

SKIN TISSUE REPLACEMENT

Business Plan

Business Goal:

Our goal is the production of new allograft RepliDerm by RepliDerm INC. for the treatment of burn victims. The objective is to initially obtain research grant for research and development of our product RepliDerm. The figure below shows our major competitors in the market and the share of market they hold. As shown in Figure 6, we will capture some part of the market share available for the product.

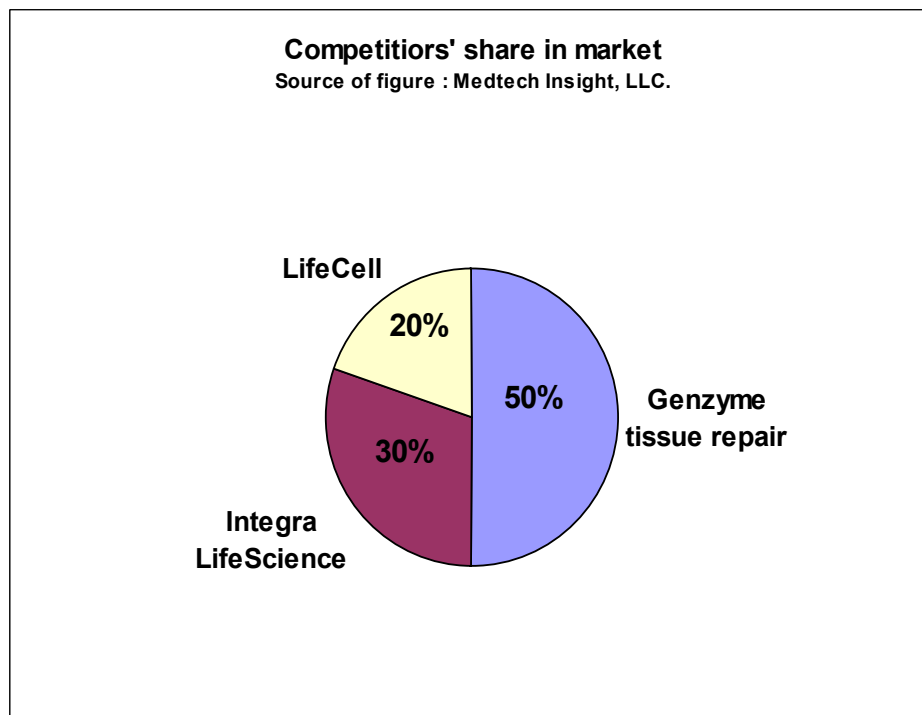


Figure 6: Market competitors

The prime sources of funding will be NIH, SBIR and STTR. There will be some personal contribution to the initial investment. Initially our production rate will be 60,000

sheets per month (based from our competitor's financial information¹². Our major competitors in skin tissue replacement are LifeCell's Allorderm template¹³, Genzyme's Epicel and LifeScience's Integra.

General Information:

As mentioned earlier, our project will start on researching in laboratory. After certain promising result is obtained, we will apply for government grant for a further research. Once a viable solution is found, we will submit our proposal to FDA to proceed phase 1 testing. After passing the first phase, a major fund raising will be needed since phase 2 and 3 is extremely costly. We will introduce our idea and testing result from phase 1 to convince investors the possibility of the project. With this funding, we will expand our company and initiate phase 2 and 3. We expect the entire project will last for about 10 years.

Location of RepliDerm INC.

Several locations were considered for headquarters of operation. The list of original selected state for the location is given below.

