

“SaveHeart”

Heart Valve Replacement

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Exclusive summary

SaveHeart, Inc. is a medical device company that intends to design, develop and sell Tissue Engineered constructs and organs to medical and health care markets as well as the private sector. One device, a patented aortic heart valve replacement (SAV) has already been designed and developed, using a new technique, with the participation of leading physicians and surgeons in cardiology. One of the founders of SaveHeart, Inc. participated in the design of one of the current market leaders in this field and has contributed to the product design and development significantly. The other founders have broad expertise with both the used technique as well as the medical field it involves. A new, revolutionary and innovative product has been created to answer the needs of the health care sector as well as patients world wide.

This new product has the following features:

- The ability to grow within the recipient without any rejection.
- Perfect function and hemodynamic performance after implantation without any further medication.

The main issue is to obtain Food and Drug Administration (FDA), a procedure which has to be followed and finalized by all new drugs, nourishments and medical implants before going to market. SaveHeart, Inc. is currently seeking for private investors to realize this. This procedure will take four years in total and preclinical studies are already started. On agreement our new technology has been licensed to a larger company Genesis Corp. This company will own a 10% of the SaveHeart shares while SaveHeart, Inc. receives further protection of IP and an amount of \$800.000 in return from September 2002. After FDA SaveHeart, Inc. intends to merge with a gorilla company or start producing and sell SAVs.

The company projects \$7.7 million in sales in the year after FDA approval is obtained with a profit of approximately \$5.2 million. This will be realized by listing patients during the FDA procedure in a promotion campaign. The company expects to have \$38.4 million in revenue in three years from this point.

The current market segments are clearly defined and our first product has great potential to exceed the 7% in the next three years after FDA approval. That is almost the total tissue heart valve replacement market in Australia. After Australia we intend to sell our product in the US (2007), Europe and Asia (2008). It is predicted that this world wide market for our product will cross the 18% in 2012. This market currently involves \$ 260 billion worldwide. Since current alternatives still present major disadvantages, this market lies wide open as soon as FDA is obtained for SaveHeart, Inc. first product.

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1. Objectives

The principal objectives of SaveHeart, Inc. are as follows:

1. To share its technology to a larger company for \$800k in September '02. (confirmed)
2. To raise \$4.65 million in private seed capital in the second half of 2003 to get through the FDA approval process.
3. To list patients to sell 96 SAVs worth \$7.7 million in sales in the first year after FDA.
4. To achieve a 7% market penetration in the Australian heart valve replacement market in three years from the point of FDA approval.
5. To achieve \$38.4 million in revenue by the year 2008.

2. Mission

SaveHeart, Inc. mission is to design, develop, and market new Tissue Engineered organs for the medical device field. The used technology will fill a current need in medical procedure by improving upon the existing technologies and its devices. SaveHeart, Inc. technology has already been acknowledged by five of the major surgeons worldwide. SaveHeart, Inc. revolutionary products will be superior in quality and performance since they provide the same functionality and performance as the native human heart valve. The first product that will be produced and sell after FDA approval has the potential to sell billions worldwide.

3. Keys to Success

The keys to success for SaveHeart, Inc. are as follows:

1. Initial capitalization obtained among founders (\$902,500).
2. 2nd round of funding in September '02 by Genesis Corp. (confirmed).
3. Recruiting top-notch CEO prior to third round financing.
4. Obtain FDA on the SaveHeart Aortic Valve (SAV) by June '06.
5. Start production of SAVs for 96 listed patients direct after FDA approval.
6. The ability to generate early revenue from non-regulated markets in Australia.
7. Merge our technology and application to a major medical device corporation or start producing.
8. Successful implementation of sales and marketing Australia managed care market to obtain a minimum 7% market share in the second full year of sales to reach \$ 20 million in revenue.

9. Release of new products: SaveHeart Mitral Valve (SMV) and the SaveHeart Bicuspid Valve (SBV).
10. Successful implementation of sales and marketing plan to US, Europe and Asia managed care market to obtain a minimum 18% market share world wide.

4. Company Summary

The original idea to grow heart valves through tissue engineering came in 1998 from two postgraduate students Biomedical Engineering of Swinburne University of Technology. To realise this idea one cardiac surgeon, with a broad background on the technique used was recruited and successively two other specialists were brought in: a microbiologist and a developer/designer who had years of experience in this field and participated with one of the current market leaders. With these five specialists the company SaveHeart, Inc. was founded and started with the development of its first product. Funding of the two postgraduates came from Swinburne University of Technology and on agreement Swinburne Knowledge has 5% equity in the company SaveHeart, Inc. In return the company has protection of intellectual property and free access to its infrastructure and R&D facilities like laser, microscopes and compressors. In this period animal trials were conducted and the promising results published in papers and conferences.

In July 2002 the founders raised \$ 902,500 among themselves and relatives. The achievement of the FDA approval is the main objective in the present business plan since without it the company will not be able to sell its products. There are several stages to finalise this approval: phase I- animal trials, phase II-human trails, phase III- trials large groups for statistic data. At the beginning some of the founders will be employed as part-time but all will be fully employed after FDA is obtained. All the resources will be initially invested to continue and succeed the FDA process, and to promote SaveHeart, Inc. first product.

SaveHeart, Inc. will receive a second round of funding in September 2002. On agreement SaveHeart, Inc. new technology has been licensed to a larger medical company, Genesis Corp. This company will own a 10% of the SaveHeart shares while SaveHeart, Inc. will receive an amount of \$800.000 in return and more Intellectual Property protection. The money will mainly be invested to continue running the company to July '03 when new investors are expected to join the Company.

FDA-approval will be obtained in four years from the present (July 2006 estimated) and by that time the company will have 96 patients listed(currently 26 patients listed) to receive the implantation of a SAV valve which will mean a direct sale of \$7.7 million. SaveHeart, Inc. is currently looking for an A\$ 4.65 million injection from private investors to increase production to get though the different stages FDA approval (phase I-III), in the meantime SaveHeart, Inc. will recruit patients though a promotion campaign, establish a company

identity and continue R&D on other future products. It is very likely that SaveHeart, Inc. will merge with a gorilla direct after FDA. If the decision to produce and sell the SAVs is made, it is likely that the company will have a profit of \$32.9 million by the third year of sales .

SaveHeart, Inc. will develop and market its products eventually through multiple distribution channels both foreign and domestic from 2007. The company just started FDA approval trails (preclinical phase) on its first final product and results on performance and quality proved to be superior to existing alternatives. It is now seeking to establish its corporate identity in the medical products field. Growth strategy calls for one joint venture license as well as the following objectives:

1. Establish corporate identity, brand names and trademarks.
2. Establish a medical advisory board.
3. Build staff, infrastructure, and retain consultants for trial and compliance issues.
4. Conduct animal trials on new product (SaveHeart Mitral Valve).
5. Prepare for FDA clinical trials on this new product (SMV).
6. Continue R & D and product development.
7. Explore options for 4th round financing (venture capital, corporate alliance, licensing, and public offering) to maximize value to shareholders.

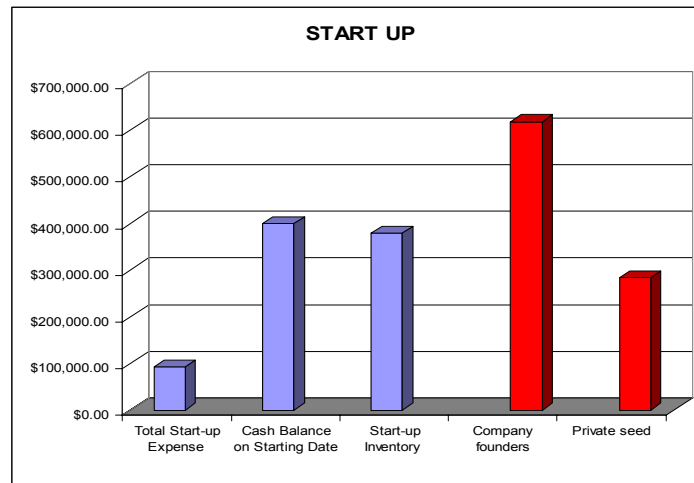
Note: Management believes that accelerated FDA approval process will be available on future products like the SMV (mitral heart valve) device since it involves only modifications on the recently developed SAV device. There is past precedent in such approvals (in an average of 3 months) in documented cases.

4.1 Start-up Summary

The key elements in the Start-up plan for SaveHeart, Inc. are:

1. The establishment of Corporate Identity.
2. Funding of additional capital raising alternatives.
3. Salary for staff, managers and founders.
4. Formulation of Strategic Plan.

\$ 902,500 was raised from the 5 founders of SaveHeart, Inc. This funding came in July 2002 and the investments have either been completed successfully or are in the final process of completion. These are treated purely as start-up expenses to continue FDA though the pre-clinical phase. Part of the start-up capital and a second round of funding in September 2002 is required to reach the first phase of FDA approval. This second round of funding will come through the sell of 10% of the company to a bigger medical company, Genesis Corp. The capital obtained will be \$800,000 and this strategy will also provide further IP protection (Appendix 4).



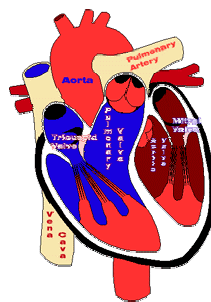
4.2 Company Locations and Facilities

SaveHeart, Inc. business offices are at 523 Burwood Road, Hawthorn in Melbourne, Australia. Phone is +61 3 914 5573. Fax is +61 3 914 5573. These offices are leased month-to-month on a temporary basis. This business plan calls for the establishment of corporate offices, expansion of R&D facilities, and prototype and small-run manufacturing facilities. SaveHeart, Inc. Web page is: www.saveheart.d2g.com.

5. Products

5.1 Introduction

Human heart is divided into four chambers, two ventricles and two atria. Between each atrium and ventricle on one side there is a valve control the flow from the atrium to the ventricle not the opposite way (mitral valve on the left side and tricuspid valve on the right side). Another two valves, the pulmonary and aortic, are placed at the orifices of the aortic and pulmonary arteries respectively.



Valve disease occurs when a valve doesn't work the way it should. If a valve doesn't open all the way, less blood can move through the smaller opening. If a valve doesn't close tightly, blood may leak backward. These problems may mean the heart has to work harder to pump the same amount of blood. Or blood may back up in the lungs or body because it's not moving efficiently through the heart. In this case the valve has to be replaced or repaired.

