CASE STUDY

WRISTOP - MARKET SELECTION FOR MEDICAL TECHNOLOGIES

by *Pasi Malinen and Thomas M. Cooney*

1. Introduction

"I think we didn't read the small print in our job contract with Suunto[1]. Guys, we must do something else instead…"

Having missed the opportunity to manufacture wrist computers for Suunto's competitors, the founders of Wristop 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 of employing wrist computers for medical use. After this initial meeting and idea generation, the company organised another brainstorming session with a group of physicians. The question the CEO was addressing was, *"For what medical purpose could a patient use a wrist computer?"* In the brainstorming session, it was noted that the medical technology sector has a small number of dominant manufacturers, but is a growing and lucrative sector. Thus, the company decided to explore an alternative market in the medical technology industry. However, there were many opportunities within different segments of the 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 should they use.

[1] Suunto is a sports accessories manufacturer

2. The Company

Wristop Technologies is a young Finnish start-up company, which specialises in the design, development, and production of wireless medical wrist computers. The primary target market is diabetic patients, and the company is currently 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 commercialise their expertise in mobile technology. The idea to start up a new venture was based on their current understanding and knowledge of customer needs. Many companies approached Suunto, requesting that they produce tailor-made wrist computers; however it was against the current strategy of the company. Consequently, Wristop was launched to serve these customers. The founders of Wristop had 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, and without annoyance, 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) are not interested in additional 'toys' on top of their purchase of a new toy (the new car). Additionally, this would be a difficult market for Wristop to penetrate, as there are 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 is very traditional; it uses large companies as suppliers and finds it suspicious for a small newcomer to offer military solutions for national or international armies (e.g. NATO).

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 established the rules for future activities. The consequence of this for the company is that Wristop is now committed to the medical industry even if potential new sectors and markets arise.

Currently, the company employs 6 people with technology, medicine or pharmacology background. The three founders each have an M.Sc. in En-

gineering from Helsinki University of Technology. The Wristop team has 12 years of experience in wrist computer technology. They have completed over 30 projects for companies, including, Suunto, FRWD, Nokia, and Clothing+. The team was the first to develop underwater data transmission, and claim that they have the most energy efficient data management in wrist computing (ARCH2.0 whereby with their technology it is possible for continuous operations for 12 months with a single coin battery; a patent is pending for this technology). The team has also developed the smallest diving computer and the lightest GPS wrist computer in the world. Therefore, it can be firmly concluded that the company has significant technical expertise in wrist computers and technology.

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

Tab. 1 - 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

GAAP: Generally accepted accourting principles

Balance Sheet **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**
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 Asset	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	78,00
Enterprise Value	n.a.	n.a.	n.a.
Employees	n.a.	4	3

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

3. The Market

Wristwatches were originally developed in the early years of the 2oth 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 have been introduced onto the global marketplace. A typical wrist computer today is designed for many uses, including activities such as sports, heart rate monitoring and GPS (Global Positioning System) navigation.

The medical device market is 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 employ tens of thousands of people and operate in all continents. The international medical device manufacturing market is presented in Table Two below.

Tab. 2 - 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 are a numerous amounts of small companies manufacturing medical devices in this industry, the sector is primarily dominated

by a dozen or so large companies. The medical device industry is a difficult sector in which to operate as there are a lot of regulations, and also institutionalised relationships between the companies. The sector is evolving and developing as people live longer, and medical treatments are developing for many types of illnesses. Actually, it is a sector where new technology has been slow to be introduced as 'old ways' have remained dominant. While the medical profession has traditionally been about treating the sick, nowadays there is more emphasis on keeping people from getting sick. Medical device technology aims at serving both sectors of this industry.

The medical device manufacturing industry is characterised by numerous factors, particularly by the FDA (US Food and Drug Administration). Companies have to adapt to the rules and restrictions made by the FDA, that is if you are entering the US market. Other countries have similar bodies which regulate the medical market. Most of the medical device manufacturers are US based and therefore the companies seeking clients among them have to understand the FDA rules, which are said to be difficult to 'newcomers and outsiders'. An additional feature of the US system is the health insurance system, which is different to those of the European systems. Companies have to follow very closely the insurance sector developments and regulations.

