Financing an early stage biotechnology company in Canada

By

Marc Mansour

A research project submitted in partial fulfillment of the requirements for the degree of Master of Business Administration

Saint Mary’s University

December 2013, Halifax, Nova Scotia

Copyright Marc Mansour

Written under the direction of Dr. E. Farrell

Approved: ___________________________ Dr Ellen Farrell
Faculty Supervisor

Approved: ___________________________ Dr. Patricia Bradshaw
EMBA Program Director

Date: ___________________________ December 18, 2013
Acknowledgements

First and foremost, I would like to thank my wife Gisela Martinez for her continuous encouragement and support.

Special thanks go to Dr. Mark Raymond, graduate coordinator and Dr. Ellen Farrell, my academic advisor, for their understanding, assistance and guidance in the development and completion of the research paper.
Abstract

Financing an early stage biotechnology company in Canada

By

Marc Mansour
December 18, 2013

Immunovaccine, a young Canadian biotechnology firm, for many years relied on several methods to finance its operations to date, including investment from angels, various forms of government grants and a reverse takeover (RTO) on the Toronto venture stock exchange (TSXV) to access the public markets. Currently the firm which has very favorable and expanding prospects is finding it difficult to raise significant funds in Canada. Investor interest is focused on natural resources stocks and the company, being listed on the TSXV, has limited access to US private equity and venture funds who view the stock as unpredictable and illiquid. Big pharma remains interested in more advanced products and the limited access to US public markets is crippling. The provincial government lends its support in the form of a repayable loan. In the end, the company turns to private investors in the UK and is over-subscribed in a private placement that extends its runway to 2015 while it contemplates its next move. This case outlines the difficulties experienced by an early stage biotechnology firm in Canada looking for capital to finance its long term requirements. Differences in the financing environment in Canada and the US and a roadmap to US capital markets are discussed. This is not intended to illustrate either effective or ineffective handling of a managerial situation. It is meant to provide a reasonable account of events and situations for the purposes of stimulating discussion.
Table of contents

Acknowledgements ii
Abstract iii
List of Tables vi

Financing an early stage biotechnology company in Canada 1
  Immunovaccine 1
  Overview of the vaccine market 3
  Immunovaccine’s business strategy 4
  Vaccine development path and commercialization 6
  Funding environment for Biotechnology in Canada 7
    Venture Capital (VC) 7
    Private equity funds 8
    Retail investors 9
  Immunovaccine’s funding history (2000-2010) 9
  Immunotherapy and Immunovaccine in 2013 14
  2013: the year of the biotech IPO 16
  What to do next 17

Teaching Aid 19
  Synopsis 19
  Teaching objectives 19
  Assignment questions 20
  Discussion points 21
    Company profile in two time periods 21
      2009-2010 21
      2013 24
    Benefits and challenges of a licensing deal with a pharmaceutical company 25
    Venture capital/ equity funds 26
    Public markets 26
  Wrap-up 28
List of Tables

Table 1: Immunovaccine's Pipeline in Q3 2010 6
Table 2: Profile of Immunovaccine Following the Equity Offering of September 16, 2010 12
Table 3: Investment History 2000-2013 13
Table 4: Profile of Immunovaccine Following the Private Placement of November 21, 2013 13
Table 5: Performance of Companies with a Market Cap Below $99 million at IPO 17
Financing an early stage biotechnology company in Canada

Immunovaccine

By the middle of November 2013, Albert Scardino (executive chairman) and Marc Mansour (chief operating officer) at Immunovaccine wrapped up investor meetings in the UK and across Canada. That same month, The Halifax, Nova Scotia, company closes an over-subscribed private placement bringing in $4.2 million. Immunovaccine just dodged a fatal cash flow problem. It bought itself another year, however serious funding issues were looming. The cash hungry biotechnology company was planning a three year-long phase 2 clinical trial for which it had no funding. “The oversubscribed placement is a reflection of strong investor support” says Albert Scardino. He adds “we now need to focus on funding the company for the next three years so we can deliver on our strategy”.

The Canadian biotechnology company which focuses on developing vaccines for the treatment of cancer relied on several methods to finance its operations since 2001, including investment from angels and various forms of government grants. In 2009, Immunovaccine listed on the TSX venture exchange (TSXV) through a reverse take-over (RTO) to access the public markets. The company was able to finance its activities through public offerings and private placements which allowed the science team to advance two cancer vaccines through phase 1 clinical trials at a cumulative cost of approximately $6 million per year.
For Immunovaccine, it became progressively more difficult however to raise significant funds in Canada. Since the 2008 crisis, venture funding in biotechnology was more limited. Additionally, being listed on The TSXV was viewed by venture capital funds and specialist US investors as problematic because of the limited trading of the stock on the junior exchange and the unpredictability of the share price. Canadian investors on the other hand were less interested in high risk biotechnology stocks with long timelines; they preferred to invest in natural resource companies.

The year 2013 was particularly difficult. Immunovaccine had announced in 2012 that it was a going concern with less than 12 months of cash resources. In the summer of 2013 and with the help of Wade Dawe, a local entrepreneur and a board member, the firm secured a $5 million Nova Scotia government loan to extend its runway to the end of the year. The conditions of the loan stipulated the completion of equity financings of at least $1.5 million.