SaveHeart, Inc. uses the most recent technology to produce the SaveHeart, Inc. Aortic (SAV) valve which uses a particular Tissue Engineering Technology. This technology ensures a lot of advantages from the practical point. As the autologous tissue engineered valve is a living, viable structure, it will demonstrate the normal biological mechanisms for growth and development, which translates in a greater durability. SaveHeart, Inc. product is completely biocompatible so there are minimal risk for infection and thromboembolic complications. Although the technology of tissue engineering is considered new, it is greatly accepted that it will take the major role in the medical field especially in tissue and organ replacements. Up till now the role of this technology is still limited as laboratories require cost effective and time efficient systems that provide the appropriate quality and quantity.

The technology ideated and developed by SaveHeart, Inc. is able now to introduce Tissue Engineering products in various fields and with maximum safety and compatibility.

5.2 Product description

Following is a general description of products for first 5 years after FDA approval.

5.2.1 SaveHeart, Inc. Aortic heart Valve (SAV)

This valve will be SaveHeart, Inc. first product as tissue engineering substitutes. It will be completely compatible with the patient needing no further medications or any later investigations. That in turn will allow every patient to regain its normal life and activities.

5.2.2 Future products

- 1- Mitral and Tricuspid heart valves
- 2- Skin graft which has its medical importance in cosmetic surgery especially in cases of severe burns.
- 3- Liver tissue as the need of liver transplantation is increased every year with more incidence of liver failure from various diseases especially virus C hepatitis and hepatocellular carcinoma.

5.3 Technology

Tissue engineering is an interdisciplinary field which applies the principles of engineering and the life sciences toward the development of biological substitutes that restore, maintain, or improve tissue function.

Currently, valve replacement represents the most common mode of surgical therapy for the treatment of end stage valve disease. Valve replacement therapy is efficacious and substantially reduces the morbidity and mortality associated with valvular dysfunction.

In the market now there are two categories of valve substitutes which are mechanical valves and tissue valves. Although the mechanical valves function well, each has its inherent limitations. The major drawback of using mechanical valves is the fact that they are foreign bodies so carrying more risk for infection and thromboembolic complications. So they require administration of life long anticoagulant drugs with its associated morbidity. In the other hand the tissue valves may not have the same complications associated with mechanical ones but still have one major complication which is low durability.

SaveHeart, Inc. uses tissue engineering technology. The principle of this technology is to harvest autologous heart valve cells and grow them *in vitro* to obtain into a complete heart valve. To do this some steps need to be followed: 1) cell harvest 2) *in vitro* cell culture and expansion 3) cell seeding 4) tissue engineered construct implantation 5) evaluation of tissue engineered product.

- 1- Cell harvest. This procedure is done under general anesthesia with the aid of a cardiothoracic surgeon for obtaining the valve cells. Cells are then handled in complete sterilized conditions to avoid any contamination. Then cells are cultured in tissue plates under specific conditions until the cells grow and expand.
- 2- After the cell expansion they are treated in specific culture media and then seeded on the tissue scaffold. SaveHeart, Inc. uses a biodegradable scaffold. This scaffold has completely match with the native aortic valve, thus the company uses a Fused Deposit Modeling (FDM), which is a rapid prototyping process that integrates computer aided design, polymer science, computer numerical control and extrusion technologies to produce three dimensional solid objects directly from a CAD model using a layer by layer deposition of molten thermoplastics extruded through a very small nozzle.
- 3- The cells and the scaffold are then left in a bioreactor for a period of about 12 weeks to obtain the valve.
- 4- The aortic valve then undergoes a lot of experiments either *in vivo* or *in vitro* to ensure its compatibility and durability.
- 5- The valve then can safely replace the diseased Aortic valve.

5.4 Ethical issues

SaveHeart, Inc. has ideated and developed a technique that aims to produce a totally bio-compatible heart valve, without the use of any animal tissue. Also, SaveHeart, Inc. does not intend to use any kind of genetically modified cells nor stem cells, recognising that their use still raise many ethical and scientific issues. SaveHeart, Inc. will use and grow recipient's own cells on a totally bio-compatible scaffold, with the only aim of producing the best heart valve for the patient interest. SaveHeart, Inc. does not intend to create a "tissue bank", nor does intend to keep patient's cells for its or others research. Through the "SaveHeart, Inc. Private Policy" and "SaveHeart, Inc. Ethical Policy" the Company takes all the responsibility of respecting those scientific and ethical issues.

5.5 Intellectual Property

The technology behind SaveHeart, Inc. Heart Valve (SAV) has been patented in Australia through a Provisional Patent in late 2001. An International (PCT) application will be submitted at the end of 2002. Since the technology was developed by two students of Swinburne University of Technology, Swinburne Knowledge has 5% equity in the SaveHeart, Inc. Company.

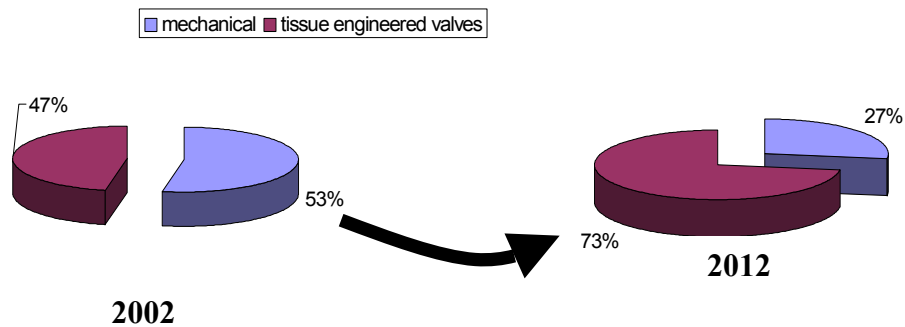
Intellectual Property is a major issue since SaveHeart, Inc has introduced a revolutionary technique in heart valve replacements. In late 2002, thus, 10% of the SaveHeart shares will be sold to a larger medical company, Genesis Corp.

6. Market Analysis

Cardiovascular diseases represent still a major cause of death worldwide, in particular in the United States where in year 2001 they caused 54% of the deaths. Heart valve defects are one of the major causes of cardiovascular diseases and their replacement is the most common and effective type of surgery, covering 84% of surgery cases in Australia and 91% in the US. The worldwide artificial heart valve industry is estimated to worth \$ 260 billion. This industry will significantly grow in the next ten years do to many social customs that enhance the probability of cardiovascular diseases, such as smoking, high-cholesterol diets etc. Australia's market is estimated to be 10% of the worldwide one, thus the national artificial heart valve industry is worth \$ 23 billion, \$2.5 billion of which are directly involved in the heart valve manufacture industry.

A recent statistics analysis on cardiac surgery in Australia has shown that among the 3868 cases of heart valve replacements, 59% have been of aortic valve. The aortic valve replacement industry represents thus the major segment of the heart valve industry, and is in this segment that SaveHeart, Inc. will start its business. In 1995, among the 3868 cases of

heart valve replacements, 76% have been mechanical valve and 24% tissue engineered (TE) heart valves. Tissue engineering is becoming more used every year, for example in Australia in year 1993-1994 the TE valve replacement increased by 41%, whereas the mechanical valve replacement decreased of 10%. This trend is confirmed in a more recent statistic analysis in the United States, where only 53% of heart valve replacements were mechanical. TE valve replacement is becoming the most important competitor for the “classic” mechanical valve, now having almost half of the U.S. market. The US market is expected to increase from the actual 47% to 70 % in the next 10 years.



The reason for such a growth can be found in the various advantages that this technique presents:

- Less risk for body rejection and greater compatibility of the valve
- Superior performance
- Superior clinical outcomes
- Dramatic decrease in the patient drug use and related costs
- Less ethical issues
- No need for long term valve replacement

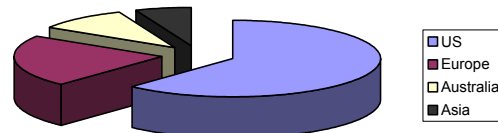
The technique that SaveHeart,Inc. has ideated and developed is totally new and revolutionary. It is a novel and very reliable tissue engineering technique that is not currently available in the heart valve market. Thus, within the “tissue engineering” market, SaveHeart,Inc. will gain a specific segmentation, that will significantly grow every year. SaveHeart,Inc. target is to reach 7% of the worldwide market in 2008 (after the third year of sell) and 18% in 2012.

6.1 Market segmentation

The heart valve industry involves many participants, mainly biochemical and medical laboratories, hospitals, private medical companies and public/private Universities.

SaveHeart,Inc. target is to approach all those participants at the promotional level, and private clinics first and public hospitals secondly at the sell level. Potential customers are spread worldwide, but the main markets are likely to be Australia, North America, Asia and Western Europe.

The current market is divided in the following participants



a) Australia

Australia has 10% of the heart valve replacement market, which is worth \$2.5 billion and will increase significantly in the next ten years, reaching \$3.2 billion. In the first year of producing and sell, SaveHeart,Inc. will market and sell in Australia, where the market has large margins of profit due to a lack of direct competitors. Since in Australia heart valve tissue engineering is a major area of research, SaveHeart,Inc. will invest \$ 112,000 in promoting the Save Heart Valve (SAV) in 2002, and will increase the promotion in the following years.

b) United States

Most of the heart valve manufacturing market is located in United States, where the industry reached \$260 billion in 2002 and is expected to grow in the following years, approaching the \$300 billion in year 2015. This industry involves heart valve manufactures, that is medical companies, as well as instrumentation companies that provide the appropriate technology, and major drug companies such as Byron, Glaxo and Roche which are involved in the maintenance and cure of the implanted heart valve. Since 62 % of this market is located in US, SaveHeart,Inc. will start selling its product in the US by the second year of the sell activity (2007).

c) Europe

95% of the European companies involved in heart valve production and sell are US-satellite companies that have been established in the last 5 years. The European market is smaller (22%), less established than the US one and also more influenced by the ethical issues that tissue engineered products arise. For this reason, SaveHeart,Inc. will first focus on the US market, gain trust and expertise and than approach the European market.

d) Asia

At the moment, Japan is the only country involved in the heart valve manufacture industry, with 6% of the market (2002). SaveHeart,Inc. plans to reach this market in 2008. The market will expand in the following years, spreading to other countries such as India and China. In the future, SaveHeart,Inc. plans to reach this market as well, through a specific pricing strategy that will make the SaveHeart,Inc. product available for those markets as well.

