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Wristop Technologies (Finland)

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This case has been prepared as a basis for class discussion rather than to illustrate either the effective or ineffective handing of a business / administrative situation.

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WRISTOP TECHNOLOGIES[1]

Introduction

"I think we didn't read the small print in our job contract with Suunto[2]. Guys, we must do something else instead."

Having missed the opportunity to manufacture wrist computers for Suunto's competitors, the founders of Wristop had started to look for alternative opportunities where mobile transmission, design and wrist computers could be used. They were seeking a match between wrist computers and various end-user sectors. The Wristop team wanted to change the direction of the company due to external (previous employer Suunto was threatening the company with law suits) and internal pressures. However, deciding what strategy they should take was proving a difficult decision. Over coffee with a medical doctor friend of his, Matti Aalto-Setälä (the CEO of Wristop) started to brainstorm ideas with him around the concept of employing wrist computers for medical use. After this initial meeting and idea generation, the company then organised another brainstorming session with a group of physicians. The question the CEO presented to the group was straight-forward:

"For what medical purpose could a patient use a wrist computer?"

In the brainstorming session, it was noted that the medical technology sector had a small number of dominant manufacturers, but it was a growing and lucrative sector. Based on this feedback the company decided to explore an alternative market in the medical technology industry. However, there were many opportunities within different segments of this market and Matti and his co-founders could not decide which one was the most attractive on a long-term basis and what market entry strategy they should employ.

The Company

Wristop Technologies was a young Finnish start-up company, which specialised in the design, development, and production of wireless medical wrist computers. The primary target market was diabetic patients, and the company was finding solutions to meet their needs. The company was founded in 2004, when 3 friends, employees of Suunto (part of the Amer Group) decided to

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[1] The authors would like to give thanks and acknowledgement to Matti Aalto-Setälä, CEO, Wristop Technologies Ltd

[2] Suunto is a sports accessories manufacturer.

commercialise their expertise in mobile technology. The idea was to start a new venture that was based on their current understanding and knowledge of customer needs. Many companies approached Suunto, requesting that they produce tailor-made wrist computers but it was against the current strategy of the company. Consequently, Wristop was launched to serve these customers. The founders of Wristop had a range of different skills in mobile technology, including mechanical engineering, electronics and industrial design. Within these sets of multi-disciplinary expertise the group was able to design, plan and manufacture wrist computers. The manufacturing process was outsourced from the initiation of the company without any difficulties as the founders knew the potential manufacturers through their previous networks.

A number of industries were initially explored. The car manufacturing industry was analysed first, and from this analysis Wristop found it too competitive, particularly as the end consumers (the car buyers) were not interested in additional 'toys' in addition to the purchase of their new toy (the car). Additionally, this would be a difficult market for Wristop to penetrate as there were many well-established long-term relationships and alliances in the car manufacturing sector. The military industry was also explored but again, the military sector as a whole was very traditional and difficult to penetrate (it used large companies as suppliers and generally found it suspicious for a small newcomer to offer military solutions for national or international armies).

The medical industry was the final potential market to be explored, and the founders of the company screened many potential products for that particular industry. Many brainstorming sessions were organised with physicians. Additionally, a survey among local university hospital patients was conducted. Based on the brainstorming sessions and survey results, the company decided to enter the medical device market for assisting people with diabetes. Venture Capital (VC) companies were approached, and as a result the company got some small VC investment for a 10% stake in the company. However, one of the conditions for this investment was that the VC company could establish the rules for future activities. The consequence of this for the company was that Wristop was now committed to the medical industry even if potential new sectors and markets were to arise.

The company employed 6 people, each with a technology, medical or pharmacology background. The three founders each had a M.Sc. in Engineering from Helsinki University of Technology. The Wristop team had 12 years of experience in wrist computer technology and they had completed over 30 projects for companies such as Suunto, FRWD, Nokia, and Clothing+. The team was the

first to develop underwater data transmission, and claimed that they had the most energy efficient data management in wrist computing (ARCH2.0 whereby with their technology it was possible for a product to have continuous operations for 12 months with a single coin battery; a patent was pending for this technology). The team had also developed the smallest diving computer and the lightest GPS wrist computer in the world. Therefore, it could be firmly stated that the company had significant technical expertise in wrist computers and technology.