In November, Albert Scardino convinces C.F. Ruffer, a London UK based private equity fund that had invested in Immunovaccine in 2010, to become the anchor investor in the private placement. Following a marketing road show on both side of the Atlantic, Canadian and UK Investors are excited about the positioning of the company in the field of cancer immunotherapy and the clinical data generated from the lead cancer vaccine DPX-Survivac. The company’s prospects are looking bright.
Overview of the vaccine market

Vaccines are considered a fast growing segment of the pharmaceutical industry. According to industry sources, the global market dominated by vaccines targeting infectious diseases had reached US$11 billion in 2006 with a growth of more than 10% a year reaching US$20 billion by 2012. New therapeutic cancer vaccines, along with new infectious diseases vaccines, are expected to maintain this growth in the coming decades. Five manufacturers dominate revenue generation in the vaccine market: Merck, GlaxoSmithKline ("GSK"), Novartis, Sanofi Pasteur ("Sanofi") and Pfizer, through its acquisition of Wyeth. Pricing for vaccine products has improved dramatically in the past decade, with newly approved vaccines demanding and achieving premium pricing solving a fundamental economics problem within the industry; Gardasil vaccine which protect adolescent girls from human papilloma virus infectious for example is selling for $160 per dose for three doses.

New therapeutic cancer vaccines are projected to be blockbuster products that will drastically improve the current standard of care for cancer patients. Current therapies rely heavily on surgery, chemotherapy and radiation therapy. Cancer vaccines are expected to become part of a multi-pronged approach for the treatment of cancer, with combination therapy approaches that incorporate vaccines expected to significantly improve patient survival. On April 30, 2010, the
FDA approved Provenge, a prostate cancer vaccine developed by Dendreon. This first approval of a therapeutic cancer vaccine in the US sets the stage for other cancer vaccines designed to retrain the body’s immune system to recognize and control tumors. The Provenge therapy is priced at $93,000 per patient.

The recent success of other therapies designed to tweak the immune system to fight cancer, including Bristol-Myers Squibb’s Yervoy™ (ipilimumab) and monoclonal antibodies targeting PD-1 had heightened the interest in immunotherapy. Because of the significant potential of immune based therapies, pharmaceutical companies aggressively pursued and acquired experimental cancer immunotherapy products, with some being in preclinical development. As a result, the interest in cancer vaccine companies also increased.

The area of therapeutic cancer vaccines, which is still in its infancy, is projected by some industry analysts to experience high growth, reaching USD$4.8 billion by 2018. Immune based therapies, of which cancer vaccines are one type, are expected to reach $35 billion per annum over the next 10 years. Pharmaceutical companies with active cancer vaccine programs in various stages of development (pre-clinical to Phase 3) include Roche, Merck KGaA, Pfizer, and GlaxoSmithKline.

**Immunovaccine’s business strategy**

Immunovaccine had developed a vaccine delivery platform that can dramatically enhance the activity of vaccines. Initially, the company pursued a
licensing model for other companies to develop novel vaccines that used the company’s DepoVax™ technology. Immunovaccine had successfully executed commercial license agreements with Pfizer animal health, giving the pharmaceutical company access to its technology for specific uses in veterinary medicine. There was a potential to generate royalty revenue in the coming years which could ultimately feed the company’s human vaccine development efforts.

Immunovaccine was now focused on human health vaccine development and started building a pipeline of products based on DepoVax™. In May of 2009, Immunovaccine gained exclusive access to a new vaccine targeting breast, ovarian and prostate cancers. This vaccine was discovered by Immunotope, a cancer research company based in the US. DPX-0907, which consisted of the new vaccine formulated in DepoVax™ was now a company controlled vaccine and the lead product in the pipeline. By the end of 2009, DPX-0907 was readied for clinical trials and a phase 1 study was initiated in the US in March of 2010. Despite its limited R&D resources which were primarily spent on advancing DPX-0907 in the clinic, Immunovaccine was also evaluating new infectious disease vaccines which were still in the discovery stage.

Business development efforts focused on identifying opportunities to acquire additional vaccine targets that can be formulated in the DepoVax™ technology to grow the pipeline. In the winter of 2010, a cancer vaccine candidate developed by Merck KgaA in Germany was identified as a potential acquisition target and a great opportunity for Immunovaccine. The vaccine named Survivac, was based on survivin which was well recognized in the
scientific community as a promising cancer target. Survivac had the potential to be applied to almost every solid tumor or blood cancer. In early 2010, Merck KgaA re-structured its pipeline and the development of Survivac was going to be halted to focus on later stage products. In July of 2010, Immunovaccine gained exclusive worldwide access to Survivac. The company quickly reformulate it in DepoVax™ and focused on advancing the new vaccine named DPX-Survivac into clinical trials, with the goal of making it its lead cancer vaccines in the near future.

Table 1: Immunovaccine’s Pipeline in Q3 2010

<table>
<thead>
<tr>
<th>Cancer</th>
<th>Phase 1 Clinical Therapeutic cancer vaccine targeting breast, ovarian &amp; prostate cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPX-0907</td>
<td>Preclinical Stage Evaluating several indications and preparing development plan for one or more of melanoma, colorectal, ovarian, prostate cancer, glioblastoma, multiple myeloma</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infectious diseases</th>
<th>Discovery Stage Pseudomonas aeruginosa vaccine to a hospital acquired infection that attacks the lungs</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPX- Petussis Aeroginosa</td>
<td></td>
</tr>
</tbody>
</table>

Vaccine development path and commercialization

Vaccine products, similar to other pharmaceutical products, must go through several stages of clinical development before a BLA (Biologic License Application) is filed in the US or its equivalent is filed in other jurisdictions. The enterprise value of a biotechnology company is generally defined by the results achieved in clinical trials and its stage of clinical development. Typically, phase 1 studies, which primarily evaluate the safety of the product in a relatively small
number of subjects, can take 1-2 years and cost approximately $5 million. After completion of a Phase 1 clinical program, the product must receive additional approvals from a regulatory body such as the FDA or Health Canada to allow the conduct of Phase 2 and Phase 3 trials. Phase 2 clinical trials can take from 2-5 years and cost $10,000,000 to $25,000,000 depending on the complexity of the trial and the number of subjects enrolled. Phase 1 and phase 2 cancer vaccine trials are generally more difficult to execute and are more costly than vaccine trials targeting an infectious disease. Phase 3 cancer vaccine programs cost an average of $80,000,000 and can be more than $300,000,000. Biotechnology companies typically conduct phase 1 and phase 2 trials to de-risk a potential product before seeking a large pharmaceutical partner to conduct large Phase III trials leading to product marketing and commercialization.

