SWAN-iCare

Early Business Approach,
Strengths Weaknesses Opportunity
Threats Analysis
and Value Chain Analysis

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SWAN-iCare

Smart wearable and autonomous negative pressure device for wound monitoring and therapy

Contract Start Date: 1 September 2012
Contract Duration: 48 months

Project Partners:
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## Revision History

<table>
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<th>Version</th>
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<tr>
<td>1.0</td>
<td>28/02/2013</td>
<td>First Issue</td>
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1 Executive Summary

As part of Work Package 9 there is a deliverable D9.3, titled “Early Business Approach, Strengths Weaknesses Opportunity Threats (SWOT) Analysis and Value Chain Analysis”, this report describes in detail the tasks required to ensure that a successful product can be researched, developed, tested, registered and ultimately launched into a competitive cost conscious medical environment.

The individual members of the consortium are pro-actively working together, sharing their knowledge, experience, skills and contacts to develop this new medical device. The requirements for the SWAN-iCare device are based on the specification within the project brief; this will be supported by feedback from patients and clinicians and will be developed to meet the demanding needs of a modern medical infrastructure.

The “Early Business Approach, SWOT Analysis and Value Chain Analysis” are activities to be followed to ensure any potential issues with the proposed delivery are highlighted early within the project and areas of strength can be built upon whilst project threats and weaknesses can be addressed. All of these events are underpinned by the value chain analysis activities to ensure each step of the process is adding value to the overall delivery. As this is a long term project (48 months), the consortium members have the chance to explore the areas of opportunity as highlighted within the SWOT analysis with the objective to transfer these into project strengths.

Smith & Nephew has been identified as the key commercial partner based on their existing business infrastructure to support the SWAN-iCare device during the research and development phase. They can provide an accurate insight into the current market place and how this differs depending on both country and patient needs. Due to their existing marketed products within the medical electromechanical device forums they also have a strong marketing, education and support organisation, which is underpinned with detailed knowledge of both diabetic foot ulcers (DFU) and venous leg ulcers (VLU).

As we are only at the start of the pathway to a successful project, our next stages within the “Early Business Approach, SWOT Analysis and Value Chain Analysis” activities is to plan together, with input from all partners, which items highlighted within the SWOT we can focus our attention upon.

It must be realised that all of these activities are constantly developing and changing as new opportunities occur and, with the exception of the Early Business Approach, continue well past the end of this project.

Informal updates of these activities will occur at regular intervals in the future, with formal reviews taking place at each consortium meeting. The outputs from these formal reviews will be used to update this document on a regular basis.
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3 Introduction

SWAN-iCARE is an ambitious project which will provide a major leap forward in the management of wound healing, mainly diabetic foot ulcers (DFU) and venous leg ulcers (VLU) treatment. It aims at a next generation integrated autonomous solution for monitoring and personalized therapy of the foot and leg ulcers. Foot and leg ulcers are caused mainly by diabetes and vascular problems but are also due to a variety of diseases such as kidney disease, congestive heart failure, high blood pressure, inflammatory bowel disease and others.

The project relies on Information and Communication Technologies (ICT) enabled on body wearable, negative pressure device and allows for:

- accurate multi-parametric monitoring of the wound via non-invasive integrated micro-sensors measuring the condition of the wound and early identification of infection.
- adapted remote personalised two level therapy via non-invasive micro-actuators as a supplement to the negative pressure wound therapy

The data collection analysed by the clinic personnel is the basis for the decision and remote control of the therapy (by the clinical doctor) and future statistical analysis of multiple patients’ wound management and treatment, thus advancing the wound management science and practice. This closed-loop approach offered by SWAN-iCare project is expected to provide improved levels of care. This in turn will help support the patient’s health condition and potentially lowers the costs and need of hospitalisation which in turn will provide a positive impact on the patient and the health provider.

SWAN-iCARE novel idea focuses on the provision of pioneering two levels of treatment at home:

- A first level treatment based on a negative pressure device, which provides a moist environment, reduces bacterial colonization, localized oedema and dead space and promotes localized blood flow, granulation and epithelialization.
- A second level treatment based on a smart interface associated to the cartridge which will be at the direct contact of the wound in order to initiate, if necessary, the integrated micro-actuators.