6.2 The competition

SaveHeart,Inc. does not have a direct competitor since it had developed a new and revolutionary technology, which is not currently used by any other heart valve manufacturer. The competitors for SaveHeart,Inc. are, thus, manufacturers that use tissue engineered techniques, such as allograft and xenograft techniques, which represent currently 47% of the heart valve market. As previously outlined, though, those techniques have important disadvantages that SaveHeart,Inc. technique does not have, which explain the enormous potential for this new technique.

Currently there are several leading mechanical heart manufacturers, as well as established tissue engineered heart valve manufacturers;

Mechanical heart valve manufacturers:

- Baxter Healthcare
- Sutter Biomedical Inc
- Pemco Inc.
- Ceratomic
- Daggett

Tissue engineered heart valve manufacturers:

- Baxter-Edwards Inc.
- Tissuemed Ltd.
- Shiley Inc.
- St. Jude Medical
- CryoLife

Each company listed has developed a specific technique for the fabrication of adult heart valve that differs for the material used (eg titanium, polymer scaffolds etc.) and for the cell growth technique. Although tissue engineered heart valve have improved the performance and compatibility of the mechanical heart valve, many disadvantages for the existing techniques still remain. The need of a technology able to overcome those disadvantages is thus thought to be urgent, as well expressed by Dr Niklason in a recent American Medical Association report (JAAA 2001):

“ donor shortages increase every year and many patients die while waiting for an heart valve (...). Mechanical devices cannot perform all of the function and therefore provide only temporary benefit (...). The use of tissue engineered organs may increase the organ pool, but substantial scientific and immunological hurdles currently limit their use”

Following is a review of the performances and limitation of the techniques currently available in the market.

Mechanical heart valves

This kind of heart valve was the only alternative to heart valve transplantation until late '80 and still represent a very common alternative to it. The main advantage they offer is a long-term durability and the ease of reproducible manufacturer. Since those valves are made of metal, ie a non-biological material, the main disadvantage they produce is the need of lifetime drug to allow the heart valve be "accepted" by the body. Rejection is not the only problem, though. The patient needs continuous monitoring, which leads to high costs and repeated operations.

Tissue engineered heart valves

This kind of heart valves are derived either from human cadavers or animals, thus one of the main disadvantage they have is a need of a "xenograft" source. The technique involves also the use of genetically modified cells and the use of stem cells. The main advantage of TE heart valves is their biocompatibility, which leads to less thromboembolic effect, lower risk of immune response, infection or disease transmission. Beside those advantages, TE heart valves that are currently available don't have long-term durability and need to be replaced every 7-10 years, with additional costs and effort from the patient's side.

The only technology that is commercially available that can compete with SaveHeart, Inc. is owned and marked by CryoLife[®], with the commercial name of SynerGraft[®]. This US based company was established in 1984 and is currently the leader in heart valve manufacturing. CryoLife[®] markets and distributes its products in 42 countries worldwide through two subsidiaries, CryoLife[®] International and CryoLife[®] Europa.

SynerGraft[®] technology centres around the removal of antigens from human and animal tissue leaving a matrix (collagen) that has the potential to be repopulated with the recipient's own cells. The technology developed has than the capability of "reproducing" a human heart valve through the use of an animal heart valve as a scaffold. SaveHeart, Inc. is presenting a technology that is able not only to produce a "copy" of an adult heart valve but has also the unique and revolutionary capability to grow. This means that the recipient can be an adult but a child as well, introducing a scientific capability that was, so far, only foreseen. The main advantages of the SaveHeart, Inc. technique are thus:

- less ethical issues (no use of animal and human modified tissues)
- no use of modified cells (which can lead to unknown and unpredictable long-term effects)
- no use of stem cells
- availability for children
- capability of the SAV to grow

CryoLife[®] has a warranty program to encourage customer interest. The Company provides a 10-year limited replacement warranty due to structural deterioration and a lifetime limited replacement warranty against explant due to endocarditis and thromboembolic events. SaveHeart, Inc. has developed a technology extremely reliable and will guarantee its products for a lifetime.

Being CryoLife[®] the main competitor, SaveHeart, Inc. promotion, marketing and sale strategy will focus in directly competing with it. The need of an extended and prolonged promotion strategy is extremely important in order to obtain the credibility and trust of future customers.

7. Strategy and implementation Summary

After obtaining FDA approval, SaveHeart, Inc. will start the Australia market first. However, since the FDA approval will be accepted in US, after a year of sales in Australia, a new laboratory will set up in US. Afterwards, the product will spread into countries in Europe and Asia.

In order to prove the superiority of the SaveHeart, Inc. product, the company follows the international Guidelines for Reporting Clinical Results. Standards for defining and reporting complications were proposed by the Ad Hoc Liaison Committee for Standardising Definitions of Prosthetic Heart Valve Morbidity, a joint committee of the American Association for Thoracic Surgery (AATS) and the Society of Thoracic Surgeons (STS). The complications determined to be of critical importance in the 1996 guidelines are summarised as follows:

1. *Structural valvular deterioration* refers to any change in function of an operated valve resulting from an intrinsic abnormality causing stenosis or regurgitation.
2. *Nonstructural dysfunction* is a composite category that includes any abnormality resulting in stenosis or regurgitation of the operated valve that is not intrinsic to the valve itself exclusive of thrombosis and infection.
3. *Valve thrombosis* is any thrombus, in the absence of infection, attached to or near to an operated valve that occludes part of the blood flow path or interferes with function of the valve.
4. *Embolism* is any embolic event that occurs in the absence of infection after the immediate perioperative period (when anaesthesia-induced unconsciousness is completely reversed).
5. *Bleeding event* (formerly anticoagulant haemorrhage) is any episode of major internal or external bleeding that causes death, hospitalisation, or permanent injury (eg, vision loss) or requires transfusion.
6. *Operated valvular endocarditis* is any infection involving an operated valve.

7.1 Sales strategy

SaveHeart, Inc. Aortic Valves are targeted first to reach the top notch of the market and then to spread out to general public. SAV is a product that differs from the existing heart valve alternatives, which are target for managed-care markets that stress lowest cost for the total treatment parameters.

SAV heart valve will hit the worldwide market in 2012. Following is a brief summary of how the company predicts its market to grow after obtaining the FDA approval (2006).

2006 – Sales start in Australia

2007 – Sales reach North America (United State, Canada); an US-based laboratory is created.

2008 (Early) – Sales reach Europe (Italy, Germany); an EU-based laboratory is created.

2008 (Late) – Asia (Singapore, Japan, Taiwan)

7.2 Price strategy

SaveHeart, Inc. Aortic Valve will adapt in the first years the “Rolls Royce” Pricing Strategy where both quality and price are set very high. The valve will be sold to surgeons as a premium product on request. The price at release will be set to AUS \$80,000. In later years when market expands and competitors imitate, a multiple-pricing strategy will be used. SaveHeart, Inc. products will have different prices according to production and marketing costs. Constant monitoring of prices and operating costs are required to ensure profits.

7.3 Distribution Strategy

SaveHeart Aortic Valve is not a mass production product. Aortic Valve will only be manufactured on request by authorised surgeon. Therefore, it is not necessary to implement distribution strategy.

7.4 Promotion Strategy

Promotion to public is the life of SaveHeart, Inc. business. SaveHeart Aortic Heart Valve (SAV) has been acknowledged to be the ideal artificial heart valve by five of the most famous heart surgeons in the World, namely:

| Doctor | Hospital/Organization |
|----------------------|---------------------------------------|
| Dr. Nick Riviera | Springfield General Hospital (US) |
| Dr. Khaled Yousif | Albred Hospital Melbourne (Australia) |
| Dr. Luigi De Stefani | Universit "La Cattolica" (Italy) |
| Dr. Michael DeBaker | Boston Hospital (US) |
| Dr. John Ross | Cleveland Hospital (US) |

SaveHeart, Inc. has allowed those doctors to observe the process of generation of the SAV, as well as the results of some in vitro and in vivo tests, under the supervision of Dr Khaled Yousif. Results will be published according to the guidelines previously described (Section 7) in journals (International Journal of Artificial Heart Valve) and conferences papers (International Annual Conferences of Artificial Organs).

Promotion strategy also includes attending international conferences, organising special dinner events and public promotion and divulgation through para-medical TV programs.

Insurance companies will also be a SaveHeart, Inc promotion target. SaveHeart, Inc. has done a cost comparison with currently available products (Appendix 2). The comparison outlines that SAV valve not only does not have hidden costs but also can provide long-term money saving, due to the lack of the need of extra therapies. This can reduce the Health Insurance Claims dramatically.

7.5 Strategic Alliance

SaveHeart customers are primary doctors, not patients. Establishing good relationships with doctors is a crucial process. Strategic Alliance with hospitals that has famous heart surgeon is the best option. It is also possible to introduce our product to insurance company, for example Australia Unity, NHIC. The potential strategic alliances are listed in Appendix 3.

8. Management summary

SaveHeart, Inc. is a VIC State "C" corporation.

Its founding shareholders and their responsibilities are:

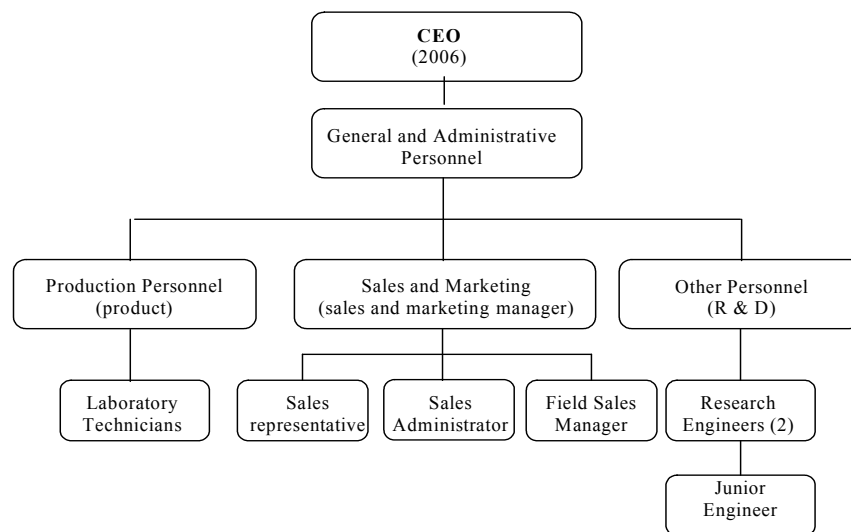
| | |
|-----------------------------|-----|
| Ihab El-Katatny (Finance) | 20% |
| Luisa Filliponi (Marketing) | 20% |
| Toby Lai (Sales) | 15% |
| Bas Damen (Manager) | 15% |
| Khaled Yousif(R&D) | 25% |

| | |
|------------------------------------|-------|
| Swinburne Knowledge and Innovation | 5% |
| | <hr/> |
| | 100% |

Genesis Corp. 10% of total (from September 2002)

8.1 Organizational Structure

SaveHeart, Inc. will have to recruit a CEO on the longer term, whose job it is to give direction to the five different department managers. Since during the FDA phase no sales are planned different tasks will be combined and Finance, Sales and Marketing will work part-time during this period. Number of employees involved at the moment is six. After the FDA phase SaveHeart, Inc. will have a full board and from that period a top notch CEO is needed, the company will have then a headcount of approximately 20 employees (Appendix 8).