**Funding environment for Biotechnology in Canada**

**Venture Capital (VC)**

Venture capital is a common source for funding early stage biotechnologies, providing seed funding that can drive the development of a technology or a product to position it for acquisition by a large pharmaceutical company. The majority of North American biotechnology focused investments funds are located in the US. There are very few Canadian VC funds and they are considerably smaller than their US counterparts (funds were less than $200 million). Following the financial crisis in 2008 and throughout 2009 and 2010, access to capital was limited and establishing new funds everywhere including the US became very difficult. Simultaneously, existing funds sought investments
that were deemed less risky; they focused on companies with products that had completed phase 2 clinical trials or were within 1-2 years of commercialization.

Traditional venture capitalists were generally mandated to invest in private companies they can control. Importantly, they had difficulty justifying the valuation of a publically traded company to warrant an investment most of the time. Having a reputable fund with a biotechnology focus invest in a company was highly desirable because of the implied validation of the technology. A phase 1 biotechnology company however was generally assigned an enterprise value of approximately $10 million by venture capitalists. This was driven in part by the 2008 crisis, when VC funds were able to acquire a significant equity stake in cash-strapped biotechnology firms with an advanced clinical pipeline at very low valuations, making earlier stage companies with longer timelines a less attractive investment unless the valuation was extremely low.

Private equity funds

Large private equity funds can be very similar to VC funds in their investment approach but have more flexibility in deploying their funds. They can invest in private or public companies. They can be biotechnology experts or generalists investing across a number of health and non-health related sectors. They can be long term investors which is often the case if they are biotechnology focused (a fundamental investor) that held a significant percentage of the company’s equity (>10%). They can also be short term investors such as hedge funds. Fundamental private equity funds, similar to VC funds, face difficulty investing in publically listed company if the company valuation assigned by the
public markets in considered high. US based funds are also more inclined to invest in US based companies.

**Retail investors**

Retail investors are high net worth individuals who could invest in the company directly or through a broker, either in a private placement in the company or as part of public offering brokered by agents. Because of the strong interest in natural resources in Canada, the Canadian investment community is generally less enthusiastic about investing in a biotechnology because of the high risk nature of the investment and the long development timelines. It is also true however that Canadian retail investors could be attracted to an exciting biotechnology story if the company's stock was trading reasonably well (high trading volume or good liquidity) with a positive momentum and a significant event that can drive the stock price higher was achievable in 12-18 months. The amount of capital available from Canadian retail investors however is limiting; Immunovaccine might attract $1-5 million from Canadian retail investors whereas a US exchange listed company with a profile similar to Immunovaccine’s may attract $10-30 million from US retail investors.

**Immunovaccine’s funding history (2000-2010)**

Between 2000 and 2009, the company had been funded mostly by Halifax, Nova Scotia angel investors and federal government research and development grants. In 2009, a private placement was completed concurrently with a reverse take-over (RTO) of Rhino Resources, a TSXV listed shell. Small institutional investors participated in the private placement, but none were
biotechnology focused institutional investors. In July of 2010, the company was considering its financing options to continue funding its clinical activities. The expanded pipeline which now included DPX-Survivac meant that Immunovaccine could choose to advance one or more of its clinical or pre-clinical vaccines. Phase 1 results from the DPX0907 program were expected in Q2 of 2011, paving the way for a phase 2 clinical study provided a positive outcome is achieved. The newly acquired Survivac vaccine would require one year of development before it would be ready for a phase 1 clinical trial and the other pre-clinical programs would require even longer before they can proceed into early clinical studies. In addition to defining a strategy of which program to advance first, the company needed to identify new investors who would participate in the next round of financing. The current shareholders were unable to re-invest to support the growing capital needs of the company.

In the summer of 2010, Randal chase, a seasoned pharmaceutical executive and CEO of Immunovaccine needed to raise the additional capital to fund the company’s increasing research and development burn. The company had raised $8.8 million the year prior, however it was burning through its cash at an accelerated rate to complete the ongoing phase 1 clinical trial that had begun in March. The yearly burn rate was projected at Can$5-6 million per year. He needed to determine how much money to raise and which mechanism to use to support the company’s research and development activities for at least two more years.
Wade Dawe, a Halifax resident and an entrepreneur with significant experience in public market financing of resource venture companies in Canada was impressed by the potential of Immunovaccine as a game changer in cancer therapy. He invested in the company 2005 and concurrently joined the board of directors to help shape the company’s financing strategy. Randal had been approaching biotech specialists and venture funds who were receptive to the Immunovaccine story but consistently said “you are too early”. At a board meeting in the spring of 2010, Wade commented, “we need to find new investors, I can help”.