For an overview of the SWAN-iCare system see Appendix #1

Swan-iCare Consortium Partners are:

<table>
<thead>
<tr>
<th>Organisation Name</th>
<th>Short Name</th>
<th>County</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre Suisse d’Electronique et de Microtechnique SA</td>
<td>CSEM</td>
<td>CH</td>
</tr>
<tr>
<td>Commissariat à l’Energie Atomique et aux Energies Alternatives</td>
<td>CEA</td>
<td>FR</td>
</tr>
<tr>
<td>European Wound Management Association Secretariat</td>
<td>EWMA</td>
<td>DK</td>
</tr>
<tr>
<td>Euroresearch</td>
<td>EUROR</td>
<td>IT</td>
</tr>
<tr>
<td>Exodus A. E.</td>
<td>EXODUS</td>
<td>GR</td>
</tr>
<tr>
<td>Haemopharm Biofluids</td>
<td>HBIO</td>
<td>IT</td>
</tr>
<tr>
<td>Institute of Communications and Computer Systems</td>
<td>ICCS</td>
<td>GR</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>S&amp;N</td>
<td>UK</td>
</tr>
<tr>
<td>SWISSINNOV</td>
<td>SWINN</td>
<td>CH</td>
</tr>
<tr>
<td>Università di Pisa</td>
<td>UNIPI</td>
<td>IT</td>
</tr>
<tr>
<td>University Hospital of Grenoble</td>
<td>CHURG</td>
<td>FR</td>
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</table>
3.1 Work Package 9 assigned efforts

3.1.1 Table #1 each project partner has efforts in WP9

<table>
<thead>
<tr>
<th>Participant number</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4a</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>4b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant short name</td>
<td>EXODUS</td>
<td>CEA</td>
<td>CSEM</td>
<td>UNIPI-CHE</td>
<td>CHURG</td>
<td>EUROR</td>
<td>HBI</td>
<td>EWMA</td>
<td>ICCS</td>
<td>S&amp;N</td>
<td>SWINN</td>
<td>UNIPI-WHR</td>
</tr>
<tr>
<td>Person-months per participant</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>2</td>
<td>10</td>
<td>5</td>
<td>7</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

The aim of deliverable WP9.3 is to ensure that the product which is currently been researched and developed will meet the current needs for both monitoring and healing of either DFU or VLU.

Deliverable WP9.3 has three separate elements:
- Early Business Approach,
- Strengths Weaknesses Opportunity Threats (SWOT) Analysis,
- Value Chain Analysis,

The following sections provide a more detailed approach to each of these items:
4 Early Business Approach

4.1 Background Information

The following early business approach for the SWAN-iCare project has been separated down into a number of different activities to help give a clear indication of the differing actions that need to be undertaken. Each point has a clear set of activities and expected output (outcomes) and builds on the activities performed prior. It must be understood at this stage of this project that a number of these activities will appear generic and these will be updated with additional information and deliverables as the project progresses to its delivery.

4.1.1 Fig #1 Business Approach to a Successful Launch
4.1 Definition of the Customer Needs

Activities: Market research (focus groups, online surveys, etc…) with different customer segments: physicians, nurses, payers.
Output: List of currently unmet needs that the product could satisfy and forced ranking across the three segments.

4.2 Definition of the Product Features and Benefits

Activities: Match the priority needs with the product features and define which benefits the product will provide. A comparison will occur against other such available devices to identify similarities, potential weakness and areas of strength.
Output: Agreed list of product features, clearly identifying “Critical”, “Non-critical” and “Nice to have”; this will be linked into Milestone No# 1 Final clinical end-user requirements.

4.3 Definition of the Value Proposition

Activities: Based on the product features and benefits, marketing defines the product Value Proposition, for each customer segment. The VP is the reason why a customer should purchase that specific product against its competitors. To be effective it needs to be CLEAR, CONCISE and COMPELLING.
Output: Value Proposition, for each customer segment.

4.4 Product positioning

Activities: Based on the product features and benefits, and the VP, a positioning statement will be defined that has the objective of “positioning” the product in the customer minds, compared to what is currently available, trying to create a differentiation and a competitive advantage.
Output: positioning statement, used to define the communication strategy.