8.2 Management Team

Bas Damen - General Manager

BME Mechanical Engineering, University of Groningen, Groningen the Netherlands. 2001

BBME–Biomedical Engineering, Fachhochschule Wilhelmshaven; Wilhelmshaven Germany. 2001

Meng (current) Multifunctional Bioreactor for in vitro Tissue Engineering, IRIS, Swinburne University of Technology.

Bas Damen began his studies mechanical engineering in Amersfoort at ROC de Amerlanden, which was followed by a double degree in both mechanical and biomedical engineering in Groningen (Netherlands) and Wilhelmshaven (Germany). With a strong background in medical and mechanical product design, he started his masters by research in the application to design bioreactors for in vitro Tissue Engineering.

Toby Lai - Sales Manager

Bachelor of Engineering / Bachelor of Comp Science, University of Melbourne, 2000.

PhD (current) in Fluid Mechanical Engineering, IRIS, Swinburne University of Technology.

Toby Lai has great understanding in the area of Sales. He has been working as a Sales and Trainee Manager for over five years before commencing his Scholarship Degree funded by his company. He has been awarded the best Junior Salesman after working in the department store for 6 months. He has been awarded as the best Salesman for three consecutive years. His understanding of sales and promotion will allow SaveHeart to maximise the sales and promotion.

Ihab Elkatatny - Financial manager

B.Sc. Degree (Hons) in Fluid Mechanics, Suez Canal University, (Egypt) 1986.

M.Eng. Degree. Swinburne University of Technology 1996.

Ihab Elkatatny has several years of experience in fluid mechanics research applied within the field of industrial and mechanical engineering. He also has a strong background in numerical analysis using difference Computational fluid dynamics codes and post-processing computer packages.

Luisa Filipponi – Promotion and Marketing

BSc(Hons), Chemistry, University of Bologna (Italy), 2001.

PhD(current), Cell-cell interaction in polymer microspheres, IRIS, Swinburne University of Technology.

Luisa Filipponi graduated in early 2001 in Chemistry, specialising in Organic Chemistry. During her undergraduate studies she spent one year at the Universidad Complutense de Madrid (Spain). After graduation she worked for a tissue engineering Italian company, FIDIA-FAB S.p.A., ideating and producing new scaffolds for tissue regeneration. The work was patented in July 2001. In February 2002 she was awarded a SPIRS scholarship at Swinburne University to conduct her PhD that started in March 2002. The research she will be doing centres on the fabrication of new polymeric and biocompatible scaffolds for tissue regeneration.

Khaled Ebaid Yousif.-Research and Development Manager

Bachelor in Medicine,Cairo University (Egypt) 1986.

Master Degree in Diagnostic radiology ,Cairo University (Egypt) 1999.

PhD (current), Coronary Artery Bypass Graft Modifications, IRIS

Khaled Ebaid began his carrier in tissue engineering at IRIS and is currently working in the project of developing tissue engineering coronary artery bypass graft. He worked for five years in diagnostic Radiology department at the Cancer Institute in Cairo, with special interest of diagnosing cardiac diseases.

9. Financial Plan

The size of the market and the value of the patent will allow several expansion strategies such as mergers, acquisitions, roll-ups or IPO. Furthermore, historically investments of \$3 to \$5 million are common for similar companies. Therefore, after successfully completing the start and seed stage a second round of venture funding is potentially available in the \$5 million range at the early stages of the plan.

9.1 Important Assumptions

The following are the financial assumptions which the plan is based on.

| General Assumptions | | | | | | | |
|----------------------------|--------|--------|--------|--------|--------|--------|--------|
| | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
| Short-term Interest Rate % | 10.00% | 10.00% | 10.00% | 10.00% | 10.00% | 10.00% | 10.00% |
| Long-term Interest Rate % | 9.00% | 9.00% | 9.00% | 9.00% | 9.00% | 9.00% | 9.00% |
| Tax Rate % | 30.00% | 30.00% | 30.00% | 30.00% | 30.00% | 30.00% | 30.00% |
| Inflation% | 3.00% | 3.00% | 3.00% | 3.00% | 3.00% | 3.00% | 3.00% |
| Personnel Burden % | 15.00% | 15.00% | 15.00% | 15.00% | 15.00% | 15.00% | 15.00% |

9.2 Break-even Analysis

Calculated break-even Maintenance point for sales once full management staffing and facility costs are reached.

| Break-even Analysis: | |
|--------------------------------|--------------|
| Quarterly Units Break-even | 9 |
| Quarterly Sales Break-even | \$720,000.00 |
| Assumptions: | |
| Average Per-Unit Revenue | \$80,000.00 |
| Average Per-Unit Variable Cost | \$1,850.00 |
| Estimated Quarterly Fixed Cost | \$640,000.00 |

A manufacturing cost of \$1,850.00 per unit includes all materials and labor for assembly. A sales price of \$80,000.00 per unit is based on company sales through distribution to be achieved primarily in the Australian market. The break-even unit target is 9 valves per quarter or \$720,000.00 of direct sales (Appendix 7).

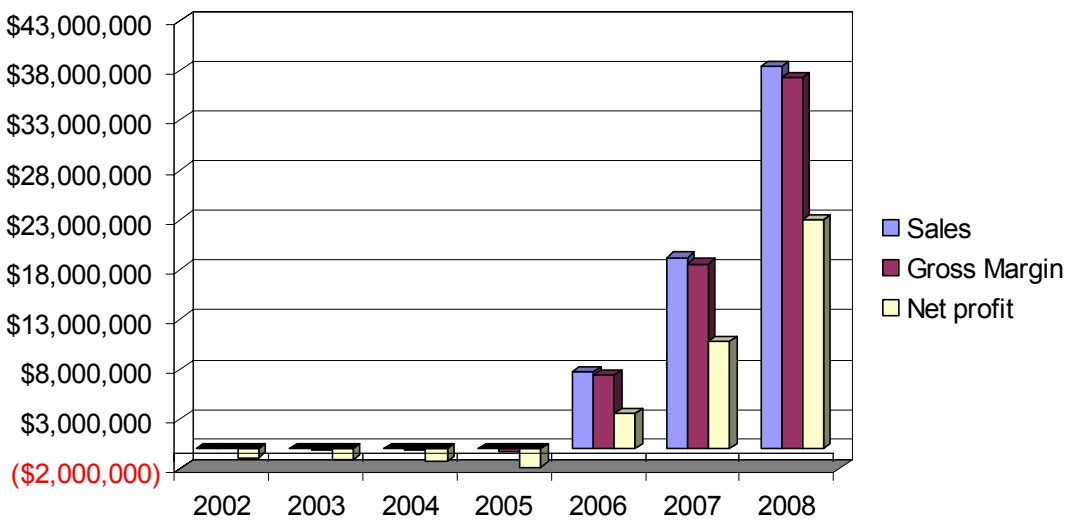
Break-even Analysis



9.3 Projected Profit and Loss

As expected the profit in the first four years is not applicable however the company is potentially profitable in year five if the FDA approval can be obtained. The third year after approval, an 85% gross margin can be achieved with \$23 million in profit reflecting excellent company performance and the potential of such a plan.

Highlights



| Profit and Loss | | | | |
|----------------------------------|-----------------------|-------------------------|-------------------------|-------------------------|
| | 2002 | 2003 | 2004 | 2005 |
| Sales | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Production Payroll | \$30,000.00 | \$32,500.00 | \$35,000.00 | \$60,000.00 |
| Direct cost of sales | \$36,000.00 | \$75,600.00 | \$79,380.00 | \$166,698.00 |
| Total Cost of Sales | \$66,000.00 | \$108,100.00 | \$114,380.00 | \$226,698.00 |
| Gross Margin | (\$66,000.00) | (\$108,100.00) | (\$114,380.00) | (\$226,698.00) |
| Gross Margin % | | | | |
| OPERATING COST: | | | | |
| Sales and marketing expenses: | | | | |
| Payroll | \$30,000.00 | \$30,000.00 | \$70,000.00 | \$110,000.00 |
| Advertising/promotion | \$75,000.00 | \$150,000.00 | \$250,000.00 | \$400,000.00 |
| Travel | \$25,000.00 | \$35,000.00 | \$50,000.00 | \$60,000.00 |
| Miscellaneous | \$12,000.00 | \$12,000.00 | \$15,000.00 | \$20,000.00 |
| Other | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Total Sales and marketing | \$142,000.00 | \$227,000.00 | \$385,000.00 | \$590,000.00 |
| Sales and marketing % | | | | |
| General and Administrative | | | | |
| Payroll | \$15,000.00 | \$15,000.00 | \$35,000.00 | \$110,000.00 |
| Payroll Burden | \$19,500.00 | \$24,300.00 | \$34,800.00 | \$56,550.00 |
| Depreciation | \$40,000.00 | \$40,000.00 | \$40,000.00 | \$40,000.00 |
| Rent | \$84,000.00 | \$86,520.00 | \$89,115.60 | \$91,789.07 |
| Insurance | \$20,000.00 | \$20,000.00 | \$25,000.00 | \$30,000.00 |
| FDA & Legal expenses | \$250,000.00 | \$320,000.00 | \$300,000.00 | \$410,000.00 |
| Leased equipment and | \$10,000.00 | \$10,000.00 | \$10,000.00 | \$10,000.00 |
| Other | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Total General and | \$438,500.00 | \$515,820.00 | \$533,915.60 | \$748,339.07 |
| General and Administrative % | | | | |
| Other expenses | | | | |
| Payroll | \$55,000.00 | \$84,500.00 | \$92,000.00 | \$97,000.00 |
| Research and development | \$50,000.00 | \$50,000.00 | \$50,000.00 | \$50,000.00 |
| Contract/consultant | \$20,000.00 | \$20,000.00 | \$20,000.00 | \$20,000.00 |
| Other | \$10,000.00 | \$10,000.00 | \$10,000.00 | \$10,000.00 |
| Total Other expenses | \$135,000.00 | \$164,500.00 | \$172,000.00 | \$177,000.00 |
| Other expenses % | | | | |
| TOTAL OPERATIONAL | \$781,500.00 | \$1,015,420.00 | \$1,205,295.60 | \$1,742,037.07 |
| Profit before interest and taxes | (\$781,500.00) | (\$1,015,420.00) | (\$1,205,295.60) | (\$1,742,037.07) |
| Interest expenses | \$90,250.00 | \$90,250.00 | \$90,250.00 | \$90,250.00 |
| Taxes incurred | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Net profit | (\$871,750.00) | (\$1,105,670.00) | (\$1,295,545.60) | (\$1,832,287.07) |
| Net Profit/Sales | | | | |