In August of 2010, Immunovaccine’s stock was trading at $1.30-1.40 assigning the company a market cap of approximately $60M. On the 11th of August, a prospectus for a public offering was announced. The share price rapidly declined in anticipation of the imminent financing, and the company saw 25% of its market cap erode. The board convenes an emergency meeting at the beginning of September and Randal Chase says “we have to price and close this financing immediately”. On the 16 of September, The equity offering closes with a price of $1.00 for one share and a half warrant (the unit) for gross proceeds of approximately $7.5 million. C.F. Ruffer, a large institutional investment firm from London, UK, with a broad investment focus becomes the largest shareholder owning approximately 7% of the company’s equity. C.F. Ruffer is identified with the help a UK-based resource focused investment banking firm that had previously done business with Wade Dawe.
Table 2: Profile of Immunovaccine Following the Equity Offering of September 16, 2010

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares Issued and outstanding</td>
<td>53.0 million</td>
</tr>
<tr>
<td>Fully diluted</td>
<td>60.9 million</td>
</tr>
<tr>
<td>Market cap</td>
<td>$50 million</td>
</tr>
<tr>
<td>50 week high</td>
<td>$1.57</td>
</tr>
<tr>
<td>50 week low</td>
<td>$0.71</td>
</tr>
<tr>
<td>Average daily volume</td>
<td>110,000</td>
</tr>
<tr>
<td>Cash resources</td>
<td>$11 million</td>
</tr>
</tbody>
</table>

With a Cash balance of $11.7 million, the new flagship product DPX-Survivac is rapidly prepared for a phase 1 clinical trial in the US and Canada. During that time, positive phase 1 results for DPX-0907 are announced and the company receives a grant of $2.9 million from the Atlantic Canada Opportunities Agency (ACOA) to fund research and development efforts in cancer therapy. The FDA and health Canada accept the company’s proposal for a clinical trial with DPX-Survivac in the second half of 2011. The clinical trial starts before the end of the year with data expected in early 2013. Marc Mansour, Chief Science Officer, tells investors “for now, we can only fund the clinical development of DPX-Survivac, our flagship vaccine”. He adds, “we will advance the other programs using grants and in collaboration with others as much as possible”. 
Table 3: Investment History 2000-2013

<table>
<thead>
<tr>
<th>2000-2009 (Immunovaccine Technologies Inc., Private company)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity Invested 2000-09                                      $11.0 million</td>
</tr>
<tr>
<td>Government Grants 2000-2009                                  $9.4 million</td>
</tr>
<tr>
<td>Equity Private Placement Sept 09 (concurrent with RTO)       $8.8 million</td>
</tr>
<tr>
<td>License Fees Collected – Pfizer Animal Health                $1.8 million</td>
</tr>
<tr>
<td>2010-2013 (Immunovaccine Inc., TSXV: IMV)</td>
</tr>
<tr>
<td>Equity offering Sept 10                                      $7.4 million</td>
</tr>
<tr>
<td>ACOA grant Mar 11                                            $2.9 million</td>
</tr>
<tr>
<td>Private placement Mar 2012                                   $2.7 million</td>
</tr>
<tr>
<td>Private placement Mar 2013                                   $1.6 million</td>
</tr>
<tr>
<td>Government loan Aug 2013 (up to $5 M available)              $1.25 million</td>
</tr>
<tr>
<td>Private placement Nov 2013                                   $4.2 million</td>
</tr>
</tbody>
</table>

Table 4: Profile of Immunovaccine Following the Private Placement of November 21, 2013

| Shares Issued and outstanding | 78.9 million |
|Fully diluted                  | 85 million |
|Market cap                     | $39.4 million |
|50 week high                   | $0.55 |
|50 week low                    | $0.22 |
|Average daily volume           | 40,000 |
|Cash resources                 | $6 million |
**Immunotherapy and Immunovaccine in 2013**

A new class of therapeutic compounds that influence the immune system (immunotherapies) and cause it to go into hyper-drive to control cancer have become of great interest to the medical community. Results released in 2012 and 2013 showed that patients can experience dramatic shrinkage in their tumors. They were living longer, some unexpectedly for several years.

The excitement in this area of research caused big pharmaceutical companies to launch aggressive licensing and acquisition programs in 2013 driven by their desire to not miss out on what promises to be one of the biggest advances in cancer treatment in recent memory. The limited number of unencumbered immunotherapy assets meant that companies had to acquire earlier stage assets. Despite being in very early development, cancer immunotherapy assets were snapped up at very high valuations that were justified by their strategic value. Astra Zeneca for example acquires Amplimmune, a privately held biotechnology company with a preclinical immunotherapy asset (anti-PD-1), for $225 million in cash and an additional 275 million in milestones. Other companies such as Bayer license preclinical immunotherapy assets from Compugen for $40 million upfront and $540 million in future milestones.

This noticeable shift toward strategies of tweaking the immune system to control cancer boded well for Immunovaccine. Results from its phase 1 study with DPX-Survivac showed that the cancer vaccine was activating the immune system exceptionally well against its intended target, the cancer signature...
survivin. The immune responses reported by the company were of higher magnitude and higher activity that had been reported by any cancer vaccine to date.

Cancer vaccines were now viewed as a critical ingredient of “next generation therapies”. In October of 2013, the head of Pharma Research and Early Research (pRED) at Roche declares his company was interested in clinical stage cancer vaccine partnerships as part of its early development strategy.

Immunovaccine hires Llew Keltner, a US based consultant with strong connections to big pharma and the finance community in the US. With his help, the company’s phase 1 data are packaged and presented to the various pharmaceutical companies in the hope of attracting a licensing agreement that will fund the planned clinical trials and the company’s research activities over the next several years.

During the year, Marc Mansour presents the results achieved with DPX-Survivac to the National Cancer Institute of Canada (NCIC). They agree to sponsor the large phase 2 trial involving 250 patients with ovarian cancer. With the NCIC sponsorship, the budget for the trial is reduced to $10 million.