4.5 Pricing positioning

Activities: The Value Proposition and the positioning needs to be validated by customers (focus groups or 1 to 1 interviews), and based on this validation, and how the product can influence positively the current clinical practice or the healthcare organization, a pricing corridor is defined.
Output: Defining of the pricing corridor, considering focus groups feedback, reimbursement, customer support, sales models etc.

4.6 Clinical data

Activities: Correlation of Clinical Data, impact of outcomes vs cost to heal. This activity will be linked to milestone No# 9 “In vivo validation results”.
Output: Reviewing of clinical DATA to confirm the product delivers the expected clinical outcomes. The correlation of this data will then be used to support the registration process and as early clinical evidence to support the commercialization plan.
4.7 Regulatory approval in the major markets: EU, USA, RoW

**Activities:** To ensure the application for registration of the SWAN-iCare product in EU, USA and RoW can be achieved as quickly as possible without the requirement for additional work. A recognized and appropriate method relating to Medical Product Development must be followed; activities will need to be managed through a formal Design Control procedure during the development phases to achieve it.  
**Output:** Successful registration will provide authorization to sell in the targeted markets. This registration will also support the necessary activities to achieve the reimbursement in each specific market (where applicable).

4.8 Communication and Key messages

**Activities:** Within these activities, a clearly defined communication strategy with key messages focused at particular medical groups will be developed and used. These messages will underpin the commercialization plan. These focused key messages will be tested with customers, to verify if they resonate and are captivating enough to generate a true desire to own a SWAN-iCare device.  
**Output:** To promote the product using the key messages and communication campaign. Representation at leading Medical events, symposiums’, endorsement by Key opinion leaders, press and technical journal articles represent just a part of the work involved.

4.9 Training of the sales and technical support teams

**Activities:** Training will take place both for the focused sales teams along with the technical and service support teams to ensure the SWAN-iCare product can be both effectively marketed whilst being technically support.  
**Output:** Detailed training schemes, support infrastructure, etc.

4.10 Commercial Launch and dissemination activities

**Activities:** Commercial launch in the key markets. Typical sequence (based on speed of registration): EU, Australia, Canada, USA, Japan. In order to generate awareness and promote the modes of therapy, participation in conferences to exhibit the product and present relevant clinical data will occur.  
**Output:** Successful launch, adoption of the SWAN-iCare mode of therapy, high interest within the appropriate Medical communities.
5 Strengths  Weaknesses  Opportunity  Threats
(SWOT) Analysis

5.1 Back ground:

This SWOT analysis is focused towards the exploitation of the SWAN-iCare system and is used as a structured planning method to evaluate the following main areas that could impact on the commercial success of the finished system. The areas that are being considered are:

- **Strengths**, this relates to the features of the system that gives it an advantage over others.
- **Weaknesses**, this relates to the features of the system that have been identified as a disadvantage relative to other such systems or current methods of treatment/infrastructure.
- **Opportunities**, elements of the SWAN-iCare system that could be exploited to give it an advantage over others.
- **Threats**, items outside of the projects direct responsibilities that could impact on its ability to be a commercial success.

The process followed to generate the SWOT analysis involved a number of consortium members discussing what are currently believed to be the individual strengths, weaknesses, opportunities and threats to the potential commercial success of the SWAN-iCare system.

The following SWOT Matrix (Table #2) represents the Strengths, Weaknesses, Opportunities and Threats involved with the commercialisation of the Swan-iCare Electromechanical Medical Device.
### 5.1.1 Table #2 Strengths, Weaknesses, Opportunities, and Threats