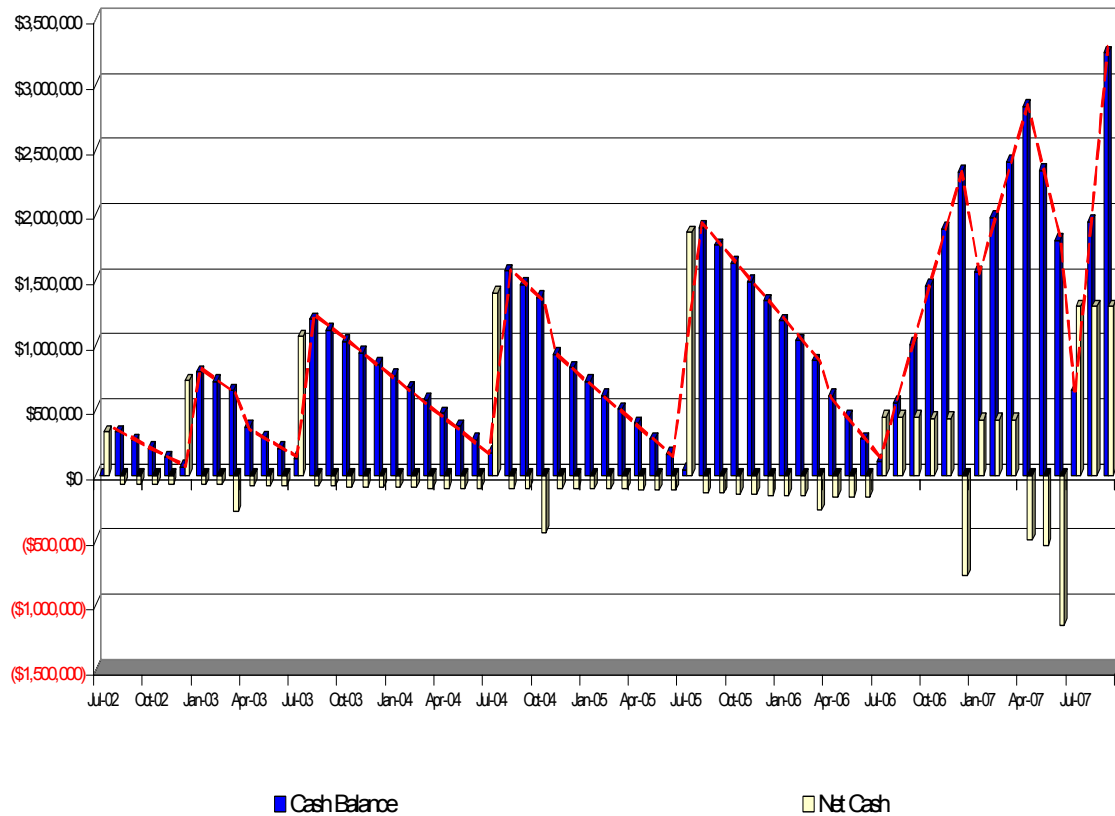
| Profit and Loss | | | |
|-------------------------------------|-----------------------|------------------------|------------------------|
| | 2006 | 2007 | 2008 |
| Sales | \$7,680,000.00 | \$19,200,000.00 | \$38,400,000.00 |
| Production Payroll | \$105,000.00 | \$200,000.00 | \$270,000.00 |
| Direct cost of sales | \$175,032.90 | \$459,461.36 | \$964,868.86 |
| Total Cost of Sales | \$280,032.90 | \$659,461.36 | \$1,234,868.86 |
| Gross Margin | \$7,399,967.10 | \$18,540,538.64 | \$37,165,131.14 |
| Gross Margin % | 96.35% | 96.57% | 96.78% |
| OPERATING COST: | | | |
| Sales and marketing expenses: | | | |
| Payroll | \$250,000.00 | \$383,000.00 | \$535,000.00 |
| Advertising/promotion | \$750,000.00 | \$1,500,000.00 | \$2,500,000.00 |
| Travel | \$75,000.00 | \$100,000.00 | \$150,000.00 |
| Miscellaneous | \$25,000.00 | \$25,000.00 | \$25,000.00 |
| Other | \$0.00 | \$0.00 | \$0.00 |
| Total Sales and marketing | \$1,100,000.00 | \$2,008,000.00 | \$3,210,000.00 |
| Sales and marketing % | 14.32% | 10.46% | 8.36% |
| General and Administrative | | | |
| Payroll | \$261,000.00 | \$339,000.00 | \$407,000.00 |
| Payroll Burden | \$114,150.00 | \$163,950.00 | \$208,950.00 |
| Depreciation | \$100,000.00 | \$100,000.00 | \$100,000.00 |
| Rent | \$94,542.74 | \$120,000.00 | \$123,600.00 |
| Insurance | \$150,000.00 | \$200,000.00 | \$200,000.00 |
| FDA & Legal expenses | \$50,000.00 | \$50,000.00 | \$50,000.00 |
| Leased equipment and | \$30,000.00 | \$30,000.00 | \$30,000.00 |
| Other | \$0.00 | \$0.00 | \$0.00 |
| Total General and | \$799,692.74 | \$1,002,950.00 | \$1,119,550.00 |
| General and Administrative % | 10.41% | 5.22% | 2.92% |
| Other expenses | | | |
| Payroll | \$145,000.00 | \$171,000.00 | \$181,000.00 |
| Research and development | \$75,000.00 | \$120,000.00 | \$150,000.00 |
| Contract/consultant | \$50,000.00 | \$50,000.00 | \$50,000.00 |
| Other | \$20,000.00 | \$20,000.00 | \$20,000.00 |
| Total Other expenses | \$290,000.00 | \$361,000.00 | \$401,000.00 |
| Other expenses % | 3.78% | 1.88% | 1.04% |
| TOTAL OPERATIONAL | \$2,469,725.64 | \$4,031,411.36 | \$5,965,418.86 |
| Profit before interest and taxes | \$5,210,274.36 | \$15,168,588.64 | \$32,434,581.14 |
| Interest expenses | \$90,250.00 | \$0.00 | \$0.00 |
| Taxes incurred | \$1,536,007.31 | \$4,550,576.59 | \$9,730,374.34 |
| Net profit | \$3,584,017.05 | \$10,618,012.05 | \$22,704,206.80 |
| Net Profit/Sales | 46.67% | 55.30% | 59.13% |

9.4 Projected Cash Flow

In the first round of funding \$902,500.00 will be raised by the company founder and private seed. This will provide our start-up capital and running cost for first six months. Furthermore, In September 2002 a sale of 10% of the company's shares is expected to bring another \$800,000.00.

The second round financing will include a venture fund where \$4,650,000.00 over a three year period is needed to cover the company's expenses and FDA costs. If sales and profit hit target, further investment will not be needed and one of the exit strategies may be adopted (Appendix 5 & 6).

Cash (Planned)



| Cash Flow | 2002 | 2003 | 2004 | 2005 |
|---------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Cash Received | | | | |
| Cash from Operations: | | | | |
| Cash Sales | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Subtotal Cash from Operations | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Additional Cash Received | | | | |
| Sales Tax | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| New Current Borrowing | \$902,500.00 | \$0.00 | \$0.00 | \$0.00 |
| New Other Liabilities (interest-free) | \$800,000.00 | \$0.00 | \$0.00 | \$0.00 |
| New Long-term Liabilities | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Sales of other Short-term Assets | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Sales of Long-term Assets | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| New Investment Received | \$0.00 | \$1,150,000.00 | \$1,500,000.00 | \$2,000,000.00 |
| Subtotal Cash Received | \$1,702,500.00 | \$1,150,000.00 | \$1,500,000.00 | \$2,000,000.00 |
| Expenditures | | | | |
| Expenditures from Operations: | | | | |
| Cash Spent on Costs and Expenses | \$632,000.00 | \$829,120.00 | \$938,495.60 | \$1,308,487.07 |
| Wages, Salaries, Payroll Taxes, etc. | \$149,500.00 | \$186,300.00 | \$266,800.00 | \$433,550.00 |
| Payment of Accounts Payable | \$90,250.00 | \$90,250.00 | \$90,250.00 | \$90,250.00 |
| Subtotal Spent on Operations | \$871,750.00 | \$1,105,670.00 | \$1,295,545.60 | \$1,832,287.07 |
| Additional Cash Spent | | | | |
| Sales Tax | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Principal Repayment of Current | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Other Liabilities Principal | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Long-term Liabilities Principal | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Purchase Other Short-term Assets | \$610,000.00 | \$0.00 | \$335,000.00 | \$0.00 |
| Purchase Long-term Assets | \$0.00 | \$0.00 | \$0.00 | \$100,000.00 |
| Dividends | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Adjustment for Assets Purchased on | \$92,500.00 | \$0.00 | \$0.00 | \$0.00 |
| Subtotal Cash Spent | \$702,500.00 | \$0.00 | \$335,000.00 | \$100,000.00 |
| Net Cash Flow | \$128,250.00 | \$44,330.00 | (\$130,545.60) | \$67,712.93 |
| Cash Balance | \$128,250.00 | \$172,580.00 | \$42,034.40 | \$109,747.33 |