Immunovaccine is now focused on securing the funds for this trial, which is considered the most significant catalyst for the company. The trial is expected to start in the second half of 2014 and deliver results in late 2017. The company needed a minimum of $30 million over the next three years.
2013: the year of the biotech IPO

Robust capital markets turned to the biotechnology sector in 2013, which was marked by the return of generalist investors who were ready to deploy cash in IPO’s. Their goal was to benefit from a run up following an IPO in the short term and many were willing to wait for an inflection point that was promised in 12-18 months. Unlike institutional who often demanded a discount for earlier stage/higher risk companies seeking an IPO, the generalists were less price sensitive.

With this strong influx of investment, more than 33 biotechnology companies completed an IPO raising approximately $25-75 million each. These transactions were executed by reputable banks with biotechnology experience including, Citigroup, Bank of America, Morgan Stanley among others. Smaller investment banking firms of which Aegis was most prominent helped earlier stage biotechnology firms raise $25-30 million through NASDAQ IPOs. The Larger banks targeted primarily institutional biotech investors whereas Aegis focused primarily on retail investors who were more likely to trade a stock following the 180 day quiet period.

Of all the companies that registered on NASDAQ in 2013, only two, Sophiris and Acasti, were Canadian. Sophiris was a TSX listed company that moved its headquarters to Southern California before raising 65 million through a NASDAQ IPO. Acasti, a TSXV listed company, met the qualification to list on the NASDAQ and did so in an attempt to increase stock liquidity.
A NASDAQ listing provided several benefits: US investors valued biotechnology companies based on reported clinical results which translated into an immediate increase in market cap. More importantly, a NASDAQ listing was an effective tool to finance cash hungry biotechnology companies because of the ready access to a large and diverse pool of investors. Unfortunately, Immunovaccine did not qualify to cross list on the NASDAQ with its current share structure,

What to do next

During 2013, Immunovaccine was watching the growing interest in immunotherapy and the strong resurgence in equity investment in the
biotechnology sector in the US. To solve its long term financing difficulties, it tries to license the technology to a pharmaceutical partner but the process takes longer than anticipated. The year 2013 was coming to a close and Immunovaccine closes a round of investment totaling $4.2 million to solve its immediate cash flow problem. Now it needed to address it funding issues for the next three years.

Over the telephone at the end of November, Albert Scardino tells Marc Mansour, “now that the private placement is behind us, we need to outline our financing strategy over the next three year at the next board meeting”.
Teaching Aid

This teaching aid is to be used with the case titled “financing an early stage Biotechnology company in Canada”. The goal is to assist students in having a deeper understanding of the financial challenges and the business issues faced by early stage biotechnology companies and evaluate short and long term solutions through discussion. The case is not intended to illustrate either effective or ineffective handling of a managerial situation.

Synopsis

The case covers two periods of Immunovaccine’s recent history (2009-2010 and the present 2013) when the company’s pipeline was in different stages of development and the capital needs were significantly different. There are significant differences in the financing climate during these two periods, one following the financial crisis of 2008 and the tightening of investments in high risk equity, the other at the end of 2013 which was considered the strongest biotechnology IPO years in recent memory in the US. The company, being listed on the TSXV, while being a funding solution in previous years, became an obstacle rather than a useful tool for financing the growing capital needs of the company in a sustainable way.

Teaching objectives

Evaluate the company’s pipeline in 2010, its projected timelines and capital needs to reach an inflection point that could lead to follow on investment to further progress its programs. Explore the benefit and drawbacks to the
company and its shareholders presented by the different sources of funds available (biotechnology specialist venture capital funds, generalist fund managers, individual retail investors). The issues of control, dilution and stability are central.

Explore the different value propositions to prospective investors in 2010, taking into account the amount of money it could expect to raise and which compelling story it may tell investors: should the company march on developing its lead asset DPX-0907 into a phase 2 clinical study, which would cost significantly more but could drive the company’s market cap higher in 2-3 years, or should it concentrate on DPX-Survivac which has not entered the clinic yet?

With the success of DPX-Survivac in the phase 1 trial, the vaccine needs to proceed to phase 2 trials and Immunovaccine now needs at least $30 million over the next 2-3 years. Discuss the company’s options in 2013 having secured a government loan and completed a 4.2 million private placement, which provided some breathing room into 2014. Compare and contrast the issues associated with funding from a pharma partner, a private equity/ VC fund, or the public markets. Evaluate the likelihood of success on the TSXV versus the NASDAQ if the public market route was pursued.

**Assignment questions**

1- Map the timelines and capital needs of the company in 2010 based on its pipeline at the time with projections into 2013. Discuss how much money would be needed to reach at least one catalyst. Being a publically listed
company, and considering its TSXV profile at the time, describe the benefits of getting the funding through a public offering. Evaluate if the amount raised in 2010 is sufficient to reach an inflection point.

2- In light of the strong phase 1 data now in hand in 2013, the growing investor and pharma interest in the area of research the company is engaged in and the active IPO market in the US, make a financing strategy recommendation (a plan A and a plan B) going into 2014 and explain the rationale.

Discussion points

Company profile in two time periods

2009-2010

In 2009 and following a private placement for $8.8 million (concurrent with the RTO) and with $1.8 million in licensing fees from Pfizer animal health, the company had cash resources of over $10 million. The projected budget for 2010 was approximately $6 million or $1.5 million per quarter. The company effectively has sufficient funds to run until Q1 2011. Phase 1 data from DPX-0907 was expected in Q4 2010/ Q1 2011.

A phase 2 clinical trial for DPX0907 required a minimum of $30 million. This was to fund the trial costs estimated at $15-20 million and the foundational operations of the company estimated at $4 million/ year for the next 3 years. There are many VC funds capable of providing this funding. Alternatively the money required could be raised through a public offering. Angels could not
provide funding of this magnitude. Angels had invested a total of $11 million between the years 2000 and 2009.