The organisation of the company and its management team are based on 'medical standards' in order to satisfy the needs of the customers, as well as regulatory bodies. The responsibilities and tasks of each member of the management team are clearly defined and customers are very well supported in terms of documentation when they approach medical authorities such as FDA (US Food and Drug Administration). The role of the management team, including their responsibilities and authorities are as follows:

1. Management Team
    a. strategy and key objectives for the company;
    b. company's financial planning and financing;
    c. human resource management.
2. CEO
    a. establishment of sales and marketing process;
    b. external communication;
    c. establishment of marketing requirements for products and applications;
    d. product marketing and sales;
    e. communication of customer requirements to the product development organisation;
    f. responsibility for marketing material.
3. Vice President – R&D
    a. establishment of R&D process;
    b. responsibility for the design (mechanical, electronic, software) including design documentation (Design History File and Device Master Record);
    c. responsibility for product development schedules, budgets, and quality targets;
    d. establishment of product requirements .
4. Vice President – Technology
    a. establishment of order and delivery process;
    b. factory price;

c. subcontracting and production organisation, coordination, development and quality planning;
d. responsibility for effective transfer of products to production;
e. responsibility for device history record (DHR).

5. CMO (Chief Medical Officer)
    a. provide skilled management and leadership to the organisation that result in effective governance, planning and monitoring of clinical evaluations;
    b. provide medical expertise to the design team;
    c. prepare policies and plans to validate the products;
    d. implement training programmes to personnel about medical care of diabetes.
6. Quality Manager
    a. maintenance and development of the quality system;
    b. definition and approval of the quality policy;
    c. managing Regulatory Affairs;
    d. responsibility for handling customer complaints and vigilance reporting;
    e. ensuring that the personnel is aware of regulatory and customer requirements.

Each of the employees was also given written documentation stating their roles and responsibilities within the company. A meeting of everyone in the organisation was held every Monday morning at 9am to discuss the work for the week ahead although as the company had grown it had become more difficult to keep these meetings on schedule.

The company vision, developed after they received VC funding, was to be the leading producer of wrist computers for diabetes management by 2015. The company mission was to improve the quality of life for diabetics by producing wrist computers to better balance glucose levels. The company was still in its start-up phase, which could be seen in the financial data presented in Appendices.

The Market

Wristwatches were originally developed in the early years of the 20th century, but it was the early 1960s before the first wearable computers were developed. Since then, with the help of computer technology developments, more devices with complicated electronics and software had been introduced onto the global marketplace. A modern-day wrist computer was designed for many uses, including activities such as sports, heart rate monitoring and GPS (Global Positioning System) navigation. The medical device market was dominated by very large global companies, such as

Medtronic, Dexcom, Abbott, J&J, Novo Nordisk, Eli Lilly, Sanofi Aventis, Roche and Cellnovo. These corporations typically employed tens of thousands of people and operated in all continents. The international medical device manufacturing market is presented in Table One below.

Table One: Manufactures and Suppliers of Medical and Dental Instruments

Turnover (Million USD)	Western Europe	North America
Less than 5	8,000	6,400
5-10	800	540
10-500	87	64
500-10,000	20	30
Over 10,000	2	2

Although there were numerous amounts of small companies manufacturing medical devices in this industry, the sector was primarily dominated by a dozen or so large companies. The medical device industry was a difficult sector in which to operate as there were a lot of regulations, and also many institutionalised relationships between the companies. The sector was evolving and developing as people would now live longer, and medical treatments were developing for many different types of illnesses. Curiously, the medical devices market was a sector where new technology had been slow to be introduced as 'old ways' had remained dominant. While the medical profession had traditionally been about treating the sick, nowadays there was more emphasis on keeping people from getting sick. Medical device technology aimed to serve both sectors of this industry.

