termsheet

PharmaVentures
Experts in deals and alliances

November 2012 Issue 7

Shrinking to Grow. Big Pharma's Changing Business Model

Over the past 10 years, Big-Pharma has faced up to perhaps its greatest challenge to-date. No longer can the blockbuster revenues from the market feed the pipeline or fund the expansion through merger and acquisition. The challenge is not just to find that future successful wonder drug, but to ensure there is a parallel strategy to ensure delivery of bottom line performance. In reality, this parallel strategy should have a greater chance of success since it relies not on external and often uncontrollable factors, such as the pipeline clinical performance, but on the existing business' fundamentals.

Outsourcing and Divesting

Divesting corporate manufacturing and research facilities around the world has become a recent feature of Big-Pharma's 'parallel strategy'. In a world of increasing pressure to maintain productivity and efficiency, the outsource suppliers – the CMOs and CROs – are better able to leverage their 'neutral' capacity to drive down costs. Unless you absolutely need to do it yourself, then it is often more cost effective to outsource. Of course every situation is unique, however the market plays a strong role in determining the outcome and defining the timeliness of the considered actions. So the first step corporations should consider is an assessment of the value and position of the business or asset.

Valuation and Positioning

At PharmaVentures, we assist our clients in all forms of dealmaking in the Bio/ Pharma and Life Sciences arena, and these sell-side mandates represent a significant portion of our overall activity. Our first deliverable in the process is an in-depth 'Valuation & Positioning' (V&P) report. This sets out in black and white the options and associated values, pulling together the unique qualities of the asset and any intrinsic value that could be part of the asset sale, along with market comparables and an assessment of the current market, the potential acquirers, and their various appetites for acquisition. This is the first step in the process towards a successful divestment but it may also be the last step, with us making a recommendation not to divest . For example, if the timing is not right then apart from wasting time and unnecessary cost in a futile process, the attempt to sell may in itself be damaging to the asset value.

Approaching the Market

In parallel to the generation of an extensive researched list of potential acquirers, PharmaVentures will prepare the appropriate marketing materials. This includes a high quality but brief marketing "teaser" and a more detailed confidential Information Memorandum (IM). At PharmaVentures, we will assemble this IM by combining the essential data supplied by our clients with our own insight into the structure and positioning needed to really sell the opportunity. A well-crafted IM is the stepping stone to a successful divestment, a poorly crafted IM could mean the ideal buyer fails to understand the opportunity and all parties will lose out.

First the non-confidential teaser will be shared with target buyers. This is normally done by phone, with direct personal contact made with the key executives within the target companies. If the opportunity is of interest, they will then sign a confidential disclosure agreement (CDA) in order to receive the IM.

Selection of Potential Buyers

The next step is to select a small group of potential buyers to go to the next stage. These are either determined by those who have expressed interest in the opportunity or have put in the best outline non-binding indicative offers based on the IM. The group selected will be offered the chance to visit the facility and meet the senior management.

Management Visits

A management visit should combine two key elements at this stage of the process. Firstly, it is the physical experience of seeing and assessing the opportunity itself and how the buyer might visualise operating it to their specific requirements. Secondly, it will provide insight into the intangible side – the management team capabilities, the processes and organisation, and of course to ask questions. This is best done through a formal management team presentation. Getting these visits right takes time and effort. It requires coaching skills to get the right data presented by the right people, in the most impressive but honest way possible. It requires organisation skills to arrange the logistics for the visits, to set out the best running order for the presentations, to manage the confidential and discrete in-flow and out-flow of interested parties, and to manage the inevitable handling of questions.

By now there will be four distinct parties involved in the process, and each will carry different responsibilities and priorities. First, the selling party will be represented by the relevant HQ Corporate team and possibly the head of the business or facility to be divested. Second, the facility or business is represented by the senior management team. Third, of course, are the potential acquirers and their entourage of advisers. And fourth, PharmaVentures who will manage and drive the process to ensure the best possible outcome.

