Simon Foucher

710 7722

IMMUNOVACCINE (IMV):

Preparing to cross the “valley of death”

MBA 625 – Strategy in Action

Contents

[Synopsis 2](#_Toc449019926)

[Analysis 2](#_Toc449019927)

[External Analysis 2](#_Toc449019928)

[Big Pharma Industry 2](#_Toc449019929)

[Biotech Industry 2](#_Toc449019930)

[New Product Development Challenges 3](#_Toc449019931)

[Internal Analysis 3](#_Toc449019932)

[Financials 3](#_Toc449019933)

[Structure 4](#_Toc449019934)

[People 4](#_Toc449019935)

[Processes 5](#_Toc449019936)

[Strategy 5](#_Toc449019937)

[Problem Statement 6](#_Toc449019938)

[Central issue 6](#_Toc449019939)

[Alternatives 7](#_Toc449019940)

[1. Refocus on Animal Health Business 7](#_Toc449019941)

[2. Take One Flagship Product through Clinical Trials 7](#_Toc449019942)

[3. Focus on Volume Innovation – Generating Many Small Licensed Patents 7](#_Toc449019943)

[Recommendation 7](#_Toc449019944)

[Implementation 8](#_Toc449019945)

[Short term (Survive) 8](#_Toc449019946)

[Financials 8](#_Toc449019947)

[Business Development 9](#_Toc449019948)

[Regulation 9](#_Toc449019949)

[Structure 9](#_Toc449019950)

[Near Term (Mid Phase 2 Testing) 9](#_Toc449019951)

[Manufacturing 10](#_Toc449019952)

[PR 10](#_Toc449019953)

[Long Term (Focus on Sales) 10](#_Toc449019954)

[Financial 10](#_Toc449019955)

[R&D 10](#_Toc449019956)

[Sales/Customer Support 10](#_Toc449019957)

[Measuring success 11](#_Toc449019958)

[Exhibit 1: Costs of product development 12](#_Toc449019959)

[Exhibit 2: Capital Structure 12](#_Toc449019960)

[Exhibit 3: Pros and Cons of Alternatives 13](#_Toc449019961)

[Alternative 1: Refocus on Animal Health Business 13](#_Toc449019962)

[Alternative 2: Take One Flagship Product through Clinical Trials 13](#_Toc449019963)

[Alternative 3: Focus on Volume Innovation – Generating Many Small Licensed Patents 13](#_Toc449019964)

# Synopsis

IMV has an extremely high potential versatile product with many potential clinical applications. With the recent divestiture from animal health, the company is attempting to focus its strategy. With insufficient funding, lack of certain critical business capabilities and geographically dispersed business units, there is still lots which can be improved. In particular, IMV needs to decide how to position itself in the market, and strengthen its relationships with prospect eventual clients.

# Analysis

## External Analysis

### Big Pharma Industry

Big pharma is a consolidated mature industry, with few large players controlling most of the market. Since large corporations tend to be slow and risk adverse, Big Pharma companies instead of investing in risky research with uncertain results, let agile biotech companies absorb the risk and simply acquire or license products with proven success.

Although developing new products is very risky, successful products are 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 reduce Big Pharma revenues thereby motivating them to look for new profitable ventures. As such, the market is poised for biotech companies to showcase new products and 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%.

Exhibit 1 provides costs per phases of product developments. Based on these estimates, taking a drug through Phase 2 costs on average 11M$, but can be as high as 20M$.

## Internal Analysis

### Financials

IMV was able to rise 30.6M$ in capital (See Exhibit 2). With only 10M$ left of working capital, and recent divestiture of animal health business (e.g. all associated revenue streams from it), IMV does not have enough capital to survive until completion of Phase 2 of their flagship product.

Historically, 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.

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.

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 are focused on short term returns, and IMV is still far from knowing when their product will be marketable and what kinds of revenues will be generated.

### Structure

The company is geographically segregated by functions: with a cluster developing in Toronto:

This results in weak communication between divisions and higher costs to manage.

