (inspired by the PTI view). Important knowledge areas are technology knowledge, business knowledge and institutional market knowledge (Eriksson et al., 1997). Based on our empirical study, we view all these knowledge types as in-

dustry-specific. These factors influence the speed and scope of the internationalization process. In our model, we explicitly include product development and production, while earlier models implicitly or explicitly have focused on international sales.

Practical implications

A number of factors are relevant to point out for other SMEs from life-sciences industries to keep in mind when internationalizing. Firstly, this study has demonstrated the importance of continuous openness to choose different market-entry strategies for different markets, of leveraging existing network linkages, as well as of financial and managerial capacities. As regulatory burdens and long lead-times cannot be avoided, it can be fruitful to proactively lobby with relevant actors involved in the buying and payment processes, in order to smoothen the sales process. Acquiring and developing an extensive knowledge-base about international business activities might facilitate the process – for example by hiring people with relevant international experience and knowledge about different markets and their specificities, by attempting to learn from all international business activities, both in terms of success factors and failures, and by attending relevant fairs to develop a market understanding and building networks. Specific to the life-sciences industry is the role played by different voluntary and other industry-specific organizations, which might influence how and which decisions are taken. For Red-sense, different nephrological associations have played an important role for disseminating information about the need for their product.

Another, more general, practical implication of this study is that managers considering to internationalize their firms might want to consider making more proactive use of their networks, leveraging these contacts for gaining relevant information and access points.

Further research

The current paper is limited to one case, which aimed at exploring in detail the internationalization process of an SME from the medical-technology industry, and the challenges this process poses. As different factors relevant for the internationalization appeared to be clearly industry-specific, it would be highly interesting to study more cases from this specific industry, as well as to broaden the study to life-sciences more generally.

Furthermore, the role of local and global networks deserves more investigation. For example, the internationalization of SMEs which belong to different local networks could be compared to that of SMEs not belonging to such networks. The roles of different types of networks in the internationalization processes also needs more detailed study. While in our case the local network did not directly influence the internationalization process, it was still crucial for the business formation and its development – the business idea would otherwise not have been put into practice.

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