The medical device manufacturing sector is said to be 'old-fashioned', as growth and development in the medical industry has been more focused in developing new drugs for treating the sick, rather than trying to develop new technologies at the same time. Therefore, there are difficulties for highly sophisticated technology companies to enter the market. When a sector is dominated by large companies it is usually very difficult to penetrate the market. However, large companies try to imitate flexible small ventures, but are usually slow to adapt to that change. Bureaucracy is a commonly used term when classifying large multinational companies. The people responsible for buying outsourced devices in large medical device manufacturers are top level employees of the company, such as the VP of Marketing and VP of R&D, and the project team under these positions. With smaller manufacturing companies the decisions are more likely to be made by the whole board of the company in question. When there are many decision makers and various company policies, the decision making becomes slow and difficult to understand from an outside perspective.

Large medical device manufacturers are guarded about their R&D operations. As a result, the majority of R&D efforts are conducted in-house. In many other sectors, joint R&D or more open innovation approaches have been selected in order to save a company money as well as getting more ideas from 'outside the box'. In many sectors, university industry collaboration is common, particularly in the drug development sector. However, the medical technology sector has not been as receptive to such collabo-

ration. In the innovation literature, the problem 'not invented here' is a typical feature in medical device manufacturing sector. The target market for Wristop consists of only three large medical device manufacturers, Medtronic, Dexcom, and Abbot. All three companies are based in California. In Europe, Roche could be a potential customer but as of August 2010 the negotiations have not been concluded or constructive in terms of sales. In Asia, there are numerous medical device manufacturers, Omron among others, but the company has been reluctant to negotiate with Asian companies due to the perceived risk of losing the IPR to copycat imitations. The question therefore is what should the company do next if these leads fail to materialise?

4. Diabetes

Diabetes is a common permanent condition where the amount of glucose in the blood is too high as 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 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, and 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 doesn't produce enough insulin or the insulin that is produced doesn't work properly. Usually it appears in people aged over 40, however in South Asians and Africans it can appear from the age of 25. However, it is 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[2].

Facts about diabetes[3]:

1. 250 million diabetics worldwide;
2. 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. Cost associated with diabetes were $174 billion USD in 2007, an increase of $42 billion US since 2002;
5. 90 percent of diabetes cost derives 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, will 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.

5. 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 are 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 referred to as the Open Innova-

[2] www.diabetes.org.uk
[3] American Diabetes Association, WHO, Stakes

tion Approach (Chesbrough 2003; Christensen 1997). From the feedback received, the company's primary objective now is to develop medical devices (wrist computers) for diabetes treatment that helps the patients by preventing them from developing additional problems related to the disease. Additional features found in their product are based on the expertise of the founders in area of sports technology. Wristop uses other monitoring technologies in their products, this means that while monitoring glucose levels additional information about the customer is being monitored, which can assist the patient, as well as his/her medical doctor, in their diabetic treatment. Wristop can additionally use mobile technology in their product which can assist parents with diabetic children. A parent can wear the wrist computer and monitor the glucose level of the child. The device (the mobile connection between the pump and wrist computer) can be operated from a long distance (for example, within a household).

The company's operations are based in Finland. They conduct the planning and design activities and use international (mainly Chinese) manufacturers to develop the end-product. Prototypes of their potential products are developed by the company. Based on their experience they have extensive networks in the manufacturing industry. The marketing budget of the company is just a few thousand Euro. The company intends to deal with large medical device manufacturers and the size of any deal is estimated at approximately one million USD but the company will wait until it grows and becomes more established before deals are to be sought. There have been many discussions regarding whether the company should open an office near the target customers. The board of the company has decided that the medical device market is the primary target market. Additional, markets have not actively been sought, even though the company has a track record in many development projects with global companies. VC companies, as well as the Finnish national development organisation TEKES, are very interested in the end-product. This is primarily due to the huge potential of diabetes management being able to save a lot of health-related expenses in the economy. However, the initial VC investments have been very modest, and the company needs additional funding urgently.

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Interviews:

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