

Renovo;
biopharmaceutical
product company



**ASSIGN
BUSTER**

RENOVO

Introduction:

Renovo is a biopharmaceutical product company which was founded in October 2000. The foundation team comprises innovative leaders like Professor Mark Ferguson, CEO and Dr Sharon O’Kane, Chief Scientific Officer. It currently has 170 employees (as per the facts stated on the company website). The company aims to be the world’s leading developer of anti scarring and scar prevention treatments. It discovers and develops drugs to improve the appearance of scars and enhance healing of wounds. Renovo is known for its highly experienced and innovative scientists and clinicians.

Renovo was formed as a University of Manchester spin-out company. None of its products are in market, but it has four products of great value which are under the clinical trial phase.

Overview on business models

“ A business model is a rationale of how an organisation creates, delivers and captures value.”

-H. Chesbrough

A business model is a summary of the strategies that a company applies to perform well in the competitive market. It predicts the present and future plans of the company and helps to create new opportunities. To create new opportunities for Renovo, the business model needs to be defined by using tools like PEST factors, Porter’s 5 forces and SWOT analysis.

Aim of the company

“ To be the first company to market a scar prevention pharmaceutical drug in the US and Europe.” -Renovo Company website

The company is a public sector company and was listed in the London Stock Exchange (LSE) in 2006. The company's subsidiaries include Renovo Limited and Renovo Technologies Limited.

Existing product line and market:

It has four leading products, namely Juvista, Juvidex, Prevascar and Adaprev, that are now in phase 2 and phase 3 of clinical trials.

Juvista- Scar reduction in skin

Juvista is Renovo's leading therapeutic application of human recombinant Transforming Growth Factor $\beta 3$ (TGF $\beta 3$), a factor that is present in low levels in adult wounds that leaves scars. Currently, Juvista is under phase 3 clinical trials.

It is administered by giving an intra-dermal injection into the wound margins.

In June 2007, Renovo signed an agreement with Shire to develop and commercialise the drug. With this agreement, the company now has the rights to commercialise it in all the countries except for the member states of The European Union.

Juvidex- Improved skin appearance

Juvidex is a formulation of the sugar Manosose-6-Phosphate (M6P), inhibits the activation of TGF $\beta 1$ and TGF $\beta 2$, which are present at high levels in adult wounds that scar. The drug is under phase 2 clinical trials.

The company is currently looking forward to develop an improved topical formulation and delivery mechanism for Juvindex.

Prevascar- Reduced scarring

Prevascar is made of the human recombinant interleukin 10 (IL-10), which is an important modulator of the inflammatory response at an adult wound site.

Currently Renovo is developing a new improved formulation of the same indication.

Adaprev- Scar reduction in tendons

Adaprev is comparatively a new drug formulated to reduce tendon adhesions following a primary surgical repair. For this indication Renovo has branded M6P (Mannose-6-Phosphate) as Adaprev.

The company after the discussions with the Medical and Healthcare products Regulatory Agency (MHRA) believes that Adaprev can be developed as a class III medical device (a device with secondary pharmacological action).

The wound care product market is growing at an average rate of 10.1% every year. The market is now worth more than US \$ 3.4 billion and is expected to double by 2015. The anti-scarring drugs are novel and are bound to gain success and popularity because of their high demand.

Company's R & D

Renovo has a world class R & D approach and has devised a Scientific and Clinical Advisory Board, which comprises world's leading scientists and clinicians. Renovo's strong research base is assisted by the fact that the

company holds about 500 granted or patent applications worldwide. Some of them have just been granted this year, which are:

1. WNT3A for inhibition of scarring. (Grant date: 18-11-2009)
2. Use of WNT3A for acceleration of wound healing. (Grant date: 18-11-2009)
3. Wound healing. (Grant date: 09-11-2009)

Renovo has long going expertise in Phase I and II clinical trials. This extensive unit is staffed with plastic surgeons, research nurses, administrators and also, recruits many volunteers. Currently, there are four drugs in clinical pipeline, all of which are of great value once they get commercialised.

Renovo also has many on-going researches which aim to improve their approach in healing wounds, without leaving scars. Key areas being:

- Wound healing in humans
- Comparison of scar-free embryonic healing with scar-forming adult healing
- Use of in-vitro and in-vivo experiments

Collaborations and auditors

In June 2007, Renovo got collaborated with Shire plc for its leading product Juvista. The agreement will bring the following benefits for Renovo:

- Renovo will be receiving US \$25 million if FDA approves filing of Juvista. On approval, it will receive an additional US \$150 million.

- On successful commercialisation of Juvista, Renovo will receive a total amount of US \$585 million.
- If approved and commercialised, Renovo would also receive royalties on Juvista sales.
- Renovo has already received US \$75 million as upfront payment and US \$50 million equity investment in Renovo Group Plc at a price of £2 a share.

The total deal amounts to US \$825 million.

Deloitte LLP is Renovo's auditor.

Current financials of the Company

The latest reviews state that the performance of the company is in line with the management expectations. The current market place of Renovo, as on 23rd November 2009 is:

Share Price 26. 25p

Change
Today +1. 00p

52 Week
High 33. 00

52 Week
Low 18. 00

Shares 189.

Issued 55m

Market Cap £49.

76m

Source: digitallook. com

Income statement is more or less the profit and loss statement of a company and shows how revenue (income that company gets in return for its sales of goods and services to the customer) transforms into net income (net income = revenue – costs and expenses).

Renovo group's revenue grew from 491. 00 k to 7. 6 m (1, 448%), while net income improved from a loss of 20. 64 m to a smaller loss of 13. 37 m.

