The Quebec City Conference 2013

PPF

Life Sciences Track

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QCC **PUBLIC POLICY FORUM** ON VENTURE CAPITAL AND INNOVATION

Quebec City, December 3-4, 2013

Life Sciences Track

"Tech transfer and seed funding models in life sciences in the context of (i) pharmaceutical companies looking for new types of partnerships with universities and VC funds and (ii) VC funds developing new models for seeding their deal flow"

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1. Introduction

The session's general theme: Tech transfer and seed funding models in the life sciences as (i) pharmaceutical companies look for new types of partnerships with universities and VC funds and (ii) VCs develop new models for seeding their deal flow.

More specifically, the meeting focused on the following questions:

- *How to bridge the "valley of death"?*
- *How can pharmas and VCs succeed in doing that?*
- *What models are needed?*
- *What kinds of partnerships with universities and non-dilutive money are required?*
- *What mechanisms exist to mitigate risk?*

These questions were successively addressed to pharmaceutical companies, intermediaries between academia and the commercial sector, VC funds and government. Each period was introduced by a short panel (see the composition of the panels in Appendix, 1) and actively moderated to include the audience in the discussion.

Discussion revolved around the following themes: (i) collaboration between pharmaceutical companies and academia, (ii) specific models to bridge the valley of death, (iii) seed funding models and (iv) government's role.

2. Fostering collaboration between pharmaceutical companies and academia

2.1 The need for collaboration

Contrary to what may have been the case five or ten years ago, the question, "Is there a need for collaboration between pharmaceutical companies, academia, VC funds and government?", has become largely rhetorical and the various players responded with a resounding "yes" for different and convergent reasons.

Pharma's perspective can be summarized as follows.

- There is strong pressure to refurbish pharma's pipeline with novel, innovative products.
- Market forces have changed dramatically and pharmas can no longer afford to do everything internally and work in silos. It does not make sense for them to build a new internal infrastructure for each new program. To lower overall costs, redundancy both between companies and between academia and industry needs to be reduced.
- Pharmas need to interact with other pharmas to reduce risk and with academia to access a source of primary publications.
- Pharmas used to be interested in external assets only in Phase 2 and beyond. Biotech start-ups once made the link between universities and pharmas. As the number of VC-funded biotech startups is diminishing, pharmas tend to establish large partnerships directly with universities. As a whole, there is an increasing need on the pharma side to partner with the external world and rely on external expertise, notably for biology and signaling.

On the other hand, there has been a huge democratization of research and universities have developed considerable expertise as well as the ability to do drug discovery, screen and advance biology programs from target to lead identification. In addition, some universities such as MIT, have greatly emphasized their entrepreneurial ecosystem, including funding for later stage research and proof of concept projects, and venture mentoring services. This has made them more attractive partners.

On the academic side,

- early stage venture capital funding has dramatically decreased;
- there is a dearth of internal financing sources ; NIH funding has notably decreased outside basic biology;

- governments want to see more commercialization of the research that they are supporting and are requiring industry partnership for funding.

There is a clear perception in academia that pharmas need new targets. To acquire them, they are building huge partnerships with big names in leading universities and are investing with government in university-based seed funds.

The challenge on both sides is to link the right talent with adequate financial sources to develop assets from hit to phase 1.

2.2 What are the hurdles?

From pharma's point of view, many academic institutions are still very much in a “push” mode, developing assets on their own and then asking: “do you want to buy this?” However in many cases, “this” does not meet the pharmas’ real needs. It may also fail to meet industry standards in terms of characterization, purification and testing robustness. One particularly significant issue is data reproducibility: more than 50% of academic results are not reproducible and in many cases key experiments are simply not done. This makes VCs and pharmas reluctant to invest.

Universities are in contact with industry. However, TTO experience seems to indicate that other than the big names, most pharmas do not necessarily provide much wanted feedback on what they observe and want. Universities need this feedback. They need to know whether a project should be killed and what pieces of data are missing, but they have nobody to talk to. This has to be improved.

2.3 How can these hurdles be overcome?

First, both parties should recognize that they have different, but complementary strengths. On the one hand, academics conduct basic research making it possible to understand and disentangle new biology. Pharmas, on the other hand, concentrate on developing new drugs and bringing therapies to the market. The key issue from pharma's point of view is to figure out ways to leverage its strengths to enable academic ideas to come to fruition.

The following recommendations emerged from a discussion in which both parties participated.