IMV also experimented with outsourced manufacturing, adding to the complexity of the structure. Although valuable to making a product appealing, developing manufacturing process for a drug that hasn’t passed Ph2 clinical trial seems like a misallocation of focus and resources, since success rates are as low as 6%. Also, since an outsourcing model is preferred, there is no rush to set up the process since there will always be 3rd parties ready to act quickly should a product make it through clinical trial.

### People

The original founder was able to secure ties with academia in, especially in the east coast, which has been valuable to help lift the company off the ground. With recent acquisition of Immunotope for R&D and the creation of an analytical chemistry team, these ties may not be as valuable.

The new CEO seems keen on the idea of delegating, unlike his predecessor who wanted to manage everything internally.

Considering the promising results of potential cancer vaccine application and the imminent patent wall approaching which push Big Pharma to eagerly search for new opportunities, the contribution of the existing VP business development is questionable.

### Processes

The new CEO’s direction is to focus on taking technology from the lab to the clinic, but IMV as a whole has little experience taking projects past lab stages. As such, they haven’t quite figured out the required business processes such as:

* Manage regulatory requirements: even with the help of external consultant, regulation could be a real show stopper or generate all kinds of delays/costs if not properly managed.
* Sustain working capital: So far, the company has amassed most of its cash from nonrenewable sources (equity, debt and grants), which are not as constant as operating income. After the spinoff of the animal division, IMV is left without operating revenues.
* New Product Innovation: IMV got some initial limited success with academia. With recent acquisition of Immunotope, it can expect a steady stream of innovation, but it hasn’t been proven yet, and there is no capability to take this innovation to the next level.
* Market products: Even with amazing test results on its cancer vaccine application, IMV was not able to generate interest in Big Pharma. IMV doesn’t seem to have a clear way to generate interest of prospective clients.

IMV was able to secure manufacturing capabilities, but this capability should have been at the bottom of their priority since it will not be used if the company can’t execute on the above deficient business processes.

### Strategy

So far IMV’s strategy has been rather unfocused; they bought patent and looks for potential problems to solve with them.

They also use to be split between the animal and human sectors. The new CEO made a clear choice to focus only on human health. Although it brings larger potential, IMV has no proven track records in that business, unlike in animal health which was generating revenues, and enabled them to form a partnership with CSL/Pfizer. The animal health business could have been spun-off as a subsidy in order to preserve relationships with Pfizer and some level of operating income.

IMV has also had an unfocused partnering strategy, with so many potential applications of IMV; the company would work with whoever comes first. Even in terms of R&D, partnerships with academia are maintained to create product pipeline, yet the company acquired Immunotope as an R&D center.

A lot of emphasis is now on building credibility by showing show that IMV can manufacture in large quantities. Although decision has been made not to peruse platform licensing since it would make them depend on Big Pharma for revenues and generate small royalties.

Recent resources have been invested in a PR firm in Halifax, but they have been more focused on tactical tasks such as logo re-design, rather than crafting new PR strategy. This could be due to the geographical disconnecting between the core of business functions in Toronto and the PR firm in Halifax.

# Problem Statement

For the time being, IMV is unfocused with no proven success and track records in human health. The company has great success in generating innovation, yet is pursuing a goal to take an existing technology to market, which does not require new ideas. Furthermore, IMV currently does not have the financial resources required to support its ambitions, and its structure is currently not efficient because of geographical disparities.

## Central issue

Should IMV focus its extremely limited resources in a high risk/reward strategy, a high potential product through clinical trial and onto the market, or rather take a more conservative approach focused on innovation, generating multiple patents which can be licensed to 3rd parties who will take them through clinical trial.

# Alternatives

*(Pros and cons in Exhibit 1)*

## 1. Refocus on Animal Health Business

This strategy implies going back and focusing on the Animal Health business and expand on existing successes. IMV was able to at least generate revenues from animal applications, and interest/partnership with big pharma, which is a step further than its endeavors in human health.