The medical device manufacturing industry was characterised by numerous factors, particularly by the FDA (US Food and Drug Administration). Companies had to adapt to the rules and restrictions made by the FDA if they were entering the US market. Other countries had similar bodies which also regulated the medical market. Most of the medical device manufacturers were US based and therefore the companies seeking clients amongst them had to understand the FDA rules, which are said to be difficult to 'newcomers and outsiders'. An additional feature of the US system was the health insurance system, which was quite different to those generally found in European countries, and so companies had to follow very closely the insurance sector developments and regulations. The medical device-manufacturing sector was said to be 'old-fashioned', as growth and development in the medical industry had been more focused in developing new drugs for treating the sick, rather than trying to develop new technologies at the same time. Therefore, there were many difficulties for any highly sophisticated technology companies that wanted to enter the

market. When a market sector was dominated by large companies it was usually very difficult to penetrate the market. However, large companies tried to imitate flexible small ventures, but were usually slow to adapt to that change, and bureaucracy was a commonly used term when describing large multinational companies. In large medical device manufacturers the people responsible for buying outsourced devices were usually top-level employees of the company, such as the VP of Marketing and VP of R&D, and the project teams underneath these positions. However, with smaller manufacturing companies the decisions were more likely to be made by the Board of the company rather than by an individual. When there were many decision makers and various company policies, the decision-making became slow and difficult to understand from an outside perspective.

Large medical device manufacturers were very guarded about their R&D operations and so the majority of R&D efforts were conducted in-house. In many other sectors, joint R&D or more open innovation approaches had been selected in order to save the company money, as well as getting more ideas from 'outside the box'. In many sectors, university-industry collaborations were common, particularly in the drug development sector. However, the medical technology sector had generally not been as receptive to such collaborations. Unfortunately for Wristop, its target market consisted of only three large medical device manufacturers - Medtronic, Dexcom, and Abbot. All three companies were based in California. In Europe, Roche could be a potential customer but as Christmas 2010 approached, negotiations with them had not been concluded nor were they constructive in terms of sales. In Asia, there were numerous medical device manufacturers, Omron among others, but the company had been reluctant to negotiate with Asian companies due to the perceived risk of losing the IPR to copycat imitations.

Companies in the medical device industry, like with many other industries, were somewhat reluctant to change their ways of operating for they already had existing products, channels of distribution, logistics chains, sub-contractors, long-term relationships, etc. Therefore, a radical type of an innovation, such as the product by Wristop, was likely to face serious resistance by traditionalists (this resistance was also based on the fact that established companies were in fierce competition with each other). Companies had invested substantial amounts of money in their current product portfolio based on their own expensive R&D, they might have many of their products in stock, and their strategy usually was to cut the cost of production and through it to generate more income from earlier investments. Additionally, as the industry was old, there were also many industry culture related issues to consider. Even in a globalised world, companies tend to

operate closely with other companies, which are relative close physically, and culturally. Tradition plays a role here too and ‘outsiders’ are truly made to feel the concept of being an outsider. An additional feature of the market was that there were only a few companies that could produce blood glucose sensors (actually, there are 3 of them in the world), and these companies were part of the medical device manufacturing network. These sensors were part of the Wristop end-product. Sensor manufacturers had a close relationship with medical device manufacturers.

Diabetes

Diabetes is a common permanent condition where the amount of glucose in the blood is too high because the body cannot use it properly. This is because the pancreas does not produce any, or not enough, insulin or the insulin that is produced does not work properly (known as insulin resistance). Insulin helps glucose to enter the body’s cells where it is used for energy. Glucose comes from digesting carbohydrate from various kinds of food and drink, including starchy foods such as breads, rice and potatoes, fruit, some dairy products, sugar and other sweet foods. Glucose is also produced by the liver. There are two main types of diabetes:

1. Type 1 Diabetes develops when the insulin-producing cells have been destroyed and the body is unable to produce any insulin. Usually it appears before the age of 40, especially in childhood. It is treated with insulin either by injection or pump, a healthy diet and regular physical activity.
2. Type 2 Diabetes develops when the body does not produce enough insulin or the insulin that is produced does not work properly. Usually it appears in people aged over 40, although in South Asians and Africans it can appear from the age of 25. However, it is now becoming more common in children and young people of all ethnicities. Type 2 Diabetes is treated with a healthy diet and regular physical activity, but medication and/or insulin is often required.

