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IMMUNOVACCINE (IMV):

Preparing to cross the “valley of death”

MBA 625 – Strategy in Action

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# Synopsis

# Analysis

## External Analysis

### Biotech Industry

Few large players, many small tech driven innovative companies

Small players can’t compete head on with pharma to develop products; mostly because of lack of funding. Mostly contribute via licensing and M&As.

Typically biotech builds around one central platform and apply it to vcarious applications. Strategy: innovate, patent and license or sell use of patent.

KSF – Innovation driven by science (and funding)

In order to sell to biotech, need to find good application for technology, and also required significant upfront investment.

Many companies fail into the valley of death; investment period when technology has been developed for use on a large scale and undergoes clinical trials. If run out of cash, need to either forego technology or accept unfavorable terms

#### Big Pharma

Big pharma is a mature and consolidated industry, with few large players controlling most of the market. Since these large corporations tend to be slow moving and risk adverse, most of the R&D in the industry has shifted to the biotech industry. Big Pharma companies, instead of investing in risky research with uncertain results, let biotech companies absorb the risk and simply acquire them or license products once they have proven success.

The risks involved, length of time and capital requirements required to develop new products make it extremely difficult for new player to enter the industry. Therefore

Because there is such a high barrier to entry,

Very high barrier to entry: mostly due to heavy financing requirements and long timeline for product development

Cost research to market - $200M – 2B$, average $800M.

Timeline for product development is 10 years

Success rate: 6% - small companies can’t bare that type of financial risk

In 2006 - $70B in development, but only 24 new drugs approved; 2.9B$ per new product

Heavy regulatory requirements

3 phases of clinical trials: small to assess safety, larger to show effectiveness, and large to show statistical significance of drug. Cost from start to final stage (pre-market/mafg) ~1B$ in testing and R&D

Successful products are highly profitable; can capture 100% market share with large profiuts protected by patents.

Have to compete with traditional businesses for investors

Targeting extremely long term risk tolerant investors

Large pharma invest very little in novel research, prefer to sit back and acquire startups with right products to minimize risks.

Slow moving, inadequate for innovating.

Patent wall approaching, soon to be flood of generics; large biotech might be looking for new sources of revenues.

## Internal Analysis

### Financials

Patented technology to control seal population in east coast. Partnered with local business person which helped secure 1M$ in investments. Allows IMV to get incorporated and purchase patents for vaccine called VacciMax platform.

Lots of local support financing in early stages

Much of management time is taken up identifying sources of money, raising money and allocating it.

Miss-alignment, management should focus on establishing direction and strategy, not finding funding. Should delegate.

Next: large amounts of capital required for clinical trials, but not enough internal data available to show value proposition. Need larger round of investments.

Source of funding: partner with Big Pharma, not been successful so far. otherwise, VC or IPO. IPO not preferred since far from having product on the market.

2009 Announced would go public in a reverse takeover.

### Structure

Biz dev function in Toronto, R&D in Halifax; resulted in weak communication

No regulatory or medical expertise in house.

Formed new analytical chemistry team.

Outsourced first production – transferred from analytical chemistry team to Dalton Pharma in Toronto. Went well. (but distance with RnD still an issue).

2008 – Acquired Immunotope, clinical stage Biotech Company based in Pennsylvania. Goal – Immunotope would continue R&D to feed IMV vaccine pipeline.

Revamped biz dev – internal person with scientific background, and experienced external consultant who would bring negotiation experience and extensive personal contacts in BigPharma. Was it enough?

### People

Original founders: CEO, CSO and VP Biz dev. CEO is ex dean of science, maintains ties with universities in order to use facilities and expertize when required.

Founder CEO use to handle all issues - should have delegated.

Hired Biz Dev with background in biotech, was not successful in attracting big pharma

Have good potential with cancer treatment application, but still no attention from BigPharma.

2006 – new CEO Dr Randal Chase.

Lots of experience in vaccine.

Good at delegating, does not want to deal with issues; rather brainstorming sessions to identify issues, prioritize and assign.

Goal – how to take technology out of lab into clinic.

Regulatory experience difficult to find and expensive to keep. Hire expert as part time consultant.

### Processes

Hire local businessman to secure 1M$ in funding

Company has little experience taking projects past lab stages.

2008 – Acquired Immunotope, clinical stage Biotech Company based in Pennsylvania. Goal – Immunotope would continue R&D to feed IMV vaccine pipeline. Immunotope to keep pipeline filled.

### Strategy

IMV strategy – hit and miss, bought patent and looks for problems to solve with it. In 2003, exploring if usable for cancer.

Started collaboration with CSL, bought by Pfiser Animal Health

Difficult to play in both human and animal health spaces; since regulation and processes completely different.

Animal – timeline shorter, lower profits and price determined by market willingness to pay.

Few biotech competing in Animal health, therefore competition for big pharma is low (low risk low reward).

Human health business: high risk high reward. Longer product developments. More regulation. Lots more competition. Risk passed on from BigPharma to small Biotech companies, Biotech base costs if initial development and if fail, take on all the risk.

Broad potential for IMV = unfocused partnering strategy. Work with whoever comes first.

Being tech platform and licensing to partners is not viable; since would always depend on bigPharma for revenues and small royalties. Decide to focus exclusively on human health field; divested form animal health business in 2008.

Now focus on building credibility, show that can manufacture in large quantities. Face choice between developing in house manufacturing capabilities, or outsource. Inhouse is difficult since GMP guidelines are difficult to follow; time consuming and costly.

In order to become more visible in the industry, hired a PR firm, small and dedicated, located near Halifax. Task – redesign logo, move IMV image away from Animal to human health and get on the radar of potential investors. Could PR work on larger issues than logo redesign?

Strategic partnerships: Academics provide access to technology and research skills, could be used to validate technology and create product pipeline. Goal to find partners for research programs to fund development of more products. IMV handle product till Phase 2 to show value through more data.

### Incentives

# Problem Statement

## Central issue

# Alternatives

*(Pros and cons in Exhibit 1)*

## 1.

## 2.

## 3

# Recommendation

# Implementation

## Short term

## Near term

## Long Term

## Measuring success

# Exhibit 1: Pros and Cons of Alternatives

## Alternative 1:

|  |  |
| --- | --- |
| Pros | Cons |
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## Alternative 2:

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| Pros | Cons |
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## Alternative 3:

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| --- | --- |
| Pros | Cons |
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# Exhibit 2: Balance Score Card