## 2. Take One Flagship Product through Clinical Trials

This is essentially continuing on the existing path of attempting to create a block buster product and take it through clinical trial into a marketable position. This strategy would imply restructuring the organization and focusing resources on evolving one flagship technology into a marketable product. It involves reducing R&D activities since a flow of new patents for potential other applications would no longer be required, would also imply significant cash injection and steering away from public markets until further clinical trial results.

## 3. Focus on Volume Innovation – Generating Many Small Licensed Patents

This strategy would imply focusing on leveraging the new R&D acquisition and ties with academia to generate a flow of innovation which can be patented and licensed to 3rd parties who would bare the risk of taking them through clinical trials.

# Recommendation

The biggest decision criteria in order to make a decision would be the risk appetite of the organization. Alternative 1 being the safest one with low potential but proven success, alternative 3 providing limited revenues but great success potential leveraging existing resources, and alternative 2 with the highest potential, but by far the riskiest.

Since divestiture of animal business is well on its way and there was a recent clear direction given to focus on human health, the first alternative can be eliminated; reverting to animal health could signal uncertainty in the industry in a time where leadership is critical.

Because of such high potential of the new technology, proven success of manufacturing capabilities and the fact that failure to generate Big Pharma interest might have been due to lack of adequate business development initiatives, the recommendation is to focus on the potential of this flagship product. IMV should slow down R&D and focus most of its (limited) resources in taking this product through clinical trial and generating big pharma attention.

# Implementation

## Short term (Survive)

### Financials

First IMV needs to backtrack on the reverse merger. Reverse mergers do not generate any capital, but rather only provide easy access to capital markets. Shareholders, as well as prospective public market investors will demand precise revenue forecasts, which will not be available until the end of clinical trial and serious conversations have been had with big Pharma. Going public right away would most likely only bring additional costs and pressure to generate cash in the short term.

In order to take the product to Clinical Phase 2, IMV would require an additional 10M$ in order to stay solvent, assuming worst case in terms of development costs (See Exhibit 1). And with Immunotope filling the pipeline of new products, IMV would need to also finance bringing potential new products to an attractive state. With a 6% success rate, IMV needs to develop 16 new products in order to come up with a second marketable product, which will require (assuming average case of 1M$ to take a new product through phase 1) an additional 16M$ in capital for phase 1 (Phase 2 of second product can be staggered after completion of phase 2 of first product, but phase 1 should be started.

The recommendation is to reduce R&D efforts to minimize capital requirements, and simply focus on rising the ~10M$ required to take their product to market. Based on their existing capital structure of roughly 1/3 in equity, 1/3 in private placements and 1/3 in government grants, IMV would require to raise 3-4M$ in equity, followed by another 3-4M$ in both grants and private placements.

To do so, IMV will need to create a dedicated financing team which will focus on prospecting potential investors, securing debt and applying for government grants. Since IMV was already able to secure 30M$ simply on good faith, having positive prospect for a product should be sufficient to generate enough interest to secure the additional equity funding.

### Business Development

Business development efforts should be increased by creating a department, led by the consultant who should be offered a VP position as permanent staff. With such high potential product and pore track record of existing VP of business development, there seems to be many lots opportunities of partnering with Big Pharma, which could potentially generate some near term revenues via licensing, or offset Clinical trial costs.

### Regulation

With focus on Human health, it will be critical for IMV to get solid understanding on regulatory requirements. Even though bringing a resource on board would be expensive, not meeting regulatory deadlines or requirements could generate significant delays in potential monetization of the products. As such, the regulatory consultant should be made permanent staff.

### Structure

IMV needs to pause investing in developing manufacturing capabilities until their product is closer to market. Should the product not make it to market, all money invested in developing manufacturing process would have gone to waste (and could instead have been invested in more R&D for new products, or business development efforts).

All primary business functions should be migrated to Toronto in order to centralize decision making and reduce communication overheads.

Since IMV already has a high potential product, IMV should also spin off the Immunotope division into a separate entity which will maintain focus on R&D, but license/sell innovation. Until IMV has more maturity, its R&D efforts should be maintained via partnerships in academia, which is low cost/low commitment.