- When funding studies on a molecule or target, pharmas need to provide universities with clear guidelines and assistance in order to help them determine whether an asset is worth bringing to industry.
- There needs to be not only funding, but active collaboration between pharmas and universities in order to focus funding on experiments that will add the most value to the project. This would help bridge the valley of death.
- In the same vein, pharmas should provide their wish list and share their ideas about what interests them most.
- Through funding and partnerships, pharmas, and governments can play a role in accelerating collaboration. Recently, Merck was instrumental in building a partnership with CDRD (Vancouver), MaRS Innovation (Toronto) and IRICoR (Montréal). Through its RFP and funding, the Government of Israel brought together a team composed of Orbimed, Johnson & Johnson and Takeda Pharmaceuticals to establish a life sciences incubator called Bioboost. Government matching funds for partnerships between pharma and academia, such as the Quebec Life Sciences Partnership Fund, play a similar role.
- From pharma's viewpoint, university TTOs and other intermediaries should be creative and open to encouraging interaction. A rigid formula may not result in meeting the needs of all of the partners.
- It is extremely valuable for all concerned that TTOs and intermediaries invite pharmas to sit on steering committees to evaluate technologies and vet projects.

The Merck Initiative on New Targets (MINT) is an example of a program through which one company reaches out to academics that have expertise in a specific area that is of interest to it and supports their research. Researchers help the pharma in the early stages of drug discovery. In return, they get tools and funding to support their research and are free to publish their findings. Most pharmas have similar programs that allow them to develop new models or links with academia. This trend was reflected in the panelists' titles that use words such as alliance, partnership and external research.

While pharmas develop teams to scout the outside world, it is important for them to maintain a strong internal research group to vet external partnerships.

Universities strongly agree that they need industry's collaboration early on for feedback and funding but not just for their top researchers. Moreover, small amounts of money should be made available for establishing proof of concept.

Having pharma companies as coinvestors in seed funds or on advisory committees is extremely positive.

Finally, pharmas should bear in mind that, when working with universities, certain lines cannot be crossed. Some of these pertain to tax issues, others to publishing rights. These need to be stated up front to avoid misunderstandings.

2.4 How to solve the problem of reproducibility of academic experiments?

All of the participants recognized reproducibility as a major issue. This situation exists because (i) academics are not incentivized to replicate data because doing so does not lead to the kinds of publications that are so highly valued by their milieu and (ii) the necessary skills for producing data that meet industry standards are not widely disseminated in universities. The same applies to information on manufacturing or scalability. This means that pharmas and VCs must be involved early on in the process.

The following recommendations emerged from the discussion.

- VCs should allocate money early on for work with PIs and third parties to ensure reproducibility of data and the running of key experiments. Small amounts can make a real difference.
- Tranche financing is highly recommended in order to reproduce results and run key experiments. Should findings prove negative, a kill early decision can then be made.
- Early stage collaboration between pharmas and academia involving industry knowhow is a must.
- Governments can and should help by de-risking the funding and sharing the costs. The German Federal Government has created a seed fund dedicated to reproducing academic experiments outside academic labs before making them available for series A.

3. Specific models to bridge the valley of death

Earlier paragraphs mentioned examples of initiatives whereby governments and pharmas, through their funding, play a catalyst role in linking pharma and academic expertise and bridging the valley of death. Each participant on the intermediaries' panel provided additional detail on his/her institution's specific model. One interesting observation that emerged from their comments was that whereas various players in Canada and France saw the need to set up a distinct intermediary outside academic institutions to focus on the commercialization of research and attract government and industry support, leading US universities have insisted on the need that their institutions be flexible and creative in order to adapt to the new environment without relying on separate entities or intermediaries.

3.1 CDRD and CDRD ventures

At a time when VC funding is on the wane, the Centre for Drug Research and Development's (CDRD) main objective is to advance early stage drug discoveries by providing both funding and infrastructure to support proof of concept. Its mandate is to de-risk discoveries stemming from publicly funded health research and transform them into viable investment opportunities for the private sector, thus successfully bridging the commercialization gap between academia and industry and translating research discoveries into new therapies for patients.

CDRD Ventures is the CDRD's commercializing vehicle designed to generate revenue through licensing or start-ups and ensure project sustainability.

The CDRD is not embedded in academic institutions because the latter have different objectives and are not motivated to produce proof of concept studies and validate and de-risk assets to make them attractive to pharmas and venture capital. It has attracted support from governments and pharmaceutical companies.

3.2 INSERM Transfert

INSERM Transfert is the TTO of INSERM, France's main medical research organization. Its objective is to develop alliances and partnerships with pharmas and VCs in an open innovation framework. It has struck major partnership deals with pharma companies, developed a seed fund called INSERM Transfert, an initiative funded by the government (2/3) and industry partners (1/3), and works closely with pharmas and VC partners to review its portfolio of projects and companies in order to kill non-performers early on and focus on the most promising among them.