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swan-iCare shall provide both user and clinical diagnostic information appropriate to the individual’s needs in order to minimise wastage of treatments and carer resources.</td>
<td>NPWT does not currently have high usage in DFU’s because of low exudation and lack of wearability for the patient.</td>
</tr>
<tr>
<td>A unique system providing both wound diagnostic and treatment in a single device for diabetic foot ulcers (DFU) and venous leg ulcers (VLU).</td>
<td>Entering an already price competitive marketplace where financial stress on the system is increasing.</td>
</tr>
<tr>
<td>Earlier identification of potential infection in order to minimise cost and risk to patient safety.</td>
<td>Lack of proven clinical DATA to support either the health economics of use versus current practice, or to show that the device will monitor the correct wound conditions.</td>
</tr>
<tr>
<td>Utilisation of increasingly adopted technology in NPWT.</td>
<td>Lack of proven clinical DATA to support health economics of use versus current practice.</td>
</tr>
<tr>
<td>Continuous remote monitoring, so reducing the impact on existing front line medical resources, number of visits to care centres or hospitals, along with a potential reduction in home visits by community nurses.</td>
<td>The Swan-iCare device could be perceived as been over complex so hindering market adoption.</td>
</tr>
<tr>
<td>Combination of unique technologies provided by the consortium members that would prove difficult to copy.</td>
<td>Reliability of the DATA to accurately indicate the wound condition.</td>
</tr>
<tr>
<td>An existing experienced NPWT sales and marketing team with a global footprint.</td>
<td>Difficulty with predictability of the success of the administered treatment on all patients.</td>
</tr>
<tr>
<td>Generation of original IP so increasing protection for the system from competition.</td>
<td>Clarity on the Realisable Market Opportunity compared against proven current practice.</td>
</tr>
<tr>
<td></td>
<td>Lack of understanding of who will pay for the device in the different healthcare systems and how it will be funded.</td>
</tr>
<tr>
<td></td>
<td>Data security.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunity</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>To release the Healthcare professional, to allow them to perform more value adding activities.</td>
<td>Unwillingness of current Hospital\Long Term Care facilities to modify\amend their current standard wound care procedures.</td>
</tr>
<tr>
<td>To give the users the opportunity and awareness to more accurately monitor and improve their treatment so improving compliance.</td>
<td>Rejection by the patient because it removes the human clinical carer contact.</td>
</tr>
<tr>
<td>To record DATA from users so helping to identify trends and potential improvements in treatment regimes.</td>
<td>Absence of committed long term development programme by the suppliers leads to early redundancy and user rejection.</td>
</tr>
<tr>
<td>Potential reduced wound healing time, with a direct impact on the Health providers cost.</td>
<td>Unable to achieve an acceptable Cost of Goods.</td>
</tr>
<tr>
<td>The product value proposition matches the commercial partners’ value proposition of reducing the human and economic cost of wounds.</td>
<td>Interface with a smartphone screen, keys can be small and difficult to operate.</td>
</tr>
<tr>
<td>To set a new standard in respect to intelligent portable NPWT devices.</td>
<td>Development of a suitable interface platform that can be migrated to the differing smartphones both now and future.</td>
</tr>
<tr>
<td></td>
<td>Reluctance of the user to use their own equipment to operate the device.</td>
</tr>
<tr>
<td></td>
<td>Weak IP.</td>
</tr>
<tr>
<td></td>
<td>South East Asian copies will appear quickly.</td>
</tr>
<tr>
<td></td>
<td>Unable to guarantee patient safety if the device does not work.</td>
</tr>
<tr>
<td></td>
<td>Lack of clarity of pan- European regulations governing remote controlled devices that administer treatment.</td>
</tr>
<tr>
<td></td>
<td>A Pharmaceutical company launches a product that supersedes the mode of therapy employed by the SWAN-iCare device.</td>
</tr>
<tr>
<td></td>
<td>A competitive product is launched into the market place prior to the SWAN-iCare device.</td>
</tr>
</tbody>
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1 This will depend on who the User/Operator is. A tech-savvy Doctor or Podiatrist may be willing, but how much time will they have to do this? The techno-phobic nurse may be reluctant to use and prefer to stick with existing easy to apply treatments.

2 One of the basic requirements of care is the human interface. In the absence of the clinician, this could be provided by the family member or via video conference. Total remoteness is unlikely to be welcome.

3 This could be seen as an opportunity also.

4 A unique separate interface unit maybe required.
6 Value Chain Analysis

6.1 Background information

Value chain (creation) analysis looks at how each disciplined or function is adding value to the network. The network refers to a number of tasks or operations, which ultimately result in a finished item, goods or services. The root of this analysis lies in the principle of adding value at each stage of the process, from original product design through to the customer. It must always be remembered that you should be adding value at each stage as it passes through your organisation. At each stage of the process you should be able to clearly see how your input has provided value in the form of a product and or services. By analysing the detailed cost structures of individual value chain participants, you can identify the types of costs that account for the majority of total value and, therefore, focus on specific areas where new investment or other improvement could have the greatest impact.

