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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

### Big Pharma Industry

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, which is more suited for innovaiton. 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 to market, heavy regulatory requirements and capital requirements required to develop new products make it extremely difficult for new player to enter the industry.

Although developing new products is extremely risky (average 800M$ investment and 6% success rate), once these products are developed, they become extremely profitable because of patent protections. Pharma companies can capture 100% market share at inflated prices.

With the patent wall approaching, the market is soon to be flooded with generics, which will hurt pharma financials thereby motivating them to look for new profitable ventures. As such, the market is poised for biotech companies to showcase new innovation.

### Biotech Industry

The industry is segmented between a few large players and many small tech driven innovative companies. These small players can’t compete head on with pharma to develop products; mostly because of lack of funding.

Their basic operating model is to focus on innovation and securing funds until they have a marketable product, then collect license or proceeds of sale of patented technology. Their key success factors are innovation and ability to secure funding.

One of the largest challenges faced by biotech besides the science to develop new technologies is that they need to compete with traditional business for investors, which tend to provide more predictable and less risky returns on investments on much shorter periods of time.

### New Product Development Challenges

Typically products will undergo 3 phases of clinical trials, with a total expected costs from start to final stage (pre-market/manufacturing) varying from $200M to 2B$, averaging $800M. The timeline for product development is approximately 10 years and the success rate roughly 6%.

## Internal Analysis

### Financials

Originally, IMV was able to secure 1M$ in local investments used to get incorporated and purchase patents for VacciMax by partnering with a local businessman.

Since then, a lot of management’s time has been taken up in identifying sources of money, raising money and allocating it. This seems to be a misalignment since management should focus on establishing direction and strategy, not finding funding.

With clinical trial coming up, IMV will need to secure significant amounts of funding in order to have enough liquidity to maintain operations until profitability.

So far, IMV has not been able to secure partnerships with a big pharma. This is rather surprising since they already has strong ties with Pfizer via their animal business, and have a very promising product. There may be reasons to believe that this lack of success sis rather due to the company’s inability to demonstrate focus, or the business development manager’s competences.

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.

In 2009, IMV announced that it would go public in a reverse takeover. This is a rather risky endeavor, since shareholders typically demand precise cash flow forecasts, and IMV is still far from knowing when their product will be marketable and what kinds of cash flows it will generate.

### Structure

The company is geographically segregated by functions, with business development and analytical chemistry in Toronto, R&D in Halifax and Immunotope R&DF

; 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.

Focused on manufacturing, but haven’t secured buyer yet. Should get sales first.

### Incentives

# Problem Statement

## Central issue

# Alternatives

*(Pros and cons in Exhibit 1)*

## 1. Go Public via Reverse Takeover

## 2. Position IMV as Acquisition Target

## 3. Position IMV as Valuable Biotech

# Recommendation

# Implementation

Forget manufacturing – re-focus on business development and financing

## 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