- New Jersey
- California
- New York
- Pennsylvania
- Texas
- Massachusetts
- Maryland
- Florida
- Ohio
- Michigan

The evaluation for the best location selection was done based on giving importance to each of the factors mentioned above in percentages. NIH funding to each state was given 30% importance in our decision making process. Employment, number of

private biotech companies, cost of living, number of hospitals, and corporate tax are given 20%, 15%, 15%, 10% and 10% importance respectively. Research is the most important factor in order for Biotech Company to start and develop. That is why NIH funding to our research project is given the most importance. Employment is second important factor because it contributes significantly to research staff needed for the production of our product. Number of private biotech companies and cost of living in each state were given equal importance because the highest number of biotech companies indicates how a state has been supporting these companies to survive and low cost of living indicates the comparative cost of each state. Number of hospitals and corporate tax rates are the least important in our evaluation however they cannot be ignored because number of hospital in a state will help us survive locally saving cost of marketing. Low corporate tax will reduce the cost for the company and can turn into big saving during the years after establishment.

Table 5: Ranking of each state for the evaluation

Location	NIH funding	No. of Hospitals	Private Biotech companies	Cost of living	Employment in Biotech companies	Corporate Tax	Rank
Importance	0.3	0.1	0.15	0.15	0.2	0.1	
New Jersey	1	1	7	8	9	3	4.8
California	10	10	10	10	10	4	9.4
New York	8	8	8	9	8	5	7.9
Pennsylvania	7	7	6	6	7	1	6.1
Texas	5	9	9	2	6	9	6.2
Massachusetts	9	3	5	7	5	2	6.0
Maryland	6	2	4	1	4	6	4.2
Florida	2	6	3	5	3	8	3.8
Ohio	4	5	2	3	2	7	3.6
Michigan	3	4	1	4	1	10	3.3

The ranking of each state was done on the scale of 1 to 10. The highest NIH fund receiving state gets rank 10 and lowest get rank 1. The highest Biotech employment holding state, state with highest number of private biotech companies, highest number hospitals and lowest corporate tax rate receive highest rank. The rank of each state was multiplied with the importance and the product is given in the column “Rank”. The highest number shows the best choice among all ten states. According to this method, California is the best choice with highest rank of 9.4. The second choice is New York with the rank of 7.9. Because California has so many advantages in comparison to the other ten locations, we chose Fairfield, California as our operation headquarters.

Since major part of our cost is FDA cost, the cost associated with location. Therefore the location is not a major concern.

Shipping and Transportation

RepliDerm is frozen at -80°C and then vacuum sealed in a sterile foil wrapper. The product is then packed up to 50 lbs in dry ice. In order to deliver our product to the patient as fast as possible, our company will use FedEx to deliver it. The cost of an overnight delivery with thermal control is about \$150 each time. FedEx shipping can ship the product overnight to any location in the US from Nebraska for \$150 or less (depending on the shipping location). If RepliDerm were based out of the New England area, shipping rates will be as high as \$340 and overnight shipping of the product would not be guaranteed in all cases. Additionally, larger shipments of RepliDerm (up to 100 lbs total shipping weight) could not be shipped in sufficient time to the western US.

Advertising

After FDA approval is obtained, we planned to develop a marketing and sale team to interact with ear, nose, and throat surgeon, plastics surgeon, burn surgeons and general surgeons. We will also participate in different national and international conference, trade shows and fellowship program.

The marketing strategy is that Major hospitals are targeted all around the United states.

The following Hospitals were considered as our major targets in sales

- Shriner's Hospital-Galveston, TX
- William R. Hearst Burn Center-NY, NY
- Jaycee Burn Center-Charlotte, NC
- Arizona Burn Center-Phoenix, AZ
- U Mich. Trauma and Burn Center.-Ann Arbor, MI
- UCSF Burn Center-Fresno, CA

The map below shows the location of the listed hospitals. The well distributed location for marketing across the United States can be easily seen.