Value chains consist of a number of different activities, some of which can be referred to as primary or direct activities and others which are more usually referred to as support or indirect activities. Examples of these are given below.

6.1.1 Primary direct activities

1. Research
2. Purchases of supplies, materials, inward shipping
3. Manufacturing and operations along with inventory control
4. Outward delivery and logistics
5. Customer service - includes, coordinating, scheduling
6. Marketing, education, training, technical support, servicing and refurbishment

6.1.2 Support or indirect activities

1. Accounting and Finance
2. Systems Support
3. Environmental
4. Safety
5. Human Resources

It must always be remembered that the last element of a value chain analysis is the profit margin.
6.1.1  Fig #2 Value Chain Analysis

6.2 **Research and Development**

- Start a preliminary investigation into how the market will accept your new product, particularly focusing on their concerns.
- Investigate and identify any competitor/competitive product that may be entering the market place prior to the launch of yours to ensure no conflict will occur.
- Identify market sensitivities and define an on-going strategy to ensure the sensitivities do not become a hindrance to the launch of successful product.
- Identify new opportunities that are not currently being fulfilled by others.
- Research occurrence IP landscape identifying areas that are protected and areas where exploitation may or could occur.
- Understand preferences and behaviours of customers in the medical sector.
- Predictably uptake of the product, based on current market expectations.
- Identify the cost value model.
- Design for effective and efficient to clinical trials.
- Identify areas of weakness within the organisation to ensure remedial action can be put into place prior to the commencement of the development of the finished product.
- Identify new manufacturing equipment or sourced suitable third party suppliers to ensure all the necessary components/assemblies will be available to ensure a successful launch product.
- Close analysis must occur between current methods of treatments and a new one to be provided by this device.

6.3 **Purchases of supplies, materials, inward shipping**

- Identify where components and services can be supplied from this relates to both either internal or external resources.
- Identify suitable supply route for components, manufacturing facilities and ensure these are all in compliance with necessary medical standards.
- Identify suitable testing facilities, and support infrastructure as needed.
- Identify equipment for the manufacture of the finished components and were necessary identify costs along with lead time for the procurement of any new plant that may be required.
- Identify sterilisation requirements, and ensure infrastructure is in place to fulfil the needs of the finished device.
- Identify inward stockholding, and expected manufacturing schedules, to ensure optimum schedules can be maintained.
6.4 **Manufacturing, quality assurance, packaging and dispatch**

- Identify specific requirements for each individual component/sub assembly and then final assembly for the finished device. Where applicable ensure such items are suitable to be sterilised as required and compliant with the necessary standards for this type of product.
- Install and optimise manufacturing equipment to support the new product.
- Determine quality assurance levels both at the component level and completed product.
- Continuous improvement procedures are integral to operations.
- Determined drivers for both internal and external suppliers define quality and performance requirements. (More efficient collaboration)
- Set up supply chain and agree stock levels along with on-going support.
- Optimise third party supply chain and identify dual source options for critical items.
- Processes are designed for maximum flow.
- Tight integration of production and demand.

6.5 **Warehouse, distribution and returns/recycling routes**

- Identify requirements for individual European and worldwide distribution outlets to ensure compliance with local and national requirements in respect to shipment, recycling and disposal of such a device.
- Set up supply route, transportation methods and customs clearance.
- Determine stock locations, distribution warehouses, to support access to potential customers, direct shipment or local distributors.
- Identifying environmental impact of the product and its manufacturing/distribution routes to ensure this is minimised.
- Optimise supply method, drop, individual packages, etc. Distribution routes will be optimised to meet customer requirements whilst still keeping the product commercially viable.
- Determine drivers of distribution channel profitability.
- Determine most profitable channel partners.
- Optimisation of packaging and configuration to minimise unnecessary waste.
- Identify rooms for returned items, servicing facilities and decontamination as required.
6.6 **Marketing activities will include but not limited to**