"We focus on adding value and minimizing risk for innovative projects at pre-industrial stage, bridging discovery and clinical research. We put emphasis on identifying high-potential projects, implementing appropriate proof of concept and IP strategies, and setting up win-win/mutually beneficial industrial partnerships".

3.3 Yale, MIT

For Yale and MIT, universities have to be creative and flexible to identify and structure partnerships in order to adapt to (i) the resurgence of pharma's interest in working directly with academic medical centers and (ii) the availability of development capabilities in CROs and chemistry organizations resulting from pharma outsourcing opens the possibility of virtual developments.

The objective is to develop/or find molecule and biologic modulators for disease pathways for which both institutions possess an unsurpassed depth of knowledge.

4. Seed funding models

The "valley of death" has two components: a lack of funding and the challenge of linking discovery (academia) with drug development (pharmas/CROs) expertise. Can new seed funding models address these issues?

4.1 Seed funding linked to academic institutions

Government-funded seed funds linked to academic institutions seem to be the new thing. They are needed because capital is scarce at this stage. However, is this a good use of capital?

Several conclusions emerged from the discussion.

- Because other sources have dried up (e.g., NIH and venture capital), new ones are required.
- Pharmas have to be present in the early stages with their much needed expertise and input.
- Hence: government-funded seed funds linked to academic institutions with support from pharmas that are invited to participate in the fund and help to review and select projects. This model would grant pharmas the right to review projects. However, it would afford them no other right.
- It must be recognized that investing in early stages (hit to lead and preclinical studies) is not profitable. It must be viewed in philanthropic terms.

Questions remained about next-stage financing (GLP studies and beyond) where venture capital remains scarce. It was noted that such seed funds can contribute to the development of an entrepreneurial culture among scientists in ecosystems where that drive is lagging.

4.2 Seed funding by VC funds

It should be recognized that stand-alone seed funding for the life sciences is not profitable. To become commercially viable, it must be included in a fund that has follow-on capacity.

The following lists the conditions for successful seed funding.

- Avoidance of investing good money after bad: early kill is recommended.
- Early syndication with like-minded investors in order to have enough money to reach the first value creation point.

- Collaboration with executives with a proven ability to move projects from academia to market and their involvement in the design of the killer experiments. The limiting factor to starting companies successfully, from very early on (validated target or lead compound) to a strong series A, is more people than money. Potential solutions developed by some of the participants include:
    - Teaming up with the portfolio's repeat entrepreneurs;
    - Using people from the pharma industry as long-term consultants and part-time CEOs of seed investment companies;
- Setting aside of a small part of the fund for direct seed funding or seed funding initiatives that will attract pharma and government funding (e.g., Sofinnova).

The discussion gave rise to the following conclusions.

- A seed investment represents a relatively small contribution toward shaping a project into a fast runner and thereby preparing it for investment. It cannot be seen as profitable and the participants agreed that it should be viewed more as philanthropy, thus necessitating a role for government to provide grants not only for advancing basic science, but translating it into applications leading to the creation of more spinout companies.
- Consequently, very few VC funds are still investing at the seed stage and developing models to do so. Some exceptions to the rule were among the session's participants.
- There is a need to develop a new model for seeding projects from early on to proof of concept that would:
    - streamline the development process from hit and lead stage to preclinical studies and phase 1 readiness, thereby making the model as profitable as possible;
    - include government money when available;
    - allow for pharma and VC participation early on;
    - foster collaboration between academics, pharmas and VCs in an open innovation model.

Finally, it should be noted that corporate VC does seed funding on a regular basis. Unfortunately, time did not allow for a discussion of this topic.

5. What roles for government?

Many of the situations or recommendations listed in earlier paragraphs involve government. The final panel drew together all of the recommendations mentioned at various points throughout the session.

5.1 Catalyst

Beyond funding basic research, government should act as a catalyst, create an environment that fosters collaboration between academia, VCs and pharmaceutical companies, and link its financing to VC and pharma expertise.

5.2 Investor in translational research

A thread that ran through the whole discussion is that bridging the valley of death will require more non-dilutive money. It will require grants from government or philanthropic endowments such as MIT's Deshpande Center or partnerships, much like the Tri-Institutional Therapeutics Discovery Institute. The latter pulls together two academic institutions and Takeda Pharmaceuticals and is supported by $20 million from private donors.

Another conclusion is that government money should be structured as much as possible to attract funding from VCs and industry and foster collaboration with academia.