| Cash Flow | 2006 | 2007 | 2008 |
|---------------------------------------|-----------------------|------------------------|------------------------|
| Cash Received | | | |
| Cash from Operations: | | | |
| Cash Sales | \$7,680,000.00 | \$19,200,000.00 | \$38,400,000.00 |
| Subtotal Cash from Operations | \$7,680,000.00 | \$19,200,000.00 | \$38,400,000.00 |
| Additional Cash Received | | | |
| Sales Tax | \$0.00 | \$0.00 | \$0.00 |
| New Current Borrowing | \$0.00 | \$0.00 | \$0.00 |
| New Other Liabilities (interest-free) | \$0.00 | \$0.00 | \$0.00 |
| New Long-term Liabilities | \$0.00 | \$0.00 | \$0.00 |
| Sales of other Short-term Assets | \$0.00 | \$0.00 | \$0.00 |
| Sales of Long-term Assets | \$0.00 | \$0.00 | \$0.00 |
| New Investment Received | \$0.00 | \$0.00 | \$0.00 |
| Subtotal Cash Received | \$0.00 | \$0.00 | \$0.00 |
| Expenditures | | | |
| Expenditures from Operations: | | | |
| Cash Spent on Costs and Expenses | \$1,594,575.64 | \$2,774,461.36 | \$4,363,468.86 |
| Wages, Salaries, Payroll Taxes, etc. | \$875,150.00 | \$1,256,950.00 | \$1,601,950.00 |
| Payment of Accounts Payable | \$1,626,257.31 | \$4,550,576.59 | \$9,730,374.34 |
| Subtotal Spent on Operations | \$4,095,982.95 | \$8,581,987.95 | \$15,695,793.20 |
| Additional Cash Spent | | | |
| Sales Tax | \$0.00 | \$0.00 | \$0.00 |
| Principal Repayment of Current | \$0.00 | \$0.00 | \$0.00 |
| Other Liabilities Principal | \$0.00 | \$0.00 | \$0.00 |
| Long-term Liabilities Principal | \$902,500.00 | \$0.00 | \$0.00 |
| Purchase Other Short-term Assets | \$960,000.00 | \$1,725,000.00 | \$0.00 |
| Purchase Long-term Assets | \$250,000.00 | \$200,000.00 | \$0.00 |
| Dividends | \$930,000.00 | \$930,000.00 | \$930,000.00 |
| Adjustment for Assets Purchased on | \$0.00 | \$0.00 | \$0.00 |
| Subtotal Cash Spent | \$3,042,500.00 | \$2,855,000.00 | \$930,000.00 |
| Net Cash Flow | \$541,517.05 | \$7,763,012.05 | \$21,774,206.80 |
| Cash Balance | \$651,264.38 | \$8,414,276.43 | \$30,188,483.23 |

9.5 Exit Strategy

As part of its exit strategy SaveHeart, Inc. intends to merge with a ‘gorilla company’ after FDA approval. An alternative is to start producing and sell SAVs. In either way the investors will receive their money back, depending on how much the ‘gorilla company’ is willing to spend. In similar cases where biomedical companies merged after FDA approval investors got ten to twenty times their money back.

In the other case, that is if SaveHeart, Inc. starts to produce and sell after FDA approval its products, it will be even more than a merger. The world wide heart valve market will give the company free access to take over since the current alternatives are not even close in terms of durability, quality and performance. We foresee a revenue of \$38.9 million in the third year after FDA approval.

Appendix 1 SWOT Analysis

| | |
|---|---|
| STRENGTHS <ul style="list-style-type: none">• Revolutionary aortic heart valve with the unique capability of grow• Few direct competitors• No hidden costs• Lifetime product• Can be implanted on children | WEAKNESSES <ul style="list-style-type: none">• Little “clinical history”• Customer scepticism• Need of FDA approval |
| OPPORTUNITIES <ul style="list-style-type: none">• Billion dollar market• Expansion into new markets (US, Europe, Asia)• Technique applicable for other organ replacement | THREATS <ul style="list-style-type: none">• market invasion by new technologies• ethical issues• incorrect handling of the product |

Appendix 2 Cost Comparisons

The initial cost for SaveHeart, Inc Aortic Valve is AUS \$80,000. This is the cost for the doctor to purchase heart valve only. This does not include the cost for the operation. To show that the price for SAV is reasonable, it is necessary to compare the total cost with other artificial heart valve available in the market. That is the cost in a long run.

Heart valve replacement patients are 65 years old on average. According to National Centre for Health Statistics, 2001. 65 years old age group will have the life expectancy of 17.8 years. Therefore patient who has heart valve replacement will have to go through 17.8 years of post treatment such as constant visit to physician and Warfarin Anticoagulation.

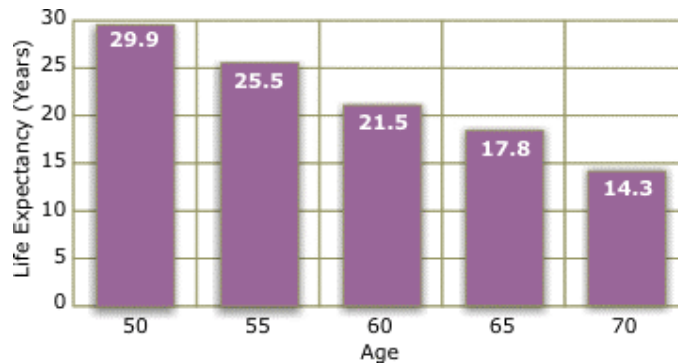


Figure 1 Life Expectancy for different age group

Normally for a Mechanical Artificial Heart Valve, on average it cost around \$15000. Due to the nature of mechanical item, Warfarin Anticoagulation (medication required for altering the properties of blood such that blood will not clot at the valve) is required for the rest of patient’s life. Also patients are required to visit physician to monitor the running of the heart valve, the number of visit for SaveHeart Valve patient will reduce by half. The cost for visiting to physician is \$50 per visit. A simple comparison between patients with SaveHeart Inc, Aortic Valve and Mechanical Valve are shown below.

| | SaveHeart Valve | | Mechanical Valve | |
|--------------------|-----------------|---------|------------------|----------|
| Heart Valve Cost | | \$80000 | | \$15000 |
| Drugs | First 2 months | \$820 | 420 per month | \$89460 |
| Visit to physician | 3 times a year | \$2670 | 6 times a year | \$5340 |
| Total | | \$83490 | | \$109800 |

In long run, the total cost for SAV is \$25000 lower than Mechanical Valve. Tissue Valve is not compare here because it is most likely that the Tissue valve require second replacement and the cost will be a lot more compare to Mechanical Valve. Therefore setting the price as \$80000 is reasonable.

Appendix 3 List of Potential Strategic Alliance

The hills Private Hospital
 John Hunter Hospital
 Lake Macquarie Private Hospital
 Liverpool Hospital

John Flynn Hospital and Medical Centre
 Mater Misericordiae Hospital
 Princess Alexandra Hospital

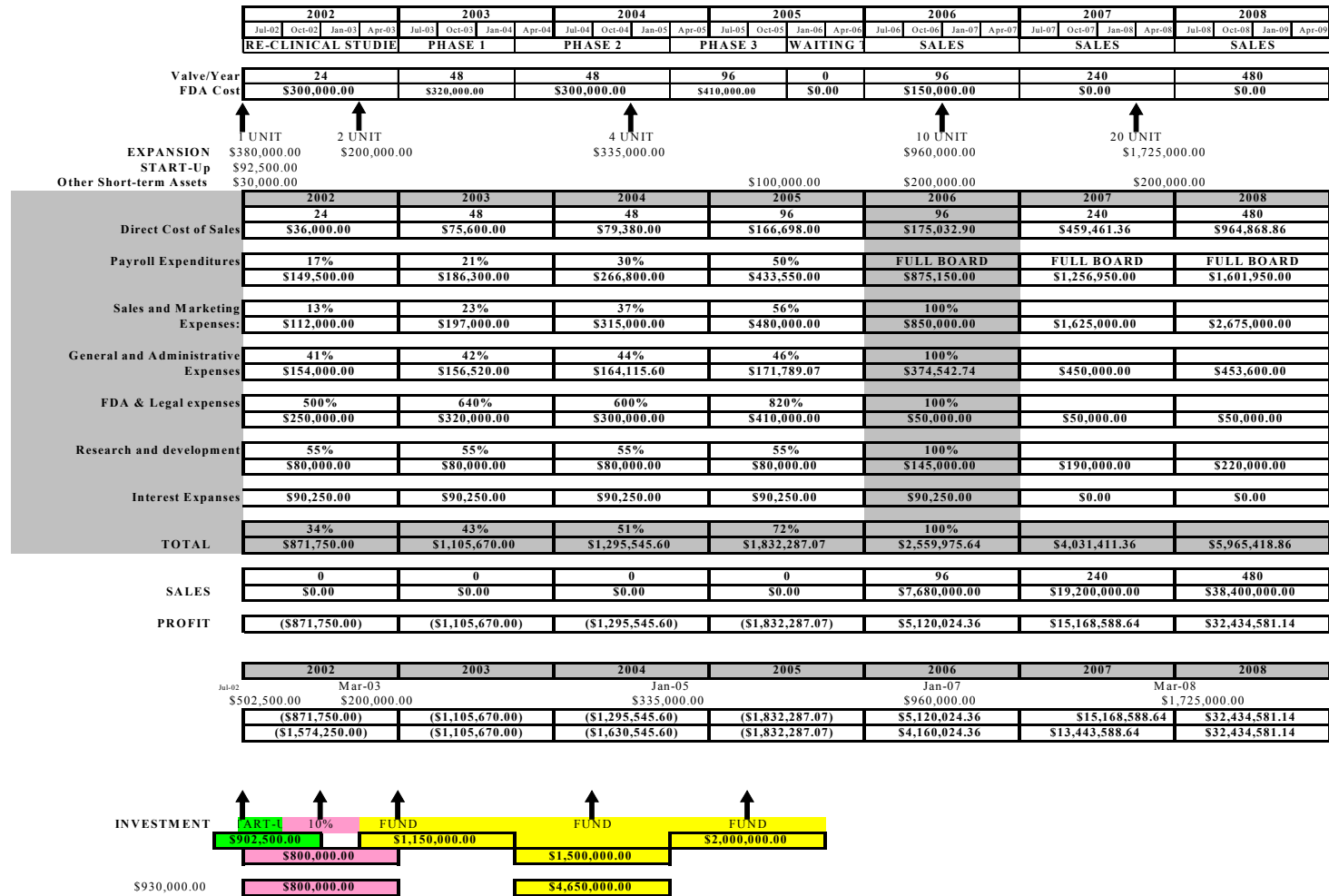
The Alfred Hospital
 Austin Repatriation Medical Centre
 Cabrini Hospital
 Epworth Hospital