- Generate test and evaluate educational training packages in line with current medical needs.
- Identify dedicated marketing and sales support teams to ensure quick take-up of new launch products.
- Identify local customer expectations and sensitivities to the launch of a new product and how this will impact on their current methods of treatments.
- Identify local support, provided by sales representative or distributors.
- Initiate internal and external technical support teams, to ensure high comfort factor can be provided to potential customers.
- Identify how to best tailor marketing and publicity information to focus this towards the key markets/institutions in which the product is to be used.
- Train technical support staff to ensure they are competent to be able to answer any questions that are raised by either potential or existing customers who may wish to transfer from our existing products to the new.
- Generating case studies to support product, and publish these in relevant journals.
- Hold seminars and one-to-one meetings with key individuals, to promote a product and to gain first-hand feedback on acceptance from the marketplace.
- Determine advertising and promotional activities. Identifying effective and non-effective routes forward from past experience.
- Determine advertising and promotional effectiveness.
- Identifying key markets with key opinion leaders who will be able to support the launch of the new product.
- Education, sales and marketing, and technical support.
- Set up websites, analyse activity.
- Understand consumer prices sensitivity.
- Determine optimum price.
- Determine the most profitable customers.
- Target offers and messages to consumers and segment.

6.7 **Support or indirect activities**

1. Accounting and Finance
2. Systems support
3. Environmental
4. Safety
5. Human Resources

**6.7.1 Accounting and Finance.**
Predict revenues and growth. Analyse cost drivers, analyse major targets, identify insider trading.

**6.7.2 Systems support.**
Predict and instigate the necessary support systems, i.e. IT, accounts, marketing, distribution and returns, ensuring all are available or replace.
6.7.3 Environmental
The environmental impact of the manufacture of this new product has to be determined at all stages and drivers need to be placed within the project to ensure that the impact on the environment is kept to a minimum. Considerations must be given, not only to the raw materials used within the product and the disposal of or potential recycling, but also the actual costs involved within the manufacture such as raw materials, energy and waste from these. Drivers will need to be put into place to ensure that these are all kept to a minimal whilst not impacting on the quality of the finished goods.

6.7.4 Safety
Safety can fall into a number of categories, but primarily is related to either product safety or the safety of individuals involved in the manufacture of the finished item. For product safety, this will be achieved through testing and compliance with the necessary standards for such a medical device. Safety of the individuals involved in the manufacture of the finished item would be covered under the local and regional health and safety requirements and will be managed on a day by day basis by the individual employer. Drivers would have to be identified to deliver a safe product manufactured in a safe environment.

6.7.5 Human resources
Determined drivers of strong performance, predict turnover.

6.8 Closure comments
The above primary activities at this stage of the project have had to be left to be quite generic until a clearer picture of the finished product and the requirements that will be needed to support its long-term manufacture, launch and support within it worldwide/global market are known. It is not possible to give clear deliverables for each of the sections. This document will be required to be updated at regular intervals during the development and delivery of this project as a clearer picture will emerge of the necessary services and infrastructure to support such a device. The key focus will be to ensure that the finished product will fulfil a need within the medical field, at a cost which is appropriate to the return of the investment made by the purchaser, whilst ensuring that all parties are able to make an operating profit from the manufacture of the finished item.

As with any new development and particularly with the Swan-iCare project, with this being a new revolutionary device with no predicate to be compared against, the acceptance of this product within the marketplace will have to be carefully managed and supported to ensure a successful launch and long term viability for all.

7 Conclusions
In conclusion, this document covers three of the main areas of the SWAN-iCare development and delivery program, “Early Business Case”, “Strengths Weaknesses Opportunity Threats” and “Value Chain Analysis”. Each of these individually can have a major impact on the success or potential failure of the overall project delivery if not managed and controlled successfully, but taken as a combined picture and if delivered as required would provide a formidable strong and compelling new medical device providing a proven improved mode of therapy for DFU’s and FLUs.
Informal updates of these activities will occur at regular intervals, with formal reviews taking place at each consortium meeting. The outputs from these formal reviews will be used to update this document on a regular basis.
8 Bibliography

9 Abbreviations

- DoW: Description of Work
- DFU’s: Diabetic Foot Ulcers
- VLU’s: Venous Leg Ulcers
- EU: European Community
- USA: United States of America
- RoW: Rest of the World
- SWOT: Strengths Weakness Opportunities and Threats
10 Appendix Title

10.1 Appendix #1 SWAN-iCare system overview
10.2 Appendix #2 Consortium Partners Overview

The following is an overview of the individual companies involved within the consortium, information relevant to the project, and their contribution to the success of the SWAN-iCare Project.