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Heads of Terms

Welcome to issue 7 of *termsheet*, PharmaVentures' quarterly publication providing the latest opinion, news and insight into the global deal making space for the healthcare sector.

Dealmaking is a global activity and this has come more sharply into focus in 2012 with growth in our sector in the emerging market territories. At PharmaVentures, whilst we continue to do much of our dealmaking business in the established markets of USA, Europe and Japan, we are seeing increasing activity in the BRIC, other Far East, and Latin territories. Within our current portfolio of projects, we have clients specifically seeking licensing partners in these territories and an Australian business whom we are advising and helping to implement their forward strategy.

In order to best represent companies and their interests, I have always advocated meeting and speaking directly with the people running these businesses. Communication is key to dealmaking since it is through the best communication that we build the relationships with the people and companies that we will do deals with. Last month, I was a panellist at BioPartnering Future Europe conference in Brussels, along with experts in journalism, branding and social media, discussing the importance of how you communicate your business and its goals with the right audience and, in our case, how you can use PharmaTelevision as a medium for this. Too many businesses approach communication in an ad hoc fashion and rely on just a website and occasional press release. This is particularly true for smaller biotech, pharma and service companies who understandably focus on delivery of the product or service more than communicating about it in the best way. As a result, they end up with great products but wonder why they can't get the attention they deserve. It is a very competitive world with hundreds of companies clamouring to get their message through to the big players with whom they want to interact or do a deal. For their part, the big companies seek to cut through the noise and get clear information on the things that matter to them and use PharmaTelevision as one way of doing this.

At PharmaVentures, we use television and video as a channel to deliver the right messages to the key individuals in formats that differentiate companies from the noise. Currently, I am attending the National AusBiotech Conference in Melbourne where I have met with several companies and also interviewed a number of key players for PharmaTelevision. Australia has had a successful biotechnology industry for many years but a lack of a substantial home market has forced them to engage with markets and companies in the major territories. Inward investment from the US and China into the country has driven significant growth in the biotech sector and even though the level of investment has slowed recently, there is still a vibrant industry here with cutting edge technology in development.

Amongst others here at AusBiotech, I have interviewed John Erb, the Chairman of Sunshine Heart who recently received FDA approval for their heart assist therapy for heart failure; George Milstein the Managing Director in Healthcare Investment Banking at Cowan USA who are interested in investment in Australian healthcare, and Dean Moss, General Manager for life sciences at Uniquest, Australia's leading research commercialisation company. These and other communication videos will be broadcast via PharmaTelevision soon.

As we head through the last quarter of 2012, we will be busy closing two more M&A deals and progressing three more business sales that we will be looking to close in the first half of 2013. As part of this, we will be communicating the key messages for these businesses via all the available channels including PTV, BIO-Europe, Economist & FT conferences as well as JP Morgan. I hope to meet and talk with many of you at one of these events. Of course I and my colleagues would be delighted to speak with any of you via conventional telephone, email or the links in this newsletter if there are ways we can help you and your businesses.

Dr Fintan Walton
Chief Executive,
PharmaVentures Ltd.

conference update

PharmaVentures will be attending the following forthcoming conferences:

- **BIO-Europe**
  Hamburg, Germany
  12-14 November 2012
- **Economist Innovation Awards**
  London, UK
  15 November 2012
- **Economist Global Healthcare Summit**
  London, UK
  29-30 November 2012
- **FT Global Pharmaceutical & Biotechnology Conference 2012**
  London, UK
  4-5 December 2012
- **JP Morgan 31st Annual Healthcare Conference**
  San Francisco, USA
  7-10 January 2013
- **The Pharma Summit**
  London, UK
  28 February 2013
- **BIO-Europe Spring**
  Barcelona, Spain
  11-13 March 2013

If you would like to arrange to meet us during the events or if you would like PharmaVentures to showcase your company or technology at these events, please contact:
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Where's the Value?