Table 6 Marketing cost detail

Advertising strategies	Description of cost	\$ Cost
Free product distribution (1 st six months)	Cost of sheets in 56 hospitals across the country considering average 5 surgeons in a hospital	\$281,120.00
Free product distribution (2 nd six months)	Cost of sheets in 56 hospitals across the country considering average 5 surgeons in a hospital	\$281,120.00
FedEx Delivery cost to above locations	Cost of each delivery with thermal control	\$16,800.00
3 National conference	One conference attendance include travel expense, hotel staying and misllaneous cost	\$6,300.00
2 International conference	One conference attendance include travel expense, hotel staying and misllaneous cost	\$11,000.00
Trade shows and fellowship	2 of each, cost estimation similar to a national conference	\$6,000.00
Total annual cost of marketing		\$602,340.00

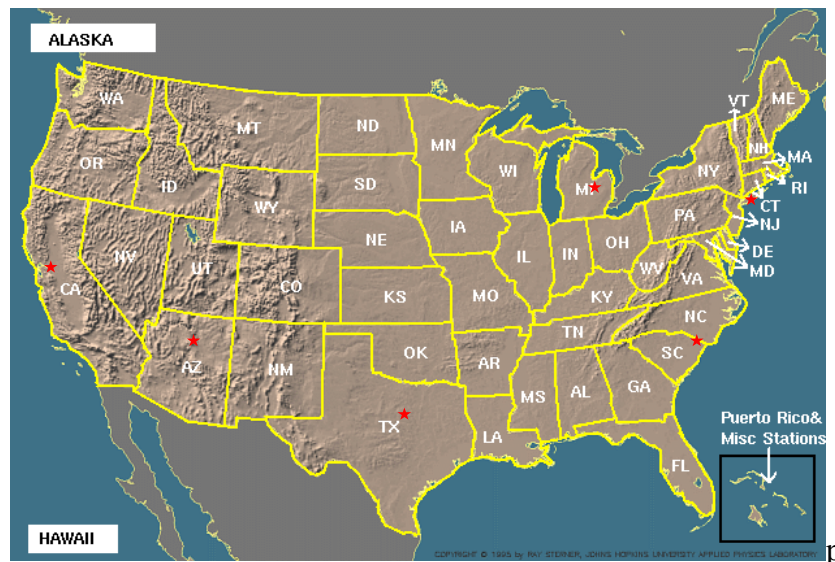


Figure 8: Location of Major Target Hospitals for Marketing and Distribution of RepliDerm

Approximately 50 hospitals other than major six hospitals listed above will be provided our RepliDerm the trial. Assuming on average five surgeons in each hospitals, we will give each surgeon 8 sheets of REPLIDEM (enough to cover one burn patient). Table 6 shows the cost of marketing of the product. We will attend at least three national and two

international conferences for the demonstration of the effectiveness of our product. The international conference will establish the credibility of the product. The cost for the conference includes transportation and staying of two individual the conference. Trade shows and fellowship programs will be also covered for the demonstration and advertisement of our product. Cost for the tradeshow and fellowship is estimated same way as it is for conference attendance.

Cost Evaluation

Table 7 shows the FCI estimate with 100% FDA investment included in Indirect cost as legal expenses. Installation cost of the equipments is estimated to be \$1,000 because there are no big equipments involved as described in production method. Cost of services and facilities is estimated to be \$600,000 which includes installation of piping, phone lines, cable, electricity and the cost of research and production staff. The cost of production staff includes 3 technician, 1 PhD and 20 additional people for the production. The major part of indirect cost is FDA and it is estimated to be \$349,079,000 as shown in Table 7.