It was difficult for any venture capitalist to justify the $60 million valuation assigned to the company by the public markets. To invest $30 million and only own 33% of the company was an expensive proposition for a VC fund. Venture capitalists also struggled with their inability to fully control a publically listed company and its valuation.

Alternatively, the funds could be raised through one or more public offerings. In 2010, the stock price had appreciated 20% (a positive trend) and approximately $110,000 shares were trading every day. A public offering in Canada could bring upwards of $10 million judging from investor interest in Immunovaccine in 2009. However a company that raises only part of the funds it needs to complete a clinical trial is very vulnerable. Investors would hesitate to fund a company part way before reaching a catalyst.

The preparation for and completion of a DPX-Survivac phase 1 trial would require approximately 2 year based on the length of time it took for DPX-0907 to deliver phase 1 data. In August 2010 the company had approximately $5 million of cash remaining ($11 million in cash resources in Sept 2009 minus approximately $6 million expenditure per year). If the company accelerated the DPX-Survivac program, it could potentially reach a phase 1 result by the end of 2012. An additional $7 million were needed assuming the yearly expenditure of approximately $6 million remains unchanged. That was a sum that was attainable
in a single public offering in Canada based on the results of the private placement completed in 2009.

There were many benefits for advancing the DPX-Survivac program: it would be more popular with investors because of the association with a pharmaceutical company and the assumption that Merck KgaA would license or purchase the product back if successful. Raising funds in a public offering was also attractive because it could be done with only a small discount (typically 10% discount to market price) which minimizes dilution. The company was trading a near all-time high, which also minimized the effect of dilution. Furthermore, a public offering was likely to involve a large number of investors, with a lower likelihood that any one shareholder would have a significant controlling stake. The board would remain in full control of the company.

Short term investors that participate in an offering, unlike long term biotech investment funds, are more likely to take advantage of spikes in the share price. This can place strong downward pressure on the stock price, particularly when a catalyst is not immediate and trading volumes are low. Trading volumes are representative of investor interest in the stock. High trading volumes can help shuffle large blocks of shares where demand can easily meet supply. Immunovaccine’s trading volume in 2010 was healthy ($100,000 on average changing hand on daily basis). The decrease in trading volume over the years and the lower share price recorded in 2013 reflected the evolution of investor sentiment toward Immunovaccine.
The year proves to be transformational for Immunovaccine. It obtains strong phase 1 data from its flagship program DPX-Survivac at a time when the medical community and pharmaceutical companies show interest in the area of research the company is engaged in. The timing is good to pursue a commercial partnership. An experienced consultant is hired to help achieve this outcome. The goal of a partnership is to fund the phase 2 program ($10 million) and provide sufficient cash upfront to fund at least a significant part of the company’s foundational operational expenses ($6 million/year). Ultimately the company is looking for $30 million dollars to cover its expenses over the next 3 years.

The possibility of a licensing deal that may be executed in 2014 is a key point made to investors while marketing the private placement in November of 2013. The interest of pharma in cancer vaccines is highlighted and emphasized in the investor presentation.

Also in the presentation, Immunovaccine’s profile and market cap on the TSXV is compared to that of NASDAQ listed companies to illustrate that the company is severely undervalued. That comparison proves to be relevant to investors who also hear that the company is evaluating a path to become listed on a US exchange at some point in the next 2-3 years.

The value proposition for investors participating in the private placement is a 5x return in the next 3 years, taking into consideration the current value of the company ($30 million), the need for an additional $30 million in equity financing.
and the possible valuation in 3 years of $300 million based on comparable NASDAQ listed companies.

**Benefits and challenges of a licensing deal with a pharmaceutical company**

A licensing or option to license deal with a pharmaceutical company would validate the technology and would be very welcome by investors. Importantly, such a deal can help capitalize a company in the form of upfront and milestone payments in addition to funding the company's clinical programs. In return, the pharmaceutical company gains access to the compound so it can develop it through the later stages and market it, eventually paying the biotechnology company a royalty stream. The future value of the licensing deal is recognized by the public markets almost immediately causing an upward shift in the stock price.

The biggest challenge in executing a licensing deal is the time it takes to execute. Assuming there is interest in the technology, due diligence processes at pharmaceutical companies can be lengthy and there is always a risk communications will falter. The pharmaceutical companies are motivated to delay the process to drive the best deal possible. Importantly, once licensed a product is no longer under the control of the biotechnology company. The success of the company becomes dependant on the success of activities managed by the pharmaceutical partner. A company become vulnerable to delays in advancing the program they have a great stake in. These challenges and limitations are typically offset by the large payments made by the pharmaceutical company throughout the life of the project. Immunovaccine will need to make sure the
upfront payments and milestones can fund the company’s operations for several years for a licensing deal to be meaningful.

**Venture capital/ equity funds**

In November of 2013, Immunovaccine is valued at $30 million, a much lower valuation than in 2010. It is also in a more advanced stage, planning phase 2 trials in collaboration with the NCIC who will help offset the cost of development going forward. The company can now attract venture capitalists at least from a valuation standpoint. VC funds remain hesitant to invest in a TSXV company.

A venture capital fund is looking for a profitable exit. The standard exits for a VC fund are acquisitions and initial public offerings. A Venture capitalist would be more likely to invest in Immunovaccine if the company were to list on a US exchange within a reasonable timeframe (12-18 months).

One benefit of receiving an investment from a VC fund is the validation of the technology that is implied by association. The challenge is a VC fund will often demand a significant discount to market price which would cause price pressure, at least in the short term, and would result in more dilution than would be experienced raising capital in a public offering.