The main symptoms of undiagnosed diabetes include passing urine frequently (especially at night), increased thirst, extreme tiredness, unexplained weight loss, genital itching or regular episodes of thrush, slow healing of wounds and blurred vision. The main aim of diabetes treatment is to achieve blood glucose, blood pressure and blood fat levels (including cholesterol) within the target ranges agreed by the individual and their healthcare team. This, together with a healthy lifestyle, will reduce the risk of developing the long-term complications of diabetes such as heart attack, stroke,

amputation, blindness, kidney failure and nerve damage[3]. Some of the key facts about diabetes include[4]:

1. Approximately 250 million diabetics worldwide have diabetes;
2. There are about 24 million diabetics in the USA – 8 percent of population;
3. It is estimated that 70 percent of people that are born in the year 2020 in the USA will have diabetes in their lifetime;
4. The costs associated with diabetes were $174 billion USD in 2007, an increase of $42 billion US since 2002;
5. Almost 90 percent of diabetes costs derive from problems in treatment;
6. Diabetes accounts for 11 percent of all health sector costs in America.

The insulin pump is a medical device used for the administration of insulin in the treatment of diabetes, and is used as an alternative method for injecting insulin by syringes or insulin pens. It consists of the pump (including controls, processing module and batteries), a disposable reservoir for insulin, and a disposable infusion set. Modern state-of-the-art diabetes devices are insulin pumps that continuously monitor glucose levels. It is expected that the wrist computers, as a diabetic device, would be better and smaller than those already available in the marketplace (even implantable). Additionally, more user-friendly Wristop devices are being developed and they are also able to improve and simplify diabetes treatment by continuously monitoring glucose levels and collecting additional data.

What To Do Next?

As way of doing some informal product testing, Matti Aalto-Setälä decided to personally use the insulin pump (even though he did not have diabetes) by using a saline solution in the insulin pump which was attached to the CEO's abdomen. He wanted personally to feel what it was like to use the insulin pump for a long period of time. At the same time, the company started using social media to participate in various international diabetes discussion groups as part of their R&D activities. The company openly informed their audience in many of these discussion forums that they were developing a new type of device for the treatment of diabetes and asked for suggestions as to what kind of an insulin pump would be user friendly. This type of openness in R&D is frequently referred to in business as the 'Open Innovation Approach'. From the feedback received, the

[3] www.diabetes.org.uk

[4] American Diabetes Association, WHO, Stakes

company's primary objective now was to develop medical devices (wrist computers) for diabetes treatment that helped the patients by preventing them from developing additional problems related to the disease. However, some of the additional features found in their product were based on the expertise of the founders in the area of sports technology. Wristop used other monitoring technologies in their products which meant that while monitoring glucose levels, additional information about the customer was being monitored which could assist the patient, as well as his/her medical doctor, in their diabetic treatment. Wristop could additionally use mobile technology in their product which could assist parents with diabetic children (e.g. a parent could wear the wrist computer and monitor the glucose level of the child). The device (the mobile connection between the pump and wrist computer) could also be operated from a long distance (for example, within a household) which gave it many other advantages for patients.