Insurance Companies
 Australian Unity +61 3 9321 0320
www.australianunity.com.au
 NHIC +21 2 2390 2187 www.nhic.com

Appendix 4 Start-up Expenses

| Start-up | |
|---------------------------------|---------------------|
| Requirements | |
| Start-up Expenses | |
| Legal | \$20,000.00 |
| FDA | \$50,000.00 |
| Stationery etc. | \$2,000.00 |
| Brochures | \$5,000.00 |
| Consultants | \$3,000.00 |
| Insurance | \$3,000.00 |
| Rent | \$8,500.00 |
| Research and development | \$0.00 |
| Expensed equipment | \$0.00 |
| Custom Software | \$0.00 |
| Logo Design | \$1,000.00 |
| Management Salaries | \$0.00 |
| Other | \$0.00 |
| Total Start-up Expense | \$92,500.00 |
| Start-up Assets Needed | |
| Cash Balance on Starting Date | \$400,000.00 |
| Start-up Inventory | \$380,000.00 |
| Other Short-term Assets | \$30,000.00 |
| Total Short-term Assets | \$810,000.00 |
| Long-term Assets | \$0.00 |
| Total Assets | \$810,000.00 |
| Total Requirements | \$902,500.00 |
| Funding | |
| Company founders | \$618,500.00 |
| Private seed | \$284,000.00 |
| Total Investment | \$902,500.00 |
| Short-term Liabilities | |
| Accounts Payable | \$0.00 |
| Current Borrowing | \$0.00 |
| Other Short-term Liabilities | \$0.00 |
| Subtotal Short-term Liabilities | \$0.00 |
| Long-term Liabilities | |
| Total Liabilities | \$0.00 |
| Loss at Start-up | (\$502,500.00) |
| Total Capital | \$400,000.00 |
| Total Capital and Liabilities | \$400,000.00 |

Appendix 5 Financial Timeline



Appendix 6 Monthly Cash flow

| | Date | Cash Balance | Net Cash | Cash Sales | Investment | Expenditures | Upgrading | Accounts | Comment |
|------|--------|------------------|-------------|------------|-------------|--------------|-------------|-------------|-----------|
| 2002 | Jul-02 | \$0 | \$334,619 | \$0 | \$902,500 | (\$65,381) | (\$410,000) | (\$92,500) | Start-up |
| | Aug-02 | \$334,619 | (\$65,381) | \$0 | \$0 | (\$65,381) | \$0 | \$0 | |
| | Sep-02 | \$269,238 | (\$65,381) | \$0 | \$0 | (\$65,381) | \$0 | \$0 | |
| | Oct-02 | \$203,856 | (\$69,014) | \$0 | \$0 | (\$69,014) | \$0 | \$0 | |
| | Nov-02 | \$134,843 | (\$69,014) | \$0 | \$0 | (\$69,014) | \$0 | \$0 | |
| | Dec-02 | \$65,829 | \$727,354 | \$0 | \$800,000 | (\$72,646) | \$0 | \$0 | |
| | Jan-03 | \$793,183 | (\$72,646) | \$0 | \$0 | (\$72,646) | \$0 | \$0 | |
| | Feb-03 | \$720,538 | (\$72,646) | \$0 | \$0 | (\$72,646) | \$0 | \$0 | |
| | Mar-03 | \$647,892 | (\$279,910) | \$0 | \$0 | (\$79,910) | (\$200,000) | \$0 | |
| | Apr-03 | \$367,981 | (\$79,910) | \$0 | \$0 | (\$79,910) | \$0 | \$0 | |
| | May-03 | \$288,071 | (\$79,910) | \$0 | \$0 | (\$79,910) | \$0 | \$0 | |
| | Jun-03 | \$208,160 | (\$79,910) | \$0 | \$0 | (\$79,910) | \$0 | \$0 | |
| 2003 | Jul-03 | \$128,250 | \$1,067,075 | \$0 | \$1,150,000 | (\$82,925) | \$0 | \$0 | |
| | Aug-03 | \$1,195,325 | (\$82,925) | \$0 | \$0 | (\$82,925) | \$0 | \$0 | |
| | Sep-03 | \$1,112,400 | (\$82,925) | \$0 | \$0 | (\$82,925) | \$0 | \$0 | |
| | Oct-03 | \$1,029,474 | (\$87,532) | \$0 | \$0 | (\$87,532) | \$0 | \$0 | |
| | Nov-03 | \$941,942 | (\$87,532) | \$0 | \$0 | (\$87,532) | \$0 | \$0 | |
| | Dec-03 | \$854,410 | (\$92,139) | \$0 | \$0 | (\$92,139) | \$0 | \$0 | |
| | Jan-04 | \$762,271 | (\$92,139) | \$0 | \$0 | (\$92,139) | \$0 | \$0 | |
| | Feb-04 | \$670,132 | (\$92,139) | \$0 | \$0 | (\$92,139) | \$0 | \$0 | |
| | Mar-04 | \$577,992 | (\$101,353) | \$0 | \$0 | (\$101,353) | \$0 | \$0 | |
| | Apr-04 | \$476,639 | (\$101,353) | \$0 | \$0 | (\$101,353) | \$0 | \$0 | |
| | May-04 | \$375,286 | (\$101,353) | \$0 | \$0 | (\$101,353) | \$0 | \$0 | |
| | Jun-04 | \$273,933 | (\$101,353) | \$0 | \$0 | (\$101,353) | \$0 | \$0 | |
| 2004 | Jul-04 | \$172,580 | \$1,397,436 | \$0 | \$1,500,000 | (\$102,564) | \$0 | \$0 | |
| | Aug-04 | \$1,570,016 | (\$102,564) | \$0 | \$0 | (\$102,564) | \$0 | \$0 | |
| | Sep-04 | \$1,467,452 | (\$102,564) | \$0 | \$0 | (\$102,564) | \$0 | \$0 | |
| | Oct-04 | \$1,364,888 | (\$437,564) | \$0 | \$0 | (\$102,564) | (\$335,000) | \$0 | |
| | Nov-04 | \$927,324 | (\$102,564) | \$0 | \$0 | (\$102,564) | \$0 | \$0 | |
| | Dec-04 | \$824,760 | (\$102,564) | \$0 | \$0 | (\$102,564) | \$0 | \$0 | |
| | Jan-05 | \$722,196 | (\$107,962) | \$0 | \$0 | (\$107,962) | \$0 | \$0 | |
| | Feb-05 | \$614,234 | (\$107,962) | \$0 | \$0 | (\$107,962) | \$0 | \$0 | |
| | Mar-05 | \$506,272 | (\$107,962) | \$0 | \$0 | (\$107,962) | \$0 | \$0 | |
| | Apr-05 | \$398,309 | (\$118,758) | \$0 | \$0 | (\$118,758) | \$0 | \$0 | |
| | May-05 | \$279,551 | (\$118,758) | \$0 | \$0 | (\$118,758) | \$0 | \$0 | |
| | Jun-05 | \$160,793 | (\$118,758) | \$0 | \$0 | (\$118,758) | \$0 | \$0 | |
| 2005 | Jul-05 | \$42,034 | \$1,862,578 | \$0 | \$2,000,000 | (\$137,422) | \$0 | \$0 | |
| | Aug-05 | \$1,904,613 | (\$137,422) | \$0 | \$0 | (\$137,422) | \$0 | \$0 | |
| | Sep-05 | \$1,767,191 | (\$137,422) | \$0 | \$0 | (\$137,422) | \$0 | \$0 | |
| | Oct-05 | \$1,629,770 | (\$145,056) | \$0 | \$0 | (\$145,056) | \$0 | \$0 | |
| | Nov-05 | \$1,484,714 | (\$145,056) | \$0 | \$0 | (\$145,056) | \$0 | \$0 | |
| | Dec-05 | \$1,339,658 | (\$152,691) | \$0 | \$0 | (\$152,691) | \$0 | \$0 | |
| | Jan-06 | \$1,186,967 | (\$152,691) | \$0 | \$0 | (\$152,691) | \$0 | \$0 | |
| | Feb-06 | \$1,034,277 | (\$152,691) | \$0 | \$0 | (\$152,691) | \$0 | \$0 | |
| | Mar-06 | \$881,586 | (\$267,960) | \$0 | \$0 | (\$167,960) | \$0 | (\$100,000) | inventory |
| | Apr-06 | \$613,626 | (\$167,960) | \$0 | \$0 | (\$167,960) | \$0 | \$0 | |
| | May-06 | \$445,667 | (\$167,960) | \$0 | \$0 | (\$167,960) | \$0 | \$0 | |
| | Jun-06 | \$277,707 | (\$167,960) | \$0 | \$0 | (\$167,960) | \$0 | \$0 | |