Now that we know what the company is about, we can use tools like SWOT (Strength, Weaknesses, Opportunities and Threats), PEST factors (Political, Economical, Social and Technological) and Porter's 5 forces to determine the environment the company is working in.

PEST analysis

Political

1. Government imposes Good Clinical Practice (GCP) to research based companies. The company will have to keep up excellence in research in order to continue their clinical trials.

2. Research and development must obtain Research Ethics Committee (REC) approval for clinical trials by NHS.

3. Drug manufacturers must obtain

Economical

1. Research plays an important role in UK and is one of the most developing areas of UK's manufacturing industry.

2. Funding to a health based research

companies is complex. This might create a barrier for the expansion of the company.

3. The current tax rate for pharmaceutical businesses is 30%,

**licence from
Medicines and**

Healthcare

products

Regulatory

Agency (MHRA).

The Act was

designated by

Secretary of State

for Health in

England, effective

from 1971.

4. MHRA keeps a

check on the

companies even

after licensing. It

records and keeps

a check on the

adverse drug

reactions (ADRs)

5. The

commercialisation

of new drugs is a

big issue for such

companies and

(National Institute

for Clinical

Excellence (NICE)

plays an

important part in

it.

6. In future, when

Renovo's first

drug comes into

market (sold to

NHS), it will be

regulated by the

Pharmaceutical

Price Regulation

which is high and

this means less

profit for the

companies. The

tax rate might fall

to 2%.

4. UK's

pharmaceutical

and biotechnology

sector is growing

after an initial

decline due to

recession, which

means that the

company can see

more growth in

the future.

5. International

exchange rates

were facing an

initial fall due to

the decline of the

economy. The

exchange rates are

now recovering

gradually.

6. The UK

unemployment

rate has increased

a lot since past

three years

according to the '

Office of National

Statistics'.

Scheme (PPRS)

wherein the profits of the company will be monitored. This will hinder the company to make more profits.

Social

1. UK, along with many other developed countries is facing the problem of ageing population. This means that less of local young manpower is available.

2. Children in UK after the age of 16 become self dependant and few of them reach for higher studies. This lowers the skilled labour rate and thus gives space to foreign nationals holding higher job positions.

3. More and more people are becoming health conscious.

(Source: Food Standard Agency,

Technological

1. In today's world technology changes for the better, very rapidly. Small businesses need to be very competitive and technologically advance to keep up in the market space.

2. Globalisation offers numerous marketing opportunities. A big advantage for small business start-ups.

3. UK ranks among the top research elites in the world. R&D resources available here are at par with best technology available worldwide.

FSA)

4. People have busier lifestyles i.e. do not have time for leisure. Stress levels have increased drastically which indirectly affects work and increases risks of diseases.

5. The general public tends to buy products not only technologically advanced but also cost-effective.

4. Most of the technology today is automated and is aided by the Information Technology. The research lab in Renovo also utilises by far the most advanced technology to produce anti-inflammatory drugs combined with anti-scarring effects.

5. Technology should also be used not only to produce efficiently, but also to reduce environmental biohazards.

Porter's 5 force analysis

SWOT analys

Strengths

1. The founding committee consists of Professor Mark Ferguson (CEO) and Dr. Sharon O' Kane (CSO), which is highly qualified and have over 30 years of experience in the field of scarring, and are significantly big in

Weaknesses

1. The product line of Renovo is still in its initial phase and lot of work is required to get the drug into market.
2. Currently, the product

- pharmaceutical experience.
2. Located at the heart of all the research in the city. The Incubator building of The University of Manchester is the centre of research excellence in the department of life sciences.
3. Juvista is a product which is very innovative and a complete new technology. This has given Renovo an edge over its expected competitors.
4. The company has over 500 different intellectual property rights which show their strong research base.
5. Collaboration with Shire Plc to obtain their required investment is a big boon for the company. Renovo would be receiving a total sum of US \$825 million.
6. The anti-scarring effect of anti-
- line is very narrow and has only one lead product that is Juvista.
3. Lack of short term objectives. Lacks portfolio for new drug Zesteem i. e. no clear information available about the product and what the company is going to do about it.
4. Financials of the company show negative effect on the company. Maybe the company needs a more efficient management group which focuses more on marketing strategies of the company.
5. Since the company is newly founded, people are not completely aware of the

inflammatory products is unique for the market. It has helped to knock out competition.

7. It is a leader in discovery and development of drugs to improve the appearance of scars and enhance wound healing. company and its products.

Opportunities

1. Expansion of present product line is one of the main factors for Renovo.

2. Products can be diversified instead of just sticking to anti-scarring effects of the drugs. Possible new products being, drugs that have both anti-inflammatory and anti-scarring effects, so that a larger scope of the product can be created.

3. Expansion of customer base would also be possible if both inflammatory and scarring effects would be made in the same drug, which is quite possible.

4. The drugs would

Threats

1. One of the main threats is the entry of a new competitor in the same field with a new and better technology.

2. A related possible threat, because of the above reason, could be price wars with the competitor.

3. Another possible threat could be a dip in the levels of performance and financials of the company.

have great export opportunities and will be of high demand in the market place.

5. Establishment of strategic relationship with partners.

Conclusion

The environment in which the company operates has been determined and business model of the company can now be identified. The political factors show that the Government has strict regulations for good clinical practice and standards of the drug, which is good, but may become hard for the company to successfully get it to market. The company's technology is new which shows that there is no potent competitor in the near future which is a good thing.