## Near Term (Mid Phase 2 Testing)

As the product enters the clinical phase 2 testing and relationships with big pharma are strengthened, the following will need to be addressed.

### Manufacturing

Manufacturing process will need to be developed in order to prepare for eventual selling of the product. Since initial traction was already made on that front, IMV should re-open its dialogue with Dalson and refine its process.

### PR

Because of geographical disparity between Halifax and Toronto, it is currently difficult for the hired PR firm to focus on major value added strategic issues. Therefore, its mandate should not be renewed once the new logo is designed. The next step in PR will be to contract a Toronto firm, closer to Big Pharma headquarters, and really focus on reshaping the image of IMV as a leading Biotech firm capable of developing high quality / high potential products, delivered manufactured.

## Long Term (Focus on Sales)

### Financial

With either a concrete order book, or even existing sales, IMV should consider going public via an IPO. Existing revenues or confirmed intent to purchase can be used as a lever in prospectus to generate investor’s interest and help acquire capital. With a product at maturity, it will be a lot easier for IMV to manage investor’s expectations.

### R&D

With a first product reaching maturity, the R&D capabilities should then be intensified in order to generate new innovation and potential next products. A possibility could be to re-integrate Immunotope into IMV, or expand academic relationships.

### Sales/Customer Support

As sales will become imminent, IMV will require a sales team capable of managing customer expectations and order fulfilment. Logistics of distribution should also be addressed by partnerships.

## Measuring success

For short term, success will essentially be based on financial survival. As such, it should be measured via maintaining various financial liquidity ratios. IMV will also need to keep a close look into the evolution of their product through clinical trial, as well as ability to generate interest from Big Pharma.

IN the long term, success can be measured by number of new products making it through various stages of clinical trials. Conversion ratios will enable IMV to focus efforts where they bring the most benefits.

# Exhibit 1: Costs of product development

The following table outlines costs per phases. Pre-Clinical and Phase 4 are based on estimates, whereas other numbers were provided in the case

|  |  |  |  |
| --- | --- | --- | --- |
|  | Low | High | Average |
| Pre-Clinical | $5 | $10 | $8 |
| Phase 1 | $0 | $2 | $1 |
| Phase 2 | $2 | $20 | $11 |
| Phase 3 | $20 | $100 | $60 |
| Phase 4 | $2 | $10 | $6 |
| TOTAL | $29 | $142 | $85 |

# Exhibit 2: Capital Structure

The following chart shows summary of financing (numbers in M$).

Based on this, a fair assumption is that IMV can achieve the following capital structure: is 1/3 Equity investments, 1/3 Government Grants and 1/3 private placements.

It is worth noting that the ~2M$ obtained from animal health business are non-renewable after divestiture.

# Exhibit 3: Pros and Cons of Alternatives

## Alternative 1: Refocus on Animal Health Business

|  |  |
| --- | --- |
| Pros | Cons |
| Proven track record | Not aligned with CEO’s vision |
| Ability to generate income | Upwards income potential is limited |
| Low competition | Reverting recent divestiture could confuse prospective customers |
| Proven success in generating interest with Big Pharma |  |
| Shorter Innovation-clinic cycles means less capital requirements |  |

## Alternative 2: Take One Flagship Product through Clinical Trials

|  |  |
| --- | --- |
| Pros | Cons |
| Already have on highly promising product | Required significant inflow of capital |
| Lots of upside revenue potential | No success in generating big pharma interest |
| Already have success in manufacturing | Extremely risky (only 6% success rate) |
|  | Not aligned with extensive focus on R&D/Innovation |
|  | Not going public could generate negative feeling in prospective investors |

## Alternative 3: Focus on Volume Innovation – Generating Many Small Licensed Patents

|  |  |
| --- | --- |
| Pros | Cons |
| Already invested heavily in R&D | Not extremely attractive products for Big Pharma |
| Proven track record in innovation with promising product | Single digit licensing revenues |
| No significant capital needs | At the mercy of Big Pharma for revenues |
| Less risky |  |
| Less worry about regulation and simpler clinical trials |  |