| | Date | Cash Balance | Net Cash | Cash Sales | Investment | Expenditures | Upgrading | Accounts | Comment |
|--------|--------------|---------------|-------------|-------------|-------------|--------------|----------------|-------------|--------------------|
| 2006 | Jul-06 | \$109,747 | \$448,002 | \$640,000 | \$0 | (\$191,998) | \$0 | \$0 | |
| | Aug-06 | \$557,749 | \$448,002 | \$640,000 | \$0 | (\$191,998) | \$0 | \$0 | |
| | Sep-06 | \$1,005,751 | \$448,002 | \$640,000 | \$0 | (\$191,998) | \$0 | \$0 | |
| | Oct-06 | \$1,453,753 | \$437,335 | \$640,000 | \$0 | (\$202,665) | \$0 | \$0 | |
| | Nov-06 | \$1,891,088 | \$437,335 | \$640,000 | \$0 | (\$202,665) | \$0 | \$0 | |
| | Dec-06 | \$2,328,423 | (\$772,665) | \$640,000 | \$0 | (\$202,665) | (\$960,000) | (\$250,000) | inventory |
| | Jan-07 | \$1,555,759 | \$426,669 | \$640,000 | \$0 | (\$213,331) | \$0 | \$0 | |
| | Feb-07 | \$1,982,427 | \$426,669 | \$640,000 | \$0 | (\$213,331) | \$0 | \$0 | |
| | Mar-07 | \$2,409,096 | \$426,669 | \$640,000 | \$0 | (\$213,331) | \$0 | \$0 | |
| | Apr-07 | \$2,835,765 | (\$497,164) | \$640,000 | \$0 | (\$234,664) | \$0 | (\$902,500) | Start-up Principal |
| May-07 | \$2,338,600 | (\$535,331) | \$640,000 | \$0 | (\$245,331) | \$0 | (\$930,000,00) | Dividends | |
| Jun-07 | \$1,803,269 | (\$1,152,005) | \$640,000 | \$0 | (\$255,998) | \$0 | (\$1,536,007) | Tax | |
| 2007 | Jul-07 | \$651,264 | \$1,297,644 | \$1,600,000 | \$0 | (\$302,356) | \$0 | \$0 | |
| | Aug-07 | \$1,948,909 | \$1,297,644 | \$1,600,000 | \$0 | (\$302,356) | \$0 | \$0 | |
| | Sep-07 | \$3,246,553 | \$1,297,644 | \$1,600,000 | \$0 | (\$302,356) | \$0 | \$0 | |
| | Oct-07 | \$4,544,197 | \$1,280,847 | \$1,600,000 | \$0 | (\$319,153) | \$0 | \$0 | |
| | Nov-07 | \$5,825,043 | \$1,280,847 | \$1,600,000 | \$0 | (\$319,153) | \$0 | \$0 | |
| | Dec-07 | \$7,105,890 | \$1,080,847 | \$1,600,000 | \$0 | (\$319,153) | \$0 | (\$200,000) | inventory |
| | Jan-08 | \$8,186,737 | \$1,264,049 | \$1,600,000 | \$0 | (\$335,951) | \$0 | \$0 | |
| | Feb-08 | \$9,450,786 | \$1,264,049 | \$1,600,000 | \$0 | (\$335,951) | \$0 | \$0 | |
| | Mar-08 | \$10,714,835 | (\$460,951) | \$1,600,000 | \$0 | (\$335,951) | (\$1,725,000) | \$0 | |
| | Apr-08 | \$10,253,884 | \$1,230,454 | \$1,600,000 | \$0 | (\$369,546) | \$0 | \$0 | |
| May-08 | \$11,484,338 | \$283,656 | \$1,600,000 | \$0 | (\$386,344) | \$0 | (\$930,000) | Dividends | |
| Jun-08 | \$11,767,994 | (\$3,353,718) | \$1,600,000 | \$0 | (\$403,141) | \$0 | (\$4,550,577) | Tax | |
| 2008 | Jul-08 | \$8,414,276 | \$2,752,594 | \$3,200,000 | \$0 | (\$447,406) | \$0 | \$0 | |
| | Aug-08 | \$11,166,870 | \$2,752,594 | \$3,200,000 | \$0 | (\$447,406) | \$0 | \$0 | |
| | Sep-08 | \$13,919,464 | \$2,752,594 | \$3,200,000 | \$0 | (\$447,406) | \$0 | \$0 | |
| | Oct-08 | \$16,672,057 | \$2,727,738 | \$3,200,000 | \$0 | (\$472,262) | \$0 | \$0 | |
| | Nov-08 | \$19,399,795 | \$2,727,738 | \$3,200,000 | \$0 | (\$472,262) | \$0 | \$0 | |
| | Dec-08 | \$22,127,533 | \$2,727,738 | \$3,200,000 | \$0 | (\$472,262) | \$0 | \$0 | |
| | Jan-09 | \$24,855,270 | \$2,702,882 | \$3,200,000 | \$0 | (\$497,118) | \$0 | \$0 | |
| | Feb-09 | \$27,558,152 | \$2,702,882 | \$3,200,000 | \$0 | (\$497,118) | \$0 | \$0 | |
| | Mar-09 | \$30,261,034 | \$2,702,882 | \$3,200,000 | \$0 | (\$497,118) | \$0 | \$0 | |
| | Apr-09 | \$32,963,915 | \$2,653,170 | \$3,200,000 | \$0 | (\$546,830) | \$0 | \$0 | |
| May-09 | \$35,617,085 | \$1,698,314 | \$3,200,000 | \$0 | (\$571,686) | \$0 | (\$930,000) | Dividends | |
| Jun-09 | \$37,315,399 | (\$7,126,916) | \$3,200,000 | \$0 | (\$596,542) | \$0 | (\$9,730,374) | Tax | |
| Jul-09 | \$30,188,483 | \$2,454,325 | \$3,200,000 | \$1 | (\$745,677) | \$1 | \$0 | | |

Appendix 7 Break-Even Analysis

| No. of unit | Production cost/unit | Running Cost/Qrt | Sales Price/Unit | Total Sales | Balance /Qrt |
|-------------|----------------------|------------------|------------------|-------------|--------------|
| 1 | \$1,850 | \$641,850.00 | 80000 | 80000 | -561850 |
| 2 | \$3,700 | \$643,700.00 | 80000 | 160000 | -483700 |
| 3 | \$5,550 | \$645,550.00 | 80000 | 240000 | -405550 |
| 4 | \$7,400 | \$647,400.00 | 80000 | 320000 | -327400 |
| 5 | \$9,250 | \$649,250.00 | 80000 | 400000 | -249250 |
| 6 | \$11,100 | \$651,100.00 | 80000 | 480000 | -171100 |
| 7 | \$12,950 | \$652,950.00 | 80000 | 560000 | -92950 |
| 8 | \$14,800 | \$654,800.00 | 80000 | 640000 | -14800 |
| 9 | \$16,650 | \$656,650.00 | 80000 | 720000 | 63350 |
| 10 | \$18,500 | \$658,500.00 | 80000 | 800000 | 141500 |
| 11 | \$20,350 | \$660,350.00 | 80000 | 880000 | 219650 |
| 12 | \$22,200 | \$662,200.00 | 80000 | 960000 | 297800 |
| 13 | \$24,050 | \$664,050.00 | 80000 | 1040000 | 375950 |
| 14 | \$25,900 | \$665,900.00 | 80000 | 1120000 | 454100 |
| 15 | \$27,750 | \$667,750.00 | 80000 | 1200000 | 532250 |
| 16 | \$29,600 | \$669,600.00 | 80000 | 1280000 | 610400 |
| 17 | \$31,450 | \$671,450.00 | 80000 | 1360000 | 688550 |
| 18 | \$33,300 | \$673,300.00 | 80000 | 1440000 | 766700 |
| 19 | \$35,150 | \$675,150.00 | 80000 | 1520000 | 844850 |
| 20 | \$37,000 | \$677,000.00 | 80000 | 1600000 | 923000 |

Appendix 8 Personnel Plan

| PERSONNEL PLAN | | | | | | | |
|---|------------------|------------------|------------------|------------------|------------------|--------------------|--------------------|
| | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
| Production Personnel | | | | | | | |
| Production Manager/CEO | \$30,000 | \$32,500 | \$35,000 | \$35,000 | \$50,000 | \$70,000 | \$80,000 |
| Lab Tech | \$0 | \$0 | \$0 | \$25,000 | \$55,000 | \$130,000 | \$190,000 |
| Subtotal | \$30,000 | \$32,500 | \$35,000 | \$60,000 | \$105,000 | \$200,000 | \$270,000 |
| Sales and Marketing Personnel | | | | | | | |
| Sales Manager | \$15,000 | \$15,000 | \$35,000 | \$35,000 | \$50,000 | \$70,000 | \$80,000 |
| Field Sales Mgr. | \$0 | \$0 | \$0 | \$15,000 | \$42,000 | \$100,000 | \$150,000 |
| Marketing/Product Mgr. | \$15,000 | \$15,000 | \$35,000 | \$35,000 | \$50,000 | \$70,000 | \$80,000 |
| Sales Reps | \$0 | \$0 | \$0 | \$0 | \$80,000 | \$85,000 | \$135,000 |
| Sales Administrator | \$0 | \$0 | \$0 | \$25,000 | \$28,000 | \$58,000 | \$90,000 |
| Other | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| Subtotal | \$30,000 | \$30,000 | \$70,000 | \$110,000 | \$250,000 | \$383,000 | \$535,000 |
| General and Administrative Personnel | | | | | | | |
| CEO | \$0 | \$0 | \$0 | \$35,000 | \$90,000 | \$100,000 | \$120,000 |
| Corp Development | \$0 | \$0 | \$0 | \$0 | \$35,000 | \$45,000 | \$45,000 |
| CFO | \$15,000 | \$15,000 | \$35,000 | \$35,000 | \$50,000 | \$70,000 | \$80,000 |
| Executive Assistant | \$0 | \$0 | \$0 | \$15,000 | \$32,000 | \$35,000 | \$35,000 |
| Executive Secretary | \$0 | \$0 | \$0 | \$0 | \$27,000 | \$29,000 | \$32,000 |
| Administrative Staff | \$0 | \$0 | \$0 | \$25,000 | \$27,000 | \$60,000 | \$95,000 |
| Other | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| Subtotal | \$15,000 | \$15,000 | \$35,000 | \$110,000 | \$261,000 | \$339,000 | \$407,000 |
| Other Personnel | | | | | | | |
| Research & Dev. | \$30,000 | \$32,500 | \$35,000 | \$35,000 | \$50,000 | \$70,000 | \$80,000 |
| Junior Engineer | \$25,000 | \$27,000 | \$30,000 | \$32,000 | \$35,000 | \$36,000 | \$36,000 |
| Research Engineers (2) | \$0 | \$25,000 | \$27,000 | \$30,000 | \$60,000 | \$65,000 | \$65,000 |
| Other | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| Subtotal | \$55,000 | \$84,500 | \$92,000 | \$97,000 | \$145,000 | \$171,000 | \$181,000 |
| Total Headcount | 6 | 7 | 7 | 13 | 19 | 24 | 30 |
| Total Payroll | \$130,000 | \$162,000 | \$232,000 | \$377,000 | \$761,000 | \$1,093,000 | \$1,393,000 |
| Payroll Burden | \$19,500 | \$24,300 | \$34,800 | \$56,550 | \$114,150 | \$163,950 | \$208,950 |
| Total Payroll Expenditures | \$149,500 | \$186,300 | \$266,800 | \$433,550 | \$875,150 | \$1,256,950 | \$1,601,950 |