While the company's operations were based in Finland, where they conducted the planning and design activities, Wristop used international (mainly Chinese) manufacturers to develop the end-product. Based on their experience they have extensive networks in the manufacturing industry so production was easy, but the problem was with the marketing budget which was just a few thousand Euros. The company intended to deal with large medical device manufactures and the size of any deal was estimated at approximately one million USD, but the company decided to wait until it had grown and become more established before deals such as these would be sought. There had been many discussions regarding whether the company should open an office near the target customers but no final decision had been taken. The Board of the company has decided that medical device market was the target market and that additional markets would not be actively sought, even though the company had a track record in many development projects with global companies. A potential opportunity was to build their own product from start to finish but the board decided against it for the costs were estimated to be €10 million. In order to follow that option international investors would have been needed. However, VC companies, as well as the Finnish national development organisation TEKES, were very interested in the idea of investing in Wristop which was primarily due to the huge potential globally of diabetes management being able to save significant health-related expenses in the economy. However, the initial VC investment had been very modest and so the company now needed additional funding urgently.

The first round VC investment had a big effect on Wristop's strategy. The medical device sector had been selected even though there were other potential sectors to be investigated. The role of investor was very clear as the investor strongly influenced the decision-making of the venture.

Additionally, the investor also had a strong voice regarding future VC round as the investor's equity value would be diluted if new investors were to be brought in. Banks were not risk financiers so that type of funding was not usually available for this kind of a venture in Finland. The company had no collateral, which could be used to secure a bank loan. But additional investment would make it possible for Wristop to increase its marketing activity, although the company itself did not view the production of prototypes or participating in trade shows as marketing. The CEO of the company had visited potential customers in the US many times and thought that was a good strategy. While the production of a prototype was expensive, the company had been able to design and produce prototypes for potential customers in the US to evaluate. The CEO of Wristop now wondered what steps he should take in order to successfully grow the company.

Appendix One

Financial Data of Wristop

Financial Profile
Unconsolidated data

	31/12/2009 12 months EUR Local GAAP	31/12/2008 12 months EUR Local GAAP	31/12/2007 12 months EUR Local GAAP
Operating Revenue/Turnover	182,000	156,738	222,000
P/L before Tax	-202,000	-243,378	-9,000
P/L for Period [= Net Income]	-202,000	-243,378	-10,000
Cash Flow	-196,000	-235,647	-5,000
Total Assets	98,000	217,593	119,000
Shareholders Funds	-537,000	-334,357	68,000
Current Ratio (x)	0.75	2.95	4.39
Profit Margin (%)	n.s.	n.s.	-4.05
Return on shareholders Funds (%)	n.a.	n.a.	-13.23
Return on Capital Employed (%)	n.a.	-159.22	-7.29
Solvency Ratio (%)	n.s.	n.s.	57.14
Price Earning Ratio (x)	n.a.	n.a.	n.a.
Employees	n.a.	4	3

Appendix Two
Balance Sheet Data of Wristop

Balance Sheet			
Unconsolidated data			
	31/12/2009	**31/12/2008**	**31/12/2007**
	12 months	**12 months**	**12 months**
	EUR	**EUR**	**EUR**
	Local GAAP	**Local GAAP**	**Local GAAP**
Fixed Assets	16,000	22,035	18,000
Intangible Fixed Assets	1,000	2,320	5,000
Tangible Fixed Assets	15,000	19,715	13,000
Other Fixed Assets	0	0	0
Current Assets	82,000	195,558	101,000
Stocks	0	0	0
Debtors	0	0	13,000
Other Current Assets	82,000	195,558	88,000
Cash & Cash Equivalent	51,000	127,722	41,000
Total Assets	98,000	217,593	119,000
Shareholders Funds	-537,000	-334,357	68,000
Capital	11,000	11,000	9,000
Other Shareholders Funds	-548,000	-345,357	59,000
Non Current Liabilities	526,000	485,625	28,000
Long Term Debt	0	5,625	28,000
Other Non-Current Liabilities	526,000	480,000	0
Provisions	n.a.	n.a.	0
Current Liabilities	109,000	66,324	23,000
Loans	6,000	7,500	0
Creditors	3,000	3,688	9,000
Other Current Liabilities	100,000	55,136	14,000
Total Shareh. Funds & Liab.	98,000	217,593	119,000
Memo lines			
Working Capital	-3,000	-3,688	4,000
Net Current Assets	-27,000	129,234	78,000
Enterprise Value	n.a.	n.a.	n.a.
Employees	n.a.	4	3