Table 7 FCI Calculation

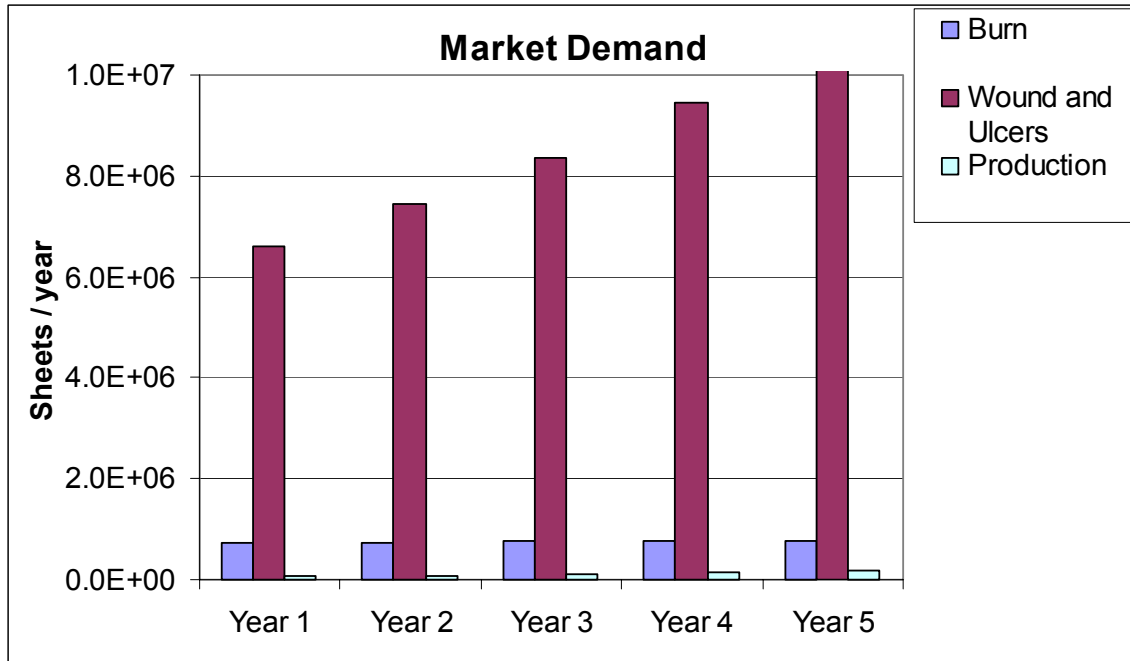
Purchased equipment cost	\$108,152.60
Installation cost	\$1,000.00
Building (Including services)	\$8,250,000.00
Service facilities	\$600,000.00
Raw material	\$7,038,000.00
Direct Cost	\$8,959,152.60
Engineering and supervision	\$30,000.00
Legal expenses	\$30,000.00
Contingency	\$60,000.00
FDA	\$350,000,000.00
Indirect Cost	\$350,120,000.00
Fixed Capital Investment	\$359,079,152.60

RepliDerm will be treating wounds and ulcer of the patients other than burn patients the demand of RepliDerm is estimated. In the year of 1996, there were 680,000 patients with requiring wound treatment, 2,350,000 patients requiring ulcer treatment and 680,000 hospitalized patients¹. The requirement of RepliDerm each type of patients is calculated as shown in Table 8.

Table 8

Injury Type	Growth Rate	# of patients in 2004	# of sheet(s) required per patient	Market demand of # of sheets/yr
Burn	1%	736343	14	10308802
Wound	1.20%	797594	2	1595188
Ulcers	14%	5818513	1	5818513

According to the growth rate shown in Table 8, the comparison between REPLIDEM production rate and requirement for burn, ulcer and wound patients is shown in Figure 8. However it does not take competitors into account.



From the information available, LifeCell produces 100,000 sheets per year¹. According to the pie chart in Figure 6, LifeCell holds 20% of the market, the estimated total market sale of alloderm sheets is approximately 500,000 sheets per year. By considering total sales, the following model is implemented to find the production rate and RepliDerm price per sheet.

Demand and Pricing Model

In order to determine how much RepliDerm must be produced and to determine at what price to sell each sheet of the product, an economic model must be formulated to explain the relationship between the quantity demanded and the price. The following equation is the most fundamental and oversimplified model of the relationship between the price and quantity demanded.

$$p_1 d_1 = p_2 (D - d_1)$$

where p_1 is RepliDerm's product price, d_1 is the demand/production rate of RepliDerm, p_2 is the average competitor product price and D is the total market demand.