EURORESEARCH Company established in 1986 in Italy who first introduced the use of collagen in wound healing. [Contribution] R&D for the medication populated with sensors and Nano particles to address faster wound healing.

CEA The Laboratoire d'Electronique et de Technologie of the Commissariat à l’Energie Atomique et aux Energie Alternatives (CEA) is a French public research organization. A dedicated division, DTBS, with a staff of 160 people has been set up for micro and nano-technology applications in the field of diagnostics, health care, life science and environment. At the frontier between micro and nano-technologies and biology, DTBS R&D activities aim to develop highly parallel and miniaturized devices as well as highly integrated portable systems, such as point of care systems. The department knowledge lies in micro machining, microfluidics, surface chemistry, integrated optical detection, electrochemistry (in particular electrochemical grafting), electronics, information processing. Facilities includes a 100m² clean room for biological microsystem development, a clean room specifically dedicated to Biochip packaging, a biological and chemical laboratory of 350m² as well as specific equipment in biosensor design, manufacturing and characterization. [Contribution] CEA will be involved in technical and project management tasks. In project management, CEA is the technical manager of the overall project. Furthermore, it will be the leader of WP4 and WP7.

CEA main technological contribution will include the development of:
- sensors for antibiotic-resistant bacteria strains,
- impedance sensors for estimation of wound healing status,
- gels including lipid nanoparticles for the delivery of growth factors and MMP inhibitors (actuators).

CHURG The University Hospital of Grenoble (France) was founded in 1973. Its main roles are to take care of patients (through 2200 in beds) and to conduct medical research as well as educating medical and paramedical students. The Department of Endocrinology, Diabetes and Nutrition has a large experience in diabetes-related clinical research, including the field of diabetic foot ulcers. [Contribution] CHURG will contribute to define the medical and end-user requirements for Diabetic Foot Ulcers in WP2. In the final part of the project, CHURG will participate to test the device on patients with DFU WP8.

CSEM "CSEM, Centre Suisse d' Electronique et de Microtechnique SA (Swiss Center for Electronics and Microtechnology), founded in 1984, is a private research and development centre, which has specialized in microtechnology, nanotechnology, microelectronics, systems engineering and communications technologies. It offers its customers and industry partners tailor made innovative solutions based on its technological expertise from applied research. Approximately 300 highly qualified and specialized employees from various scientific and technical disciplines work for CSEM in Neuchâtel and the two centres in Zurich and Alpnach. They represent more than 20 nationalities and constitute the basis of the company's creativity, dynamism and innovation potential. CSEM has long term and widespread competencies in the development of complex systems and microsystems with medical monitoring applications. [Contribution] CSEM will develop optical biosensors to measure several biomarkers in the wound exudate. It will develop the needed physiological sensors and electronic interfaces. CSEM will develop the complete electronic system from most sensor interfaces, sensor network, and microprocessor unit to wireless communication. CSEM will lead WP3 (complete system design) and WP5 (Electronics and wireless connectivity developments and component integration). Furthermore CSEM will be technically participating in WP2, WP4, WP7 and WP8, it will participate to the dissemination and exploitation of the project results in WP9.
EWMA  The European Wound Management Association (EWMA) is an umbrella organisation linking wound management associations across Europe. EWMA is a multidisciplinary group bringing together individuals and organisations interested in wound management. The association works to promote the advancement of education and research into native epidemiology, pathology, diagnosis, prevention and management of wounds of all aetiologies. EWMA works to reach its objectives by being an educational resource, organising conferences, contributing to international projects related to wound management, actively supporting the implementation of existing knowledge within wound management and providing information on all aspects of wound management. *(Contribution)* EWMA will contribute by means of:

- Bringing the perspective of the patient and end users into the device development process.
- Providing access to information on research and clinical practice from key stakeholders and researchers across all European countries.
- Providing opportunities for contact between clinicians and consortium partners at the annual EWMA Conference and other wound care events.
- Providing opportunities for disseminating information about the SWAN-iCare project at the annual EWMA Conference and other wound care events.
- Dissemination of project information including milestones and final results through its extensive European network of wound associations and clinicians.