**Public markets**

The profile of the company was very different in 2013 compared to 2010. The share price was around 30 cents for the majority of the year, and the trading volume was considerably lower. Daily trades were less than $10,000, which was a reflection of the limited interest from investors. Near the end of 2013 however,
interest had increased and the share price started to climb reaching a high of 55 cents. This was driven by marketing efforts in Canada and the UK leading to the close of the private placement.

Access to US retail investors was limited. US based brokers were not allowed to solicit investment in a company that was not listed in the US. US based Institutional investors were not interested in investing in a TSXV listed company unless there was a clear path to a listing in on a US exchange. It was clear that the company needed to list on a US exchange as soon as possible to access US investors.

The company needed to raise $30 million. This could not be achieved easily on the TSXV. The recent private placement was led by one generalist institutional investor that wanted to increase their holding to 15%. Any future private placements are likely to be of the same magnitude or lower considering that C.F Ruffer participation would be limited to 15% of any future financings.

To execute a public offering in the US, the company needed to cross list on the NASDAQ. Several banks could help but several were restricted by the size of the offering. The typical offering was $60-75 million, and large institutions such as Bank of American and Citigroup would not lead a smaller offering ($30-40 million for example). Smaller banks (Aegis for example) specialized in smaller financing (under $30 million). Working with mid tiered banks such Leerink and Cowen however was preferred.

Working with mid tiered banks provides the following benefits
- They have access to long term biotech Institutional investors

- Their research analysts are well respected

- They can do smaller offerings ($30-40 mil) and support follow-on financing activities.

Smaller banks focused on retail investors for executing the smaller offerings under $30 million. Retail investors were less likely to negotiate the price of the offering. Of the companies that had a market cap of less than $99 million at IPO and used Aegis as their investment banker, the offering generally priced at the bottom of the pricing range. In contrast, earlier stage companies that used seasoned biotechnology investment bankers priced below the range. This was a reflection of institutional investors demanding a discount for earlier stage companies they viewed as more risky.

Despite pricing pressures, it is always more desirable to bring in institutional investors that would support the company in the long term and participate in follow-on rounds of financing. Retail investors were more likely to trade as soon as they were allowed, which would add significant volatility to the stock price.

Wrap-up

After a rough period between 2010 and 2013, Immunovaccine had positioned itself as a pioneer in the immunotherapy space and its prospect were improving. It had partnered with the NCIC to help advance its programs. Its share price was gaining momentum because of the improved investor interest in the
company. The vision of the company to list on a US exchange in the coming years was welcome. In light of the recent IPO activity in the US, there was a potential window of opportunity to do so earlier than previously anticipated. Several companies with similar valuations to Immunovaccine’s had succeeded in executing smaller IPO in the range of $30-40 million.
Immunovaccine’s corporate Presentation for the private placement of November 2013

(Reproduced with permission of the copyright owner)
MARKET OPPORTUNITIES FOR DepoVax™ BASED THERAPIES AND VACCINES

- Cancer immunotherapies including vaccines:
  - To become treatment of choice for up to 60% of cancers
  - To exceed $35 billion/year in the next decade

- The vaccine market for infectious diseases was estimated at nearly $19 billion in 2012, with a CAGR of 6.9%

- US Biodefense contracts and national stockpiling programs awarding $50-200 million for individual company products represent a significant market opportunity

“NEXT-NEXT” GENERATION IMMUNOTHERAPIES—COMBINING NEXT GENERATION IMMUNOTHERAPIES WITH TARGETED T CELL ACTIVATION (CANCER VACCINES)

<table>
<thead>
<tr>
<th>Company</th>
<th>Announcement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janssen (Johnson &amp; Johnson)</td>
<td>October 3, 2013: Research and option agreement with DCPprime BV</td>
</tr>
<tr>
<td>Roche</td>
<td>October 3, 2013: Interest in clinical stage cancer vaccine partnerships as part of the new strategy</td>
</tr>
<tr>
<td>Merck KGaA</td>
<td>September 25, 2013: Vaccines one of four focused areas of R&amp;D, continuing phase 3 development with Stimvax</td>
</tr>
<tr>
<td>Pfizer</td>
<td>September 11, 2013: Preliminary cancer vaccine program announced</td>
</tr>
<tr>
<td>GSK</td>
<td>September 5, 2013: Multiple vaccine programs in development, continuing phase 3 development with MAGE-A3 vaccine</td>
</tr>
</tbody>
</table>
IMMUNOVACCINE INC. (TSX:IMV)

- Programs in multiple cancer and infectious disease indicators

- 21 employees with scientific capabilities in:
  - Preclinical immunology
  - Analytical chemistry
  - Formulation research

- Currently uses consultants and outsources for:
  - Medical and Regulatory affairs
  - Immune monitoring
  - GMP product production
  - Clinical trial management

Strong Leadership and Experience

Board Members

Wade K. Dawe, CEO of Brigus Gold (NYSE Amex: BRD; TSX: BRD)

James W. Hall, CA, Senior VP of Investments GrowthWorks

Stephanie Léouzon, Senior Advisor to Torreya Partners, formerly Credit Suisse

Wayne Pisano, Former President and CEO of Sanofi Pasteur

Brad Thompson, Ph.D., CEO of OncoLYTICS (TSX: ONC, NASDAQ: ONCY)
DEPOVAX: A NEW WAY TO PRESENT VACCINES TO THE IMMUNE SYSTEM

Optimized depot formulation enables strong immunity

Histology of subcutaneous injection site in mouse

Controlling vaccine processing by the immune system

IMMUNOVACCINE’S PIPELINE
PRODUCTS BASED ON THE PATENTED DEPOVAX™ PLATFORM
DPX-Survivac Opportunity