This relationship shows that the quantity of RepliDerm demanded is inversely proportional to the price at which it is sold. It also shows that a price for RepliDerm, equal to that of the competitors' price, results in an evenly shared demand. This would be a realistic expression of the market if, in addition to equal prices, both RepliDerm and its competitors were in the market for a long time, the quality of each product was the same, advertising campaigns were equally effective for RepliDerm and for its competitors and production capacity was the same.

The competitors have a clear advantage over RepliDerm in that they have been on the market already for a number of years. They have earned loyal customers and have successful advertising campaigns.

On the other hand, RepliDerm is a superior product which will save burn and wound centers time and money. Just as competitors have run successful advertisement campaigns, RepliDerm will likewise be able to run such campaigns.

To account for influences from market demand and advertising on the market, two functions are introduced to the model:

$$\beta(t, a) \cdot p_1 d_1 = p_2 (D - d_1) \cdot \alpha(t, a)$$

The function α is a function of time (t) and RepliDerm's advertisement campaign (a). It represents RepliDerm's competitors' competitive advantage by virtue of their present standing in the market. α is a number between zero and one. At time=0 α is zero and RepliDerm's demand is zero no matter what the price is. Over time α should increase approach a limit of one.

The function β is also a function of time and RepliDerm's advertisement campaign. It represents the superiority of RepliDerm as a wound treatment and ultimately its competitive edge. At time=0, β is one, thereby representing no advantage. As time increases β approaches zero. If β could reach zero, RepliDerm's revenue would be infinite.

The graph on the following page shows values for alpha and beta that were chosen to reflect the strong foothold that the competitors enjoy in the current market and the superiority of the RepliDerm product.

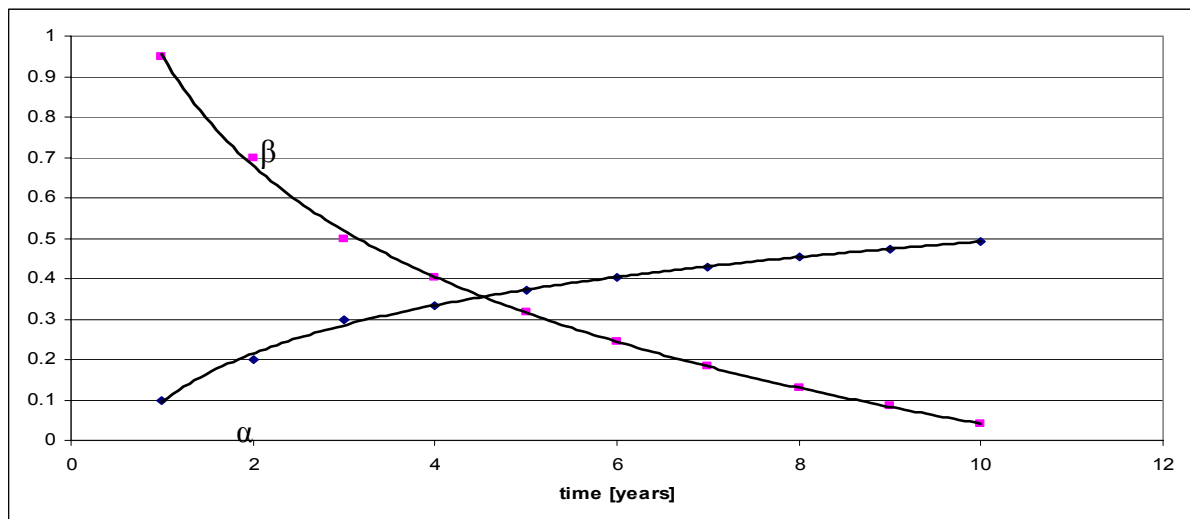


Figure 15: Values for alpha and beta as a function of time

These values for alpha and beta are just estimates based on the performance of similar novel products in the past. Limited access to information concerning competitor's sales creates a good deal of uncertainty in these values. It is expected that following initial sales of RepliDerm trends can be observed to better define the functions that influence the demand of the product.