It was also mentioned that government could contribute by de-risking and sharing the costs of reproducing academic experiments. However, this should only be done in collaboration with pharmas and VCs.

5.3 Specific examples

Some examples of government acting as a catalyst or linking its financing to VC and pharma expertise were noted.

- Bioboost, Israel's incubator program that attracted Orbimed, Johnson and Johnson and Takeda Pharmaceuticals.
- The CQDM, the Neomed institute and the Life Sciences Partnership Fund, three Quebec initiatives designed to attract funding and expertise from industry and foster collaboration between industry and academia.
- MaRS Innovation in Toronto and CDRD in Vancouver, two centers of excellence for the commercialization of research that are affiliated with academic institutions and have attracted funding from several different pharmaceutical partners with whom they share risk and expertise on early stage technology development.
- Massachusetts' Life Sciences Accelerator program developed with VCs, Angels and corporate investors that provides non-dilutive funding (debt) to pre-series A companies to de-risk them and facilitate private investment. This program is coupled with a consortium of corporate investors that adds grants that are combined with the program's loans. In exchange, these corporations get the right to look at the program's deal flow and deal flow reviews, which may lead them to invest in the companies.
- The discussion highlighted two particular situations: Japan where the low level of entrepreneurial culture and VC funding makes it particularly difficult for government to act as a catalyst and the United States where, depending on the state, it may be hard to engage the government at all and philanthropy plays a more important role as illustrated by the Tri-Institutional Therapeutics Discovery Institute.

5.4 The one thing governments could do to improve innovation and the commercialization of applications

As a conclusion, panelists were asked a more general question: what is the one thing governments could do to improve innovation and the commercialization of applications?

Answers varied by country. The two main priorities were the following:

5.4.1 Open up the healthcare system to innovation

Governments invest large amounts in life sciences research. Maximizing the commercialization of this research would be a big step toward improving patient care.

Another important initiative would be to open up the healthcare system and create a big pull from this system for innovation.

This should be the next big thing for governments to do, especially in single-payer systems such as Canada's. How this should be done is still to be worked out.

5.4.2 Make the regulatory system less unpredictable

This is particularly a concern in the United States.

Appendix 1: Program

1. **Introduction – 4:30 pm**

   - Cédric Bisson, Venture Partner, Teralys Capital, (Canada)
   - Rafi Hofstein, President and CEO, MaRS Innovation (Canada)

2. **First period: pharmaceutical companies – 4:45 pm**

   Moderator:

   - Rafi Hofstein, President and CEO, MaRS Innovation (Canada)

   Panelists

   - Angus Grant, VP Business Development and Global Alliances, Celgene Corporation (USA)
   - Christine Grygon, Head BI Partnering, Boehringer Ingelheim, (USA)
   - Ron Newbold, VP Strategic Research Partnerships, Pfizer Inc., (USA)
   - Steve Xanthoudakis, Director, World Wide Licensing and External Research, Merck (Canada)

3. **Second period: intermediaries – 5:20 pm**

   Moderator:

   - Jerel Davis, Versant Ventures, (USA)

   Panelists

   - Natalie Dakers, CEO, CDRD Ventures, (Canada)
   - Lita Nelsen, Director of Technology Licensing Office, Massachusetts Institute of Technology, (USA)
   - Jon Soderstrom, Executive Director, Office of Cooperative Research, Yale University (USA)
   - Cécile Tharaud, CEO, INSERM Transfert, (France)

4. **Third period: VCs – 5:55 pm**

   Moderator:

   - Cédric Bisson, Venture Partner, Teralys Capital, (Canada)

   Panelists:

   - Hubert Birner, Managing Partner, TVM Life Science
   - Jens Eckstein, President, SR One (USA)
   - Brian Halak, Partner, Domain Associates (USA)
   - Denis Lucquin, Managing Partner, Sofinnova Partners (France)
   - Sander van Deventer, General Partner, Forbion Capital Partners (NL)

5. **Fourth period: The role of government money – 6:30 pm**

   Moderator:

   - Chris Coburn, Vice President Research, Venture and Licensing, Partners Healthcare (USA)

   Panelists

   - Cy Frank, CEO, Alberta Innovates (Canada)
   - Juan Harrison, VP New Frontier Science, Takeda Pharmaceuticals (USA)
   - Marc Leduc, Québec Ministry of Economy and Finance (Canada)
   - Parimal Nathwani, Vice President, MaRS Innovation (Canada)
   - Susan Windham Bannister, President and CEO, Mass Life Science Center (USA)

Cocktail reception – 7:00

Appendix 2: List of participants

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Klein, Steven
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