Should Pharma and Biotech be adopting IP monetisation strategies?

Earlier this year, Adrian Dawkes participated in a panel discussion at the IPBC annual conference in Portugal for global IP leaders alongside Sherry Knowles (Knowles Intellectual Property Strategies), Bill Geary (MPEG LA, LLC), John Pryor (ICAP) and Peter Villax (Hovione), discussing the various models for monetising IP and why Pharma and Biotech seemed not to participate in the same way as other industries. Major IP monetisation deals in the computer, electronics and device space have concluded for what appear to be astronomic sums (Nortel patent suite sold for $4.5Billion), while the pharma and biotech deals just don't seem to happen often at the IP end of development. The average total deal value for a preclinical pharma or biotech asset is around $306M and this includes more tangible data than just IP. Some critics have said that the pharma and biotech industries are fundamentally not structured to benefit from monetisation models while investors, auctioneers and patent accumulators scratch their heads and wonder if they are missing hidden gems. Pharma insiders note that industry players would rather abandon pharmaceutical patents they are not using than attempt to extract value. What is the truth about barriers to monetisation of pharma and biotech IP assets, and is there a path forward?

Data shows us that large pharma companies carry patent portfolios that include at least 9 filings that are never used for each patent that is eventually commercially useful to the company. So why are these portfolios maintained and not monetised by auction or patent pooling, as in other industries? This situation is changing, and some IP is being auctioned or pooled, but it is certainly not the norm. Whilst IP underpins the value of drugs that eventually make it to market, the value of the IP is enhanced by the generation of data along the clinical drug development path. This value creation in inversely proportional to the risk reduction that associates the ultimate product with the IP. By definition, therefore, the value of the patent per se is not as great as the value of patent plus product. That is not to say that the industry does not generate highly valuable platform IP that is widely licensed across the industry (Cabilly, Cohen & Boyer, Winter etc.) to generate significant revenues for their owners, but all are commercially successfully reduced to practice before widespread adoption and monetisation. Furthermore, the risk in releasing something that might be valuable in the future is too great for some pharma to take. For example, we only have to look at Viagra as an example which was shelved as a drug for hypertension and angina only to rise again as the blockbuster we know today. Until this and other opposing forces, such as the cost of drug development, periods of exclusivity and drug pricing and reimbursement pressures, provide more clarity, it is hard to see how models from other industries for IP monetisation can be adopted by the pharma and biotech sectors.

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meet the team

Adrian Dawkes PhD

Vice President

Adrian is an experienced corporate business developer with a strong technical background. With over 26 years in the pharmaceutical, biotechnology and medical device industries, he can identify strategic drivers and represent a wide range of commercial propositions to the market. With a broad commercial network, he can reach key individuals in relevant companies. Adrian has participated in numerous transaction projects, consultancy assignments and provided expert opinion services in litigation cases. Before joining PharmaVentures, Adrian held senior positions with Johnson & Johnson, drug discovery platform company Acumen Bioscience and the Healthcare Consultancy company Execute Technologies. Adrian has a BSc in Biochemistry and a PhD in Immunochemistry.

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PharmaVentures Adds High Level Corporate Finance Experience

Stephen Waterman has joined PharmaVentures as Vice President in our Corporate Advisory business, significantly enhancing our corporate finance capabilities and offerings to the global healthcare and investment communities.

Stephen has an impressive track record in investment banking and he brings a wealth of experience in private and public markets that will assist our clients with their deal making and Stephen's addition to PharmaVentures will therefore be of great benefit."

Stephen has previously worked with WG Partners, Matrix Corporate Capital, Elixir Securities, Commerzbank, Teather & Greenwood and Evaluate Pharma Plc. He has a BSc from Nottingham University and PhD from Cambridge University.