A general rule of thumb in the tissue engineering industry states that a company should try to recover their investment within two to three years after FDA approval. The

science of tissue engineering and biomimetic materials is growing so rapidly that any product on the market can be expected to be replaced by a superior product within a short number of years. For this reason it is advisable to recover any incurred debt in a short amount of time.

Assuming that we will recover all investment within the first three years of operation following FDA approval we set the cumulative cash flow equal to the FDA costs and fixed capital investment costs as shown by the following equation:

$$\sum_{i=1}^3 p_1 d_{1i} - PC = FDA + FCI$$

where $PC = pc \cdot d_1$ and pc is the production cost per sheet.

Rearranging our economic model to solve for d_1 the following expression is obtained:

$$d_1 = \frac{p_2 D \alpha(t)}{\beta(t) p_1 + \alpha(t) \cdot p_2}$$

Substituting this model into our cumulative cash position equation for the first three years:

$$\sum_{i=1}^3 \frac{p_1 p_2 D \alpha_i}{\beta_i p_1 + \alpha_i \cdot p_2} - \frac{pc \cdot p_2 D \alpha_i}{\beta_i p_1 + \alpha_i \cdot p_2} = FDA + FCI$$

The current market situation is estimated as follows:

$$p_2 = \$1000/\text{sheet}$$

$$D = 500,000 \text{ sheets}$$

$$pc = \$195/\text{sheet}$$

Solving for p_1 yields the suggested sale price of RepliDerm at \$1870/sheet. This is almost twice the cost of competitor's products. The increase in price is justifiable by virtue of the fact that RepliDerm will save hospitals time and money by allowing for a faster and therefore cheaper patient recovery.

Substituting this price back into the economic model the production for each year can be determined.

Cumulative Cash Position Calculations

Year	Sale price with 2% inflation rate (\$)	Rate of production (sheet/yr)	\$Revenue/yr	Raw material cost (\$)	Total product cost/yr	Cash flow (\$)
1	1870	26645	49826805	5209166.001	6086701.5	43740103.72
2	1870.02	67594	1.26E+08	13479005.96	14504513.4	111898429
3	1870.04	126364	2.36E+08	25702285.9	26902608.9	209403822.2
4	1870.06	162155	3.03E+08	33641736.72	35048812.7	268191315.5
5	1870.08	208902	3.91E+08	44206907.26	45858758.6	344804770.8
6	1870.1	258947	4.84E+08	55893175.89	57810939	426446161
7	1870.12	313359	5.86E+08	68990528.39	71224808.1	514793458.8
8	1870.14	373203	6.98E+08	83809463	86420881.9	611520924.7
9	1870.16	439648	8.22E+08	100705454.4	103766652	718444989
10	1870.18	514044	9.61E+08	120101538.9	123699573	837655169.6

The cumulative cash position chart shows cash flow projection of 10 years after production and 15 years before the production assuming 2% inflation rate. The production growth rate will follow the model as shown in Figure 10 below.