EXODUS  The health sector is one of the sectors where EXODUS had operations in Greece. Through active involvement in mainline European projects in the ICT and health domain, EXODUS envisages to expand its health sector operations at a European level. SWAN-iCare has a great exploitation potential which will enhance EXODUS service offerings, lying within its strategy and organisation structure to work in new promising areas of research which in the long term will fuel further products and services. *(Contribution)* EXODUS will contribute to the development of mobile software for remote monitoring of the NPWT device and of a clinical software application that will be used by clinicians. The goal is to provide a medical-standards compliant software suite for remote monitoring of the SWAN-iCare device and to disseminate the developed solution in conferences and industrial for working in the domain of ICT health applications.

HBIOFLUIDS  Company established in 2007 in Italy, as Pharma plant for drug fluids in soft bags for Diabetic patient application. In 2008 a new area approved for Medical Device was developed for realizing collagen dressings in wound healing. *(Contribution)* Will take care of the R&D of a biomaterial, biocompatible and bio absorbable, like the collagen, and relative integration with the electrical and electronic devices. It will then make the final Medical Device interfaceable with the external instrument to supply info about the wound treated by the device in order to adjust the therapy on-going during the wound treatment.

ICCS  The Institute of Communications and Computer Systems (ICCS) is a non-profit Academic Research Body established in 1989 by the Ministry of Education in order to carry research and development activities in the fields of all diverse aspects of telecommunications and computer systems. ICCS is associated with the School of Electrical and Computer Engineering of the National Technical University of Athens. The personnel of ICCS consists of a number of Research scientists and more than 500 Associate scientists (including PhD students). The research carried out in ICCS is substantially supported by School of Electrical and Computer Engineering University Professors. *(Contribution)* ICCS will contribute by means of:

- embedded software development;
- development of the data fusion algorithm and storage model
- development of the embedded control application;
- contributing to the user scenario definition process and the definition of system requirements.

In addition, ICCS will contribute to the integration and validation of the prototype. Finally, ICCS will carry out dissemination activities mainly focused on the development of the embedded software and the user application.
SMITH & NEPHEW WOUND MANAGEMENT  
Company established in 1856 in England, specialising in the development, manufacture and marketing of medical devices and wound dressings for use in both hospitals and long-term care facilities. *(Contribution)* Will contribute to defining the system requirements, support the development and testing of the finished system, provide expert knowledge of the current NPWT landscape with the ultimate object of globally launching and marketing as a unique negative pressure wound healing medical device.

SWISSINNOV PRODUCT  
Company established in 2003 in Switzerland, specialized in fluidics system, development of innovative disposable pumps for healthcare, pharmaceutical and industries. *(Contribution)* Will develop the negative pressure pump of the system based on an innovative rotary piston pump technology.

UNIPI-WHR  
The Wound Healing Research Unit at Department of Dermatology, University of Pisa has gained international reputation in clinical and laboratory research, academic activities and in outpatients and inpatients services. The team has been working for 12 years with consistent increase of knowledge, leading to major results such as participation in FP5 and FP7 research project. Recently the unit has received the role of official organizing secretariat for the Fifth World Union of Wound Healing Societies (WUWHS) conference to be held in Florence, Italy in 2016. *(Contribution)* UNIPI-WHRU will contribute to the development of sensors for venous leg ulcers monitoring. The unit will perform the clinical tests on patients.

UNIPI-CHEM  
The Department of Chemistry and Industrial Chemistry, University of Pisa, is involved in a wide range of research fields such as biochemistry, organo-metallic chemistry, science of polymers, analytical chemistry of real systems, and theoretical chemistry. Research staff includes about 84 permanent positions (7 Full Professors, 23 Associate Professors, 29 researchers, 25 technicians) and more than 100 students. In recent years, a new research branch has been established for the study, design and exploitation of sensor systems. *(Contribution)* UNIPI-CHEM will contribute to define the requirements and design the system, develop sensors to measure skin temperature, pH, TEWL and dorsiflexion, test the system on patients.