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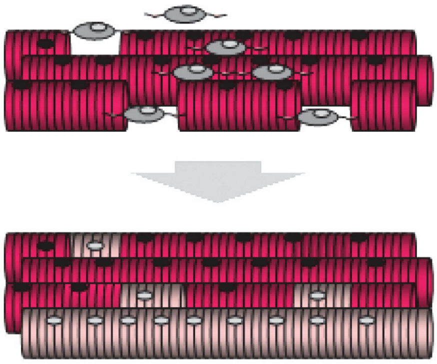
featured client

innovacell
biotechnologie



Novel cell therapy to repair sphincter muscle using myoblasts delivered by a specially designed, CE-marked, ultrasound-guided cell Injection device.

PharmaVentures is currently assisting **Innovacell Biotechnologie AG** to commercialise their personalised treatment for stress urinary incontinence and faecal incontinence, based on autologous cell therapy and patented injection technologies. Urinary incontinence (UI) is a very large and expanding market (c. €1.4bn). Innovacell's lead product (UI) addresses 2.2 million female patients. Current treatments for SUI consist of:

- **Surgery** – Numerous surgical options available; however, complications occurred in 18.8% of procedures in USA
- **Sling procedures** – Fastest growing segment of SUI in developed countries. Recent FDA warnings and withdrawal of leading products are expected to slowdown market growth
- **Medication** – Dulotexine, antidepressant, is marketed for SUI in Europe. It is withdrawn in the USA due to increased risk of suicide. Under "everyday conditions" it shows a high rate of adverse effects.

Innovacell's treatment consists of injecting the patient's own muscle cells (that have been specifically cultured by Innovacell) into the appropriate sphincter muscle using a patented injection device to deliver regeneration of the muscle and restoration of function. This is a one time treatment delivering a lifelong cure and in the case of SUI is especially beneficial for women who are of child bearing age.

Innovacell's second product for treatment of faecal incontinence (FI) addresses 200.000 patients.

Innovacell are seeking licensees and investors for further development of these therapies. ICES13, the stress urinary incontinence treatment is currently in Phase III and has shown excellent safety and efficacy data in over 200 patients. ICEF15, the faecal incontinence treatment is currently in Phase IIb. There is currently high prevalence and high unmet need for incontinence and a multi-billion dollar opportunity exists.

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industry insight

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Access to the Data Room

The next stage in the process involves those potential buyers who now wish to continue with the acquisition process, submitting a confirmatory or revised non-binding indicative offer. These offers can be quite complex as they will include the key terms of the Sale and Purchase Agreement and additional agreements including the key terms of the supply agreements back to the seller where appropriate. Here, PharmaVentures will provide guidance to potential bidders on how their offers should be structured. This usually results in the first dialogue or discussion of commercial terms and PharmaVentures' experienced negotiation skills will play a key role. On receipt of these non-binding indicative offers and based on a preset criteria list developed for the seller by PharmaVentures, the seller will be able to narrow those making an offer down to a smaller select group that meets the best profile of an ideal acquirer. Those selected as good potential buyers by the seller will gain access to the data room to engage in their due diligence process. PharmaVentures plays a key role in the assembly of information in the data room. Here, the quality of data and the response to questions or the provision of additional information is key. The due diligence process provides the potential for the buyer to identify reasons for lowering their offer. PharmaVentures and the seller will work together to ensure that there is no opportunity for buyers to legitimately reduce their offer.

Negotiating the Agreement

If all has gone to plan and the market has responded to the opportunity, there will be one more opportunity for final non-binding offers to be submitted by a date set out in the process letter. The seller can now select a single buyer to start exclusive negotiations. This last bout of contractual negotiations tend to be conducted through the respective legal teams and can be the most tedious part of the whole process, with commercial terms being re-negotiated. At this stage, PharmaVentures is often invited to bring the process back on track when things appear to be slipping.

When the final contracts are crafted and signed, a date will be set to close the deal. The length of time between signing and closing can vary considerably but is usually influenced by obligations being completed by either side. Upon closing, the strategic goals of both parties are finally achieved and a new era begins for each party.

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