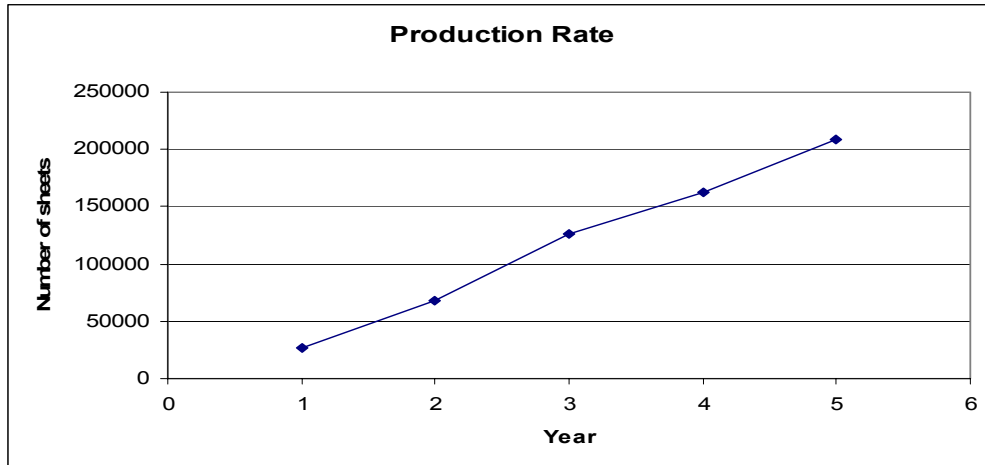


Figure 10 Production Growth Rate for 10 years

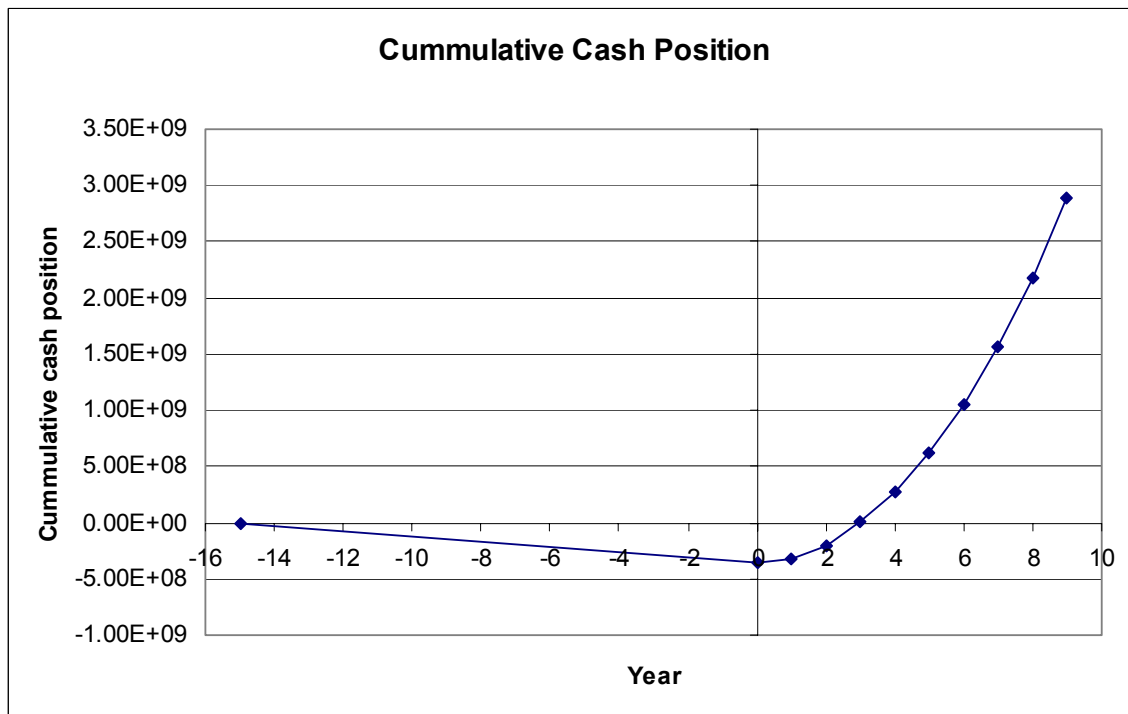


Figure 11: Cummulative Cash Position

As discussed above in the model, FCI will be recovered in three years after production. The marketing cost is increased by 20 % and number of employees also were increased by 25 % to meet the need for the production growth.