- A T cell activator immunotherapy targeting the broadly expressed tumor and cancer stem cell associated antigen Survivin

- One of the strongest immunogenicity profiles in cancer patients reported in the literature

- Entering two (2) large randomized controlled phase 2 studies in ovarian cancer (in partnership with NCIC) and glioblastoma (Italy)

- Potential for combination with checkpoint inhibitors, T cell modulators, ablative therapies, targeted therapies, and tumor growth inhibitors
Infectious Disease and Bioterrorism Applications

Infectious Disease and Bioterrorism Vaccines

- RSV vaccine for the elderly
  - Targeting a new RSV antigen with a novel mechanism of action
  - Entering a fully funded phase 1 study in 2014

- Anthrax vaccine for civilian and military use
  - Rapid response potential demonstrated in NIH-led studies
  - Establishing an advanced development program with US agencies
IMMUNOVACCINE GOALS

Capitalize on the potential of DepoVax™ in cancer immunotherapy

Diversify by pursuing select applications and licensing opportunities

Transform into a mid-stage clinical development company

Pursue a Pharma Partnership for DPX-Survivac

Evaluate a path to a US listing

IMV AND PROFILE OF SELECT NASDAQ LISTED COMPANIES
PUBLICLY TRADED BIOTECH COMPANIES WITH CANCER VACCINE PROGRAMS: TSX versus NASDAQ

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Cap (M)</th>
<th>Vaccines</th>
<th>Indication (Phase)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunovaccine TSV: IMV</td>
<td>28.3</td>
<td>DPX-Survivac DPX-2007</td>
<td>Ovarian (Phase 1-2)</td>
</tr>
<tr>
<td>Genta Biopharma, Inc</td>
<td>193.35</td>
<td>Nelaprevir (Nevirapine)</td>
<td>Breast Cancer (Phase 3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PRO 1044</td>
<td>Prostate cancer (Phase 1)</td>
</tr>
<tr>
<td>Immunocore Therapeutics</td>
<td>143.39</td>
<td>ICT-107 ICT-140</td>
<td>GBM (Phase 2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>GBM (Phase 2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ovarian, Cancer (Phase 1)</td>
<td></td>
</tr>
<tr>
<td>NeoBiocare Genetics Corp</td>
<td>556.13</td>
<td>HyperAcute  Pancreas</td>
<td>Pancreatic Ca (Phase 3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HyperAcute  Lung Cancer</td>
<td>NSCLC (Phase 2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HyperAcute  Prostate Cancer</td>
<td>Prostate Cancer (Phase 1)</td>
</tr>
<tr>
<td>Northwest Biotherapeutics</td>
<td>118.13</td>
<td>DOV/L  Prostate</td>
<td>GBM (Phase 3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DOV/L  prostate</td>
<td>Prostate Ca (Phase 3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DOV/L  Head/Neck</td>
<td>Colon Ca (Phase 1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Head and Neck Ca (Phase 1)</td>
</tr>
<tr>
<td>Anthera, Inc. NASDAQ: AGEN</td>
<td>51.20</td>
<td>Ad-ADE Q(0-200) R(200)</td>
<td>RCC (Phase 1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>GBM (Phase 2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>RCC (Phase 2)</td>
</tr>
<tr>
<td>Siemagine Therapeutics, Inc</td>
<td>559.29</td>
<td>BiVQ1</td>
<td>GBM (Phase 3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Prostate Ca (Phase 3)</td>
</tr>
<tr>
<td>Oxbil Therapeutics, Inc.</td>
<td>2.636.16</td>
<td>Rizoximut</td>
<td>GBM (Phase 3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CDX-1401</td>
<td>AML, solid tumor (Phase 1)</td>
</tr>
</tbody>
</table>

IMMUNOVACCINE (TSX: IMV) TODAY (NOV 4, 2013)

- Share price: 0.45
- 52 week range: 0.22 - 0.47
- Mkt cap: 30.79M
- Shares Outstanding: 68.4M
- Avg. Vol: 82,308 00

Oct 28, 2013
- Immunovaccine Announces a Non-Brokered Private Placement of $3.2 million (up to $5M sought)
- Minimum of 8 million shares to be sold at $0.40;
- Offer expected to close November 15, 2013
FINANCIALS AND PROJECTED GROWTH

- Current Yearly burn rate- $6M
- Private placement will provide sufficient cash resources into 2015

2013 IMV (TSXV) $30M

2014 Additional 30M raised from Pharma deal, institutional investors and/or US IPO

2015 Projecting a >5X ROI in 3 years

2016 IMV (NASDAQ) >$300M

PROJECTED MILESTONES IN 2014

1Q14
- Phase 2 Glioblastoma trial initiated
- Anthrax data in non-human primates released
- Partnership with BARDA established (Anthrax vaccine)

2Q14
- Pharma partnership for DPX-Survivac announced

3Q14
- Phase 2 DPX-Survivac trial (NCIC sponsored) initiated
- Phase 1 RSV trial initiated (6-12 month trial)

4Q14
- Phase 2 glioblastoma trial initial results released
- Phase 1 RSV trial initial results released
- Results of pre-clinical anthrax studies released
PROJECTED MILESTONES THROUGH 2017

2015
- Phase 2 Glioblastoma trial results released
- Phase 1b/2 RSV trial initiated
- Phase 1 anthrax trial initiated

2016
- Additional Glioblastoma trial results released
- Phase 1b/2 RSV trial released
- Phase 1 anthrax trial released

2017
- Phase 2 ovarian cancer data released

IMMUNOVACCINE INC. (TSX-V: IMV)

For more information:

Marc Mansour, PhD
Chief Operating Officer
T: 902-492-1819
E: mmansour@imvaccine.